



The Theory and Practice of **Vacuum Therapy**

**Scientific Basis, Indications for Use,
Case Reports, Practical Advice**

- ▶ Vacuum-assisted closure
- ▶ V.A.C. therapy
- ▶ Vacuum dressing
- ▶ Topical negative pressure (TNP) therapy
- ▶ Sealed surface wound suction
- ▶ Vacuum sealing therapy
- ▶ Subatmospheric pressure therapy
- ▶ Foam suction dressing

Christian Willy
(Editor)



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The Theory and Practice of Vacuum Therapy
Scientific Basis, Indications for Use, Case Reports, Practical Advice

Edited by Christian Willy

The Theory and Practice of Vacuum Therapy

**Scientific Basis, Indications for Use,
Case Reports, Practical Advice**

Edited by Christian Willy

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Dedicated to the memory of
Heinz Gerngross, MD, Professor of Surgery
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The vacuum therapy of wounds was developed independently of each other by Fleischmann (Federal Republic of Germany) and Argenta and Morykwas (USA) in the early 1990s. Since then, it has found numerous applications in both inpatient and outpatient care. For some indications, vacuum therapy (commonly used synonyms are: vacuum-assisted closure therapy, vacuum sealing therapy, V.A.C.-therapy, TNP treatment, topical negative pressure treatment) is even regarded as a "revolutionary" therapy option. The use of the method has spread widely across the USA and Canada, as well as in Europe, particularly in Germany, Austria, Switzerland, France, the Netherlands and the U.K. Vacuum therapy is also increasingly being used in Australia and parts of Asia.

Despite an extensive international literature on the subject of vacuum therapy, the bulk of which consists of case reports or case studies reporting the success of this method, no comprehensive monograph on the subject has appeared to date (August 2006).

Thus, some ten years after the introduction of this therapeutic method, the authors, encouraged by numerous professional colleagues, take pleasure in presenting an updated review of current knowledge of the subject of "vacuum therapy" from both scientific and clinical/practical angles. The authors incorporate the results of numerous discussions with colleagues in the areas of clinical and home care and have reviewed the knowledge available today from a study of the literature as well as practical tips from experienced practitioners.

For the less experienced user, the book should serve as an introduction to the subject matter, while the seasoned practitioner will find of interest the detailed overview of the scientific and theoretical background knowledge that has been published to date. The clinical/practical user will welcome the collection of interesting case examples as well as

practical advice regarding the application of vacuum therapy in technically difficult locations or in cases of unfavourable wound geometry.

Predominantly, only reports published in *peer-reviewed* journals through July 1st, 2006 were cited. This focus should enable the reader to find answers to specific questions in reliable sources.

The editor of the present work is the Assistant Medical Director of the Surgical Clinic at the Military Hospital in Ulm, where he had established the clinic's wound consultation service. There, the entire spectrum of chronic wounds is treated in an interdisciplinary manner, together with specialists in internal medicine and dermatology. In addition, he was responsible for organising the first three congresses of the German Wound Care Society together with the long-time president and initiator of the society, Prof. Heinz Gerngroß, Colonel of the Medical Corps, former Chairman of the Clinic of Surgery.

This unique compilation constitutes a comprehensive review of the various clinical and scientific aspects of vacuum therapy from the perspective of an experienced "wound therapist" and clinically active surgeon – a true twenty-first-century update on vacuum therapy.

Munich, August 2006

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On the basis of our previous observational studies and case descriptions and more, mainly number of controlled studies and randomised clinical trials (RCTs), the effectiveness of vacuum therapy is today regarded as conclusively proven, clinically. The high importance that this therapy has achieved today is founded on **"Knowledge is educated guessing"** studies have been conducted, there is a considerable deficit of basic pathophysiological research. It is striking that a small number of explanation **"Life is practice in problem solving"** the most frequently mentioned explanation approaches for the therapy success of vacuum therapy (improvement in perfusion, bacterial clearance and increase in proliferation rate as a result of favourable mechanotransductive effects) have not been conclusively proven by experimental studies.

Nevertheless, the present state of knowledge on the physiological effects of vacuum therapy allows the following statements to be made:

- D The foam-under-suction system **"In the first place, we know nothing."** on the heterogeneity of the pressure has, so far, only been investigated in a computer simulation. **Thus we should be quite modest – that is the second place.**
- D During vacuum therapy, hypoperfusion develops in the tissue directly adjacent to the wound. This is more pronounced in the subcutaneous tissue than in the muscle. **That we do not claim to know.**
- D The ischemic marginal zone **when we do not know – that is the third."** (subcutaneous tissue, 50 - 200 mmHg) and - 0.5-1.5 cm (muscle, 50 - 200 mmHg) while there is hyperperfusion (Sir Karl Popper, 1902-1994) (subcutaneous tissue) and 1.5-2.5 cm (muscle). Outside this shell, vacuum therapy has no measurable effects.
- D No increased tissue oxygenation could be found in the tissue layers close to the wound.
- D The reduction of bacterial wound contamination can be achieved in acute and exudative wounds. In a few studies, vacuum therapy produced a shift in the species distribution. What effects this shift ultimately has on wound healing remains to be elucidated.
- D **The future strategy is:**
"Analyse your problem exactly; then objectively seek out the best possible solution."
- D The antioedematous effect of vacuum therapy is undisputed. This can be utilised particularly in burn therapy on extremities. (Popper's student, Hans Joachim Niemann's formulation of the critical-rational imperative)
- D Local vacuum therapy can prevent systemic effects of some syndromes (crush syndrome).

While this list shows many approaches for scientific studies, it also reveals research deficits. It would be desirable that the unsettled questions be addressed so that the potential of vacuum therapy, which is already so successful today, can be utilised even more fully in the future, while at the same time systematically advancing the progress of possible further technical developments.

This book would not have been possible without the generous assistance of many people. I would like to express my sincere thanks to KCI International in general and to P. Appelt, T. Hauser, J. Pfaender, R. Meier and J. Menten in particular, who made it possible for me to complete this book. I am particularly indebted to my colleagues Ralf-Uwe Peter, Raymund E. Horch, Peter Vogt, Wim Fleischmann, Walter Wetzel-Roth, Matthias Augustin and Peter Mauckner for many helpful discussions and constructive suggestions. I am grateful to my colleagues Matthias Schwamborn and Michael Kramer, who were introduced to the principles of vacuum therapy by Wim Fleischmann and Lothar Kinzl and communicated their knowledge to the staff of the Department of Surgery at the Military Hospital of Ulm in the early 1990s when vacuum therapy was still in its infancy. I would like to thank R. Koerper and K. Schneider of Koesel Publishing Company for their professional support and expertise. I am also indebted to Axel Winter and Falk von Luebken for their support and especially for their invaluable assistance in updating the literature review. My grateful thanks go to our operating theatre staff for their patience during the time it took to take the photographs for this book. Special thanks to Heinz Gerngross, the late Director of the Department of Surgery, for his constructive suggestions, his valuable advice and many lively and fruitful discussions. He was a great teacher and friend. My sincerest thanks to my colleagues and the many authors who have helped me with this project. Their contributions and expertise are greatly acknowledged. Last, but not least, I would like to thank my wife, Anna, for her unfailing support and invaluable assistance in the preparation of this book.

Christian Willy
Ulm, August 2006

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Part A / Chapter 1

The Principle of Vacuum Therapy

C. Willy and R. Schmidt

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Vacuum therapy has been in routine clinical use for the treatment of wounds since the 1990's. Stated simply, the method consists of application of negative pressure (usually 75 to 125 mmHg) to a foam that has been placed inside the wound. Immediate sealing of the wound with an airtight adhesive drape prevents subsequent entry of air from the environment, hence the term "vacuum sealing".

The most important benefits of this therapy include a reduction of the wound area secondary to the negative pressure acting on the foam, together with induction of new granulation tissue formation, effective wound cleansing (removal of small tissue debris by suction) and the continuous removal of wound exudate. The most significant advantage in terms of management and patient comfort is the hygienic seal that prevents the contamination of the wound and its surrounding area and the bother of constant discharge into the dressing.

An essential prerequisite for the success of vacuum therapy is a clean wound. Consequently, adequate primary surgical debridement of the wound must be performed first, if necessary.

Vacuum therapy as a method for the treatment of acute and chronic wounds was developed simultaneously in the USA and Germany in the late 1980s and has enjoyed increasingly widespread clinical use over the past fifteen years^{1,12,15,16}.

Vacuum therapy can be regarded as an established wound care method in routine clinical use since the mid to late 1990's.

Functional Principle

The principle of vacuum therapy involves extending the usually narrowly-defined suction effect of drainage across the entire area of the wound cavity or surface using an open-pore foam that has been fitted to the contour of the wound (Figs. A1.1 and A1.2).

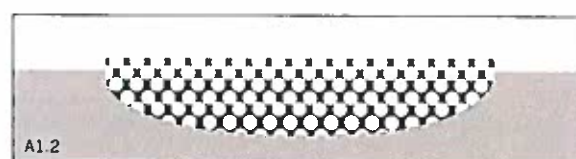
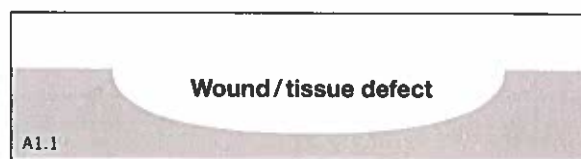
To prevent air being sucked in from the environment, the wound and the foam that rests inside or upon the wound are hermetically sealed with an airtight adhesive polyurethane drape that is permeable to water vapour, transparent and bacteria proof (Fig. A1.3). A "suction pad" (*trac-pad connector*) is then applied over a small hole that has been made in the drape (Fig. A1.4) and connected to a vacuum source by means of a tube (Figs. A1.5 and 6).

Effects on Wound-Healing

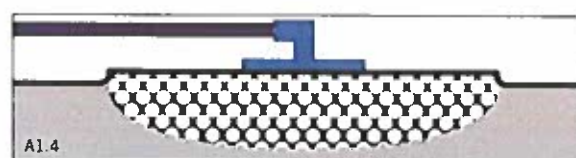
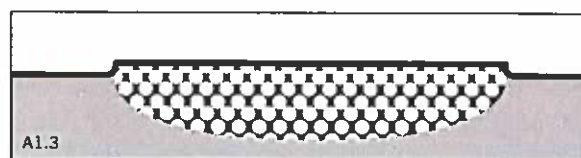
The following effects on wound healing and affected tissue resulting from the applied suction that acts evenly on the entire wound surface are considered to be the primary clinically significant benefits of vacuum therapy^{1-10,12,14-18,23-25}:

Effect on the Wound:

- Reduction of the wound area secondary to the negative pressure that acts on the foam and pulls together the edges of the wound (wound retraction).
- Stimulation of granulation tissue formation in an optimally moist wound milieu even over bradytrophic tissue (tendons), bone or metal implants.
- Continuation of effective wound cleansing (removal of small tissue debris by suction) after adequate primary surgical debridement of the wound.
- Reliable, continuous removal of wound exudate (and, consequently, fewer dressing changes) within a closed system.
- Pressure-related reduction of interstitial edema with consecutive improvement of microcirculation.



Figs. A1.1 and A1.2 The wound (A1.1) and a foam which has been fitted to the wound geometry, cut to size and placed inside the wound (A1.2)



Figs. A1.3 and A1.4 The wound is sealed airtight with a thin adhesive drape (A1.3 left); right: same, with the attached "suction pad" (*trac-pad connector*) including the drainage tube (A1.4)



Fig. A1.5 The wound is hermetically sealed with a thin adhesive drape and connected to the vacuum source by means of the attached "suction pad" (suction strength 0 mmHg).

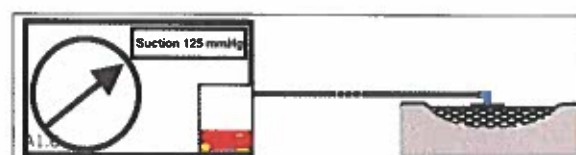


Fig. A1.6 Suction strength 125 mmHg. The foam has collapsed and the exudate collection reservoir is already partly filled.

Handling:

- Bacteria proof wound dressing for sealing the wound in order that no bacteria from the outside can enter the wound and the patient's own wound bacteria are not spread. This is particularly important in the event of contamination with problematic bacteria, as in patients with MRSA-infected wounds; it also reduces the risk of cross-infections and development of a resistance within the hospital.
- Transparent dressing that permits continuous clinical monitoring of the surrounding skin through the film with which the wound has been sealed.
- Capability for exudate analysis, microbial determination from the collecting reservoir.
- Odourless and hygienic dressing technique; constant seeping through the dressing onto the patient's clothing and bedding can be avoided, with reduced time demands on nursing staff.
- Reduction in the number of required dressing changes (dressing change is only necessary every two to three days; under controlled and sterile conditions, the dressing may be left in place for up to seven days), with substantial reduction in nursing time requirements, particularly in patients with exudative wounds.
- Easy and safe handling after brief instruction.
- Possibility of intermittent application of antiseptics and antibiotics and their removal by suction (for instillation therapy, see Part A, Chapter 5).

Patient Comfort:

- Easy and early patient mobilisation with use of a closed (sometimes battery-operated) system.
- Visually appealing dressing method due to clean, exudate-free dressing conditions even during mobilisation.

Community Solidarity

- Cost-effectiveness as shown by cost-benefit analyses (less frequent dressing changes, possibility of outpatient treatment)^{19,22}.

Handling and Duration of Application

Clean surgical conditions must be created before vacuum therapy is started. Surgical debridement of the wound may be required. Only after that can vacuum therapy be started (it is frequently first applied in the operating theatre).

The applied dressing can be left for two to seven days (depending on the wound, the microbial load and the chosen foam material). Depending on the patient's expected degree of discomfort, the necessary technical equipment and the sterility requirements, the vacuum foam can be changed under inpatient conditions on the ward, in the operating theatre or under outpatient conditions.

The duration of the treatment is determined by wound healing success. An interim therapy for conditioning the wound may take a few days to a few weeks while definitive therapy may be postponed until wound closure is achieved (for special wounds see Parts B and C).

Modifications of Vacuum Therapy

Some parameters in vacuum therapy can be adapted to special wound situations. The following aspects can be modified:

1. Foam material (polyurethane foam or polyvinyl alcohol foam)
2. Suction strength (values between 50 and 200 mmHg can be selected)
3. Suction mode (intermittent or continuous)
4. Vacuum source (storage-battery operated therapy units, wound drainage systems etc.)
5. Application of medication (instillation therapy)

The rationale for each of these modification options is briefly addressed below.

Selection of Foam Material

Foams differ with regard to properties such as pore size and stability. Polyurethane (pore size 400-2000 µm, soft, black) forms a fairly strong mechanical bond with the wound tissue after approximately three to four days due to the in-growth of granulation tissue. The foam should thus be changed after two to three days. Polyvinyl alcohol, the slightly firmer and less pliable white foam material (pore size 700-1500 µm), can be left in the wound for up to seven days without any tendency to adhesion and is thus particularly suitable for wounds in which the foam can be left (clean wound) or should be left (condition after mesh-graft) for a prolonged period without being changed.

Selection of Suction Strength

According to findings published from an animal study by Morykwas et al., a suction of 125 mmHg is the optimal suction strength for new tissue formation and wound cleansing^{14,16}.

However, it was found that the capacity to vary the suction strength can be useful under certain circumstances. For instance, in certain cases of patients with pain, with deep soft tissue injuries where vessels are in close proximity to the wound, or with more extensive dressings where the dressing may be applied to an extremity in a circular fashion, it can be appropriate to choose a suction setting of between 75 and 100 mmHg. On the other hand, the generation of higher suction values is extremely useful in those cases in which minor air leaks remain after the wound has been sealed. Some commercially available suction generator systems perform this compensatory increase in suction automatically with the aid of integrated control loops.

Selection of Suction Mode

There are experimental indications that vacuum therapy with intermittent suction (e.g. 2 minutes suction followed by 5 minutes without suction) may be of benefit for wound healing. Morykwas et al., for instance, showed that new granulation tissue formation is significantly greater in intermittent suction mode than in continuous suction mode¹⁵. In the literature, it is currently recommended that, after surgical debridement of the wound, continuous suction should initially be applied for two to three days for better exudate management and the removal of small pieces of wound debris, with subsequent change to the intermittent suction mode for new granulation tissue formation.

Selection of Vacuum Source

One manufacturer of vacuum therapy foams also supplies commercially available vacuum sources (so-called "therapy units"). All therapy and safety functions are integrated in both systems (VAC^{ATS} and VAC^{Freedom}). The suction strength and suction mode can be selected as described above; loss of suction and overfilling of the reservoir result in the staff being alerted. While a 500 ml collecting reservoir can be inserted into the VAC^{ATS} vacuum pump system, a container with a capacity of 300 ml is integrated in the smaller, storage-battery operated VAC^{Freedom} pump system. This smaller system, which can easily be worn on a strap over the shoulder or around

the neck, is particularly suitable for outpatient therapy.

These two vacuum therapy units are not the only systems currently used for vacuum therapy. In principle, after sealing the wound, it is possible to create the vacuum in the wound with other suction generators. Commonly used systems are the Redon drainage container in its numerous modifications and wall suction (in the inpatient setting). Suction systems supplied by other companies can also be used for this purpose. However, see Part A, Chapter 4 (Technical Equipment) and Chapter 8 (Side-Effects and Risks) for further details.

Instillation Therapy

In addition, so-called instillation therapy can be performed according to the method of Fleischmann et al. to deal with any residual contamination of the wound¹¹. This modification involves the retrograde instillation of an antiseptic or antibiotic substance (e.g. pyrrolidinone homopolymer compound with iodine, octenidin dihydrochloride/phenoxyethanol) into the sealed wound via an additional tube system while the vacuum therapy unit is switched off. The foam is thus impregnated with the installed fluid. The substance is allowed to take effect for 5 to 15 minutes after which the therapy unit resumes the original suction and the remaining fluid is removed. This process can be repeated as often as required. Using the programmable therapy unit (VAC^{Instill}) it will be possible to automatically control the instillation therapy (duration of instillation, time for which the substance is allowed to take effect, frequency of the therapy, etc.). For further details, see Part A, Chapter 5 (Instillation Therapy).

Example of Application

We now present a patient case in order to illustrate the individual steps involved in vacuum therapy. The case shows the hygienic and comfortable management of an infected and unstable sternal wound (status after emergency sternotomy) in a 73-year-old patient.



Fig. A1.7 Infected sternal wound, unstable sternum after sternotomy, fibrinous membranes and necrosis, particularly in the cranial part of the wound.



Fig. A1.8 Debridement and irrigation of the wound.



Fig. A1.9 The foam is fitted to the shape of the wound (black polyurethane [PU] foam).



Fig. A1.10 Fixation of the foam to the lateral wound edges with skin staples (alternatively, this can be done with a skin suture or without any fixation).



Fig. A1.11 Sealing of the wound with an airtight transparent adhesive drape.



Fig. A1.12 A small hole is cut into the drape.

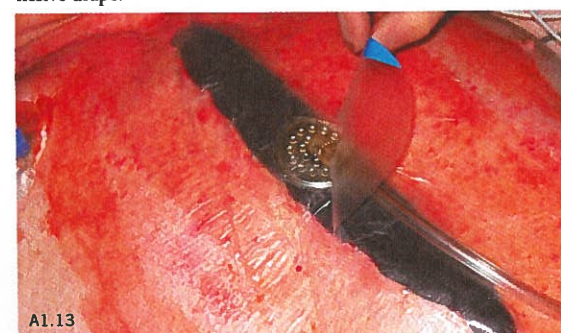


Fig. A1.13 The *trac-pad* connector is applied onto this hole.



Fig. A1.14 Wound after connection of the vacuum source at 125 mmHg. Compared to the initial finding (on the left), there is a distinct narrowing of the wound due to the "shrinking" of the foam caused by suction.

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Part A / Chapter 2

A Review of the Literature on Vacuum Therapy

C. Willy

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A total of 550 *peer-reviewed* citations on the subject of vacuum therapy were identified in the literature (as of June 2006). The keywords that returned the most "hits" were "vacuum-assisted closure" and "VAC". Although the technical basis of the therapy was established before 1990, the first publications date from 1993. The annual publication rate has significantly increased since the year 2000. From then on, the spectrum of indications has been continuously expanded so that vacuum therapy is today used in almost all areas of surgery. When taking into account the aspects of Evidence-based Medicine, one finds that the vast majority of publications—over 80%—are case reports or case series. Most of them have been written by authors from the United States and—in Europe—from Germany, the United Kingdom, Austria, the Netherlands, Switzerland, France, and Sweden.

Introduction

Many hundreds of national and international articles on the subject of vacuum therapy have appeared in the medical literature to date. This new wound care method has repeatedly been the main subject at congresses worldwide. Since 2001, international congresses have been dedicated exclusively to vacuum therapy and provided a forum for discussions on clinical, scientific and economic aspects of this method (e.g. the three-country congresses held by Germany, Austria and Switzerland or the annual Focus Group Meetings on Topical Negative Pressure in the United Kingdom).

An analysis of the literature shows that a large proportion of the publications on vacuum therapy are congress reports, opinions and experience reports, which were not submitted to a formal *peer-review* process (whereby research is scrutinised by independent experts and the editorial board).

The following analysis of the available literature provides an overview of the *peer-reviewed* literature published to date.

Attention is directed to the following:

- Keyword effectiveness
- Development of the annual number of publications
- Proportion of studies on the pathophysiological background of vacuum therapy
- Proportion of publications based on animal studies
- Language area where the publications originated
- "Quality" of the studies under the criteria of Evidence-based medicine (EbM)
- Medical fields of application
- Development of the spectrum of indications over the years

Literature Search and Selection Method

In order to identify publications that satisfy at least a minimum quality standard, we selected only papers that met the following AND or OR criteria:

- Published in a journal with clearly defined author guidelines and a defined description of the *peer-review* procedure³
- Published in a journal considered to be particularly relevant for the development and dissemination of medical knowledge (Abridged Index Medicus [AIM] journal = 120 of the approximately 3800 medical journals worldwide)⁷
- Published in a journal that supports the CONSORT statement (154 journals)⁴
- Published in a journal that has an impact factor⁶

The analysis was based on the results of a computerised MEDLINE (with PubMed), EMBASE and Cochrane search and an extensive hand search, in which the references of all available citations were assessed as well (we used the "snowball" method and searched the references of the self-researched publications). Irrespective of the evidence of the publications (all languages), the search involved randomized clinical and experimental studies, systematic and non-systematic reviews, meta-analyses, expert opinions, case reports, experimental papers (animal and human studies) and result reports of consensus conferences.

The universally valid biometric requirements - such as suitability of the primary endpoints for the statement, sufficient number of cases, representativeness of the study population, relevant dosages and significance of the results - were taken into account for an assessment of the studies. However, where necessary, the assessment also considered the particular nature of the question addressed (e.g. Part A, Chapter 6 "Experimental Basis I"). In these cases, the assessment criteria played a secondary role (see page 43 ff.). It should be mentioned that, for some of the questions addressed (e.g. Part A, Chapter 7 "Experimental Basis II"), a search was also carried out for relevant theses, unpublished research reports and congress minutes.

All publications that met the above-mentioned criteria were available to the team of authors as full texts (not merely as abstracts).

Search Period and Search Keywords

The search covered the period from 1955 to 2006 (as of 30 June 2006). The following keywords were used:

- vacuum therapy
- vacuum (-) assisted closure
- V.A.C. (and VAC)
- vacuum dressing
- (topical) negative pressure (wound therapy)
- sub(-)atmospheric pressure
- sealed surface wound suction
- (vacuum) sealing therapy
- foam suction dressing

The same keywords were used for a search of the Internet using common search engines (Altavista, Excite, Hotbot, Infoseek, Google, Lycos, UK Health Centre). The search results are listed in Part E.

Criteria of Evidence-based Medicine (EbM)

Today, there are over 50 different classifications of evidence levels that have been published worldwide. In this book, the evaluation of the relevant literature was based on the classification of the Oxford Centre for Evidence-Based Medicine (as of May 2001)⁹. Although the choice was arbitrary, it was guided by the fact that this classification is used in the Journal of Bone and Joint Surgery (American Volume) for the classification of all articles (see Table A2.1).

Results

Results of Keyword Searches

A total of 550 citations fulfilled the conditions described above. For the purpose of comparison, it should be mentioned that 63,796 hits were obtained with the keyword "wound healing" and 340,439 hits were returned for "wound therapy". A total of 567,839 citations included the keyword "wound". The search results for the various keywords are given in Table A2.2. The majority of all search hits was obtained using the two keywords "vacuum-assisted closure" and "VAC".

Development in the Number of Annual Publications

The first publications date from 1990 to 1995. However, there is a veritable flood of publications from the year 2000 onwards (see Fig. A2.1). Apart from these 550 articles, there are earlier publications by Russian authors. Only the abstracts, however, are available in English so that we were not able to assess to what extent the publications had been subjected to a *peer-review* process. They were not included in the further analysis.

Of the 550 citations published in *peer-reviewed* journals as full texts or (extended) abstracts, more than one third (37.3%, n=205) was published by authors from the United States (see Fig. A2.2). About one quarter (25.8%, n=142) was published by German authors and one seventh (14.5%, n=80) by authors from the United Kingdom. 4% (n=22) of all publications come from

Table A2.1 Evidence levels according to the Oxford Centre for Evidence-Based Medicine (as of May 2001)

Evidence Level	Therapy / Prevention, Aetiology, Risks / Side-Effects
1a	Systematic review (with homogeneity) of RCTs
1b	Individual RCT (with narrow confidence interval)
1c	All or none*
2a	Systematic review (with homogeneity) of cohort studies
2b	Individual cohort study (incl. low quality RCT, e.g. follow-up < 80%)
2c	"Outcomes" research, ecological study
3a	Systematic review (with homogeneity) of case-control studies
3b	Individual case-control studies
4	Case series (and poor-quality cohort studies and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes (November 1998)^{9,10}

*e.g. when all patients died before the therapy became available, but some now survive on it, or when some patients died, but none now die on it.

Table A2.2 Number of search hits by search keywords (as of 30 June 2006)

Keyword	Number	in %
vacuum therapy	47	8.5%
vacuum(-)assisted closure	78 (159)	14.2% (28.9%)
VAC (V.A.C.)	419 (103)	76.2% (18.7%)
vacuum dressing	13	2.4%
(topical) negative pressure wound therapy	58	10.5%
sub(-)atmospheric pressure	31 (5)	5.6% (0.9%)
vacuum sealing therapy	2	0.4%
(foam) suction dressing	5 (1)	0.9% (0.2%)

One must bear in mind that two different keywords may produce the same search result. The total of the search results is thus higher than the number of citations (or 100%).

Table. A2.3 Number of publications for the various evidence levels (according to the Oxford Centre for Evidence-Based Medicine) in the literature on "vacuum therapy"

EBM Level	Therapy / Prevention, Aetiology, Risks / Side-Effects	Absolute Number	Relative Number = %
no level	Research reports, technical reports, editorial, guidelines, ...	52	9.5 %
1a	Systematic review (with homogeneity) of RCTs	5	0.9 %
1b	Individual RCT (with narrow confidence interval)	16	2.9 %
1c	All-or none	0	0.0 %
2a	Systematic review (with homogeneity) of cohort studies	0	0.0 %
2b	Individual cohort study (incl. low-quality RCT, e.g. follow-up < 80%)	1	0.2 %
2c	"Outcomes" research, ecological study	0	0.0 %
3a	Systematic review (with homogeneity) of case-control studies	0	0.0 %
3b	Individual case-control studies	5	0.9 %
4	Case series (and poor-quality cohort studies and case-control studies)	145	26.4 %
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	326	59.3 %
Total		550	100.0 %

Classification produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes (November 1998)

Austria, 3.5% (n=19) from the Netherlands, 2.4% (n=13) from Switzerland, 2% (n=11) from France and 1.8% (n=10) from Sweden. Further publications originate from Japan (n=7), China (n=7), Israel (n=5), Italy (n=4), Denmark (n=4), Canada (n=4), Taiwan (n=3), the former USSR (n=3), Australia (n=3), and New Zealand (n=3). Countries like Turkey, South Africa, the Czech Republic, Brazil, Belgium and Argentina produced only

one publication each.

Forty-one of the *peer-reviewed* articles investigate scientific aspects (~ 7.5%). Nineteen *peer-reviewed* reports involve investigations in patients and 18 are animal studies (in a total of 417 animals). The remaining articles include a computer simulation, two reviews and a discussion. The greatest number of research reports comes from the United States (n = 14), followed by Germany (n =

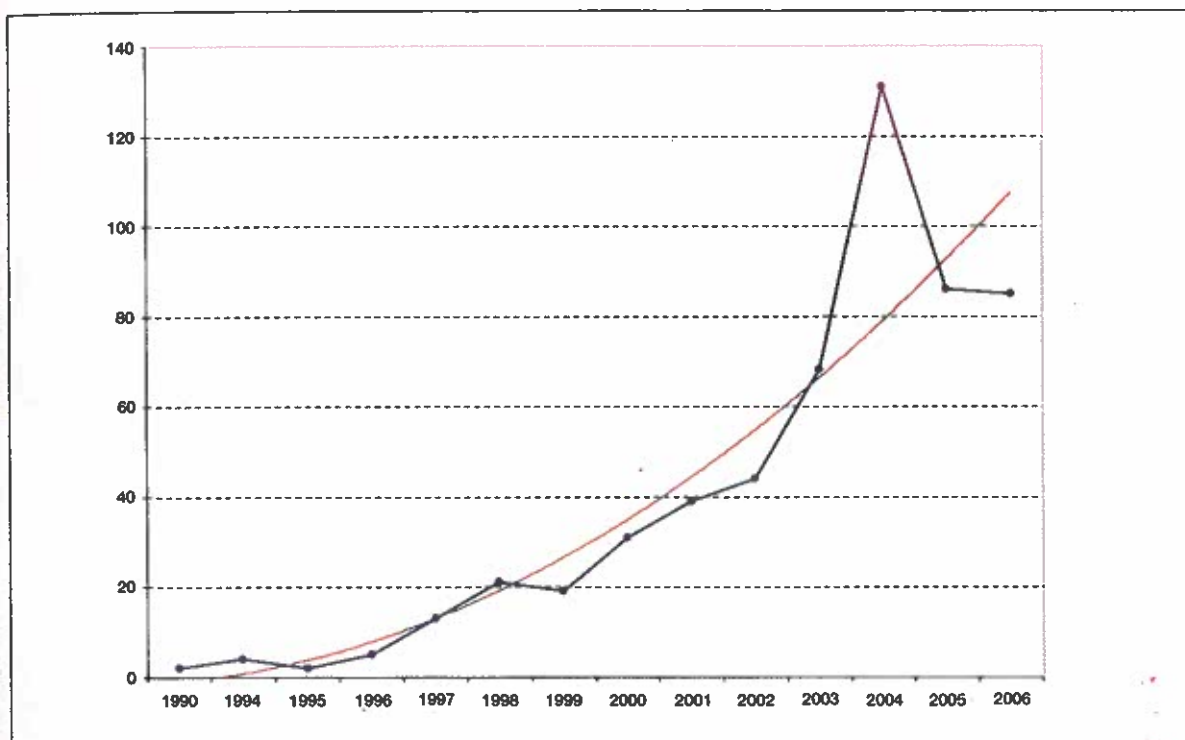


Fig. A2.1 Number of articles published on vacuum therapy in *peer-reviewed* journals in the last 15 years (blue line; the red line represents the trend). It should be taken into account that the last update was made on 30 June 2006.

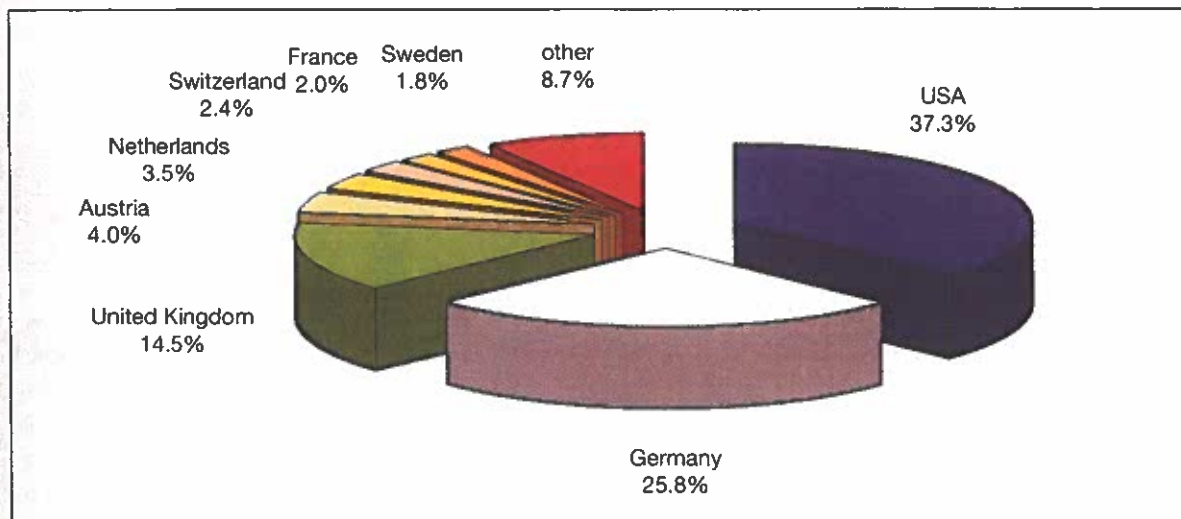


Fig. A2.2 Countries where the 550 *peer-reviewed* publications originated (as of 30 June 2006)

11). The Netherlands and China are next with four first authors each, followed by Sweden with three, Switzerland with two publications and, finally, the United Kingdom, Austria, and Japan with one article each.

Evidence-based Medicine (EbM)

An evaluation based on the evidence levels defined by the Oxford Centre for Evidence-based Medicine shows that the vast majority of reports - over 85% - are case

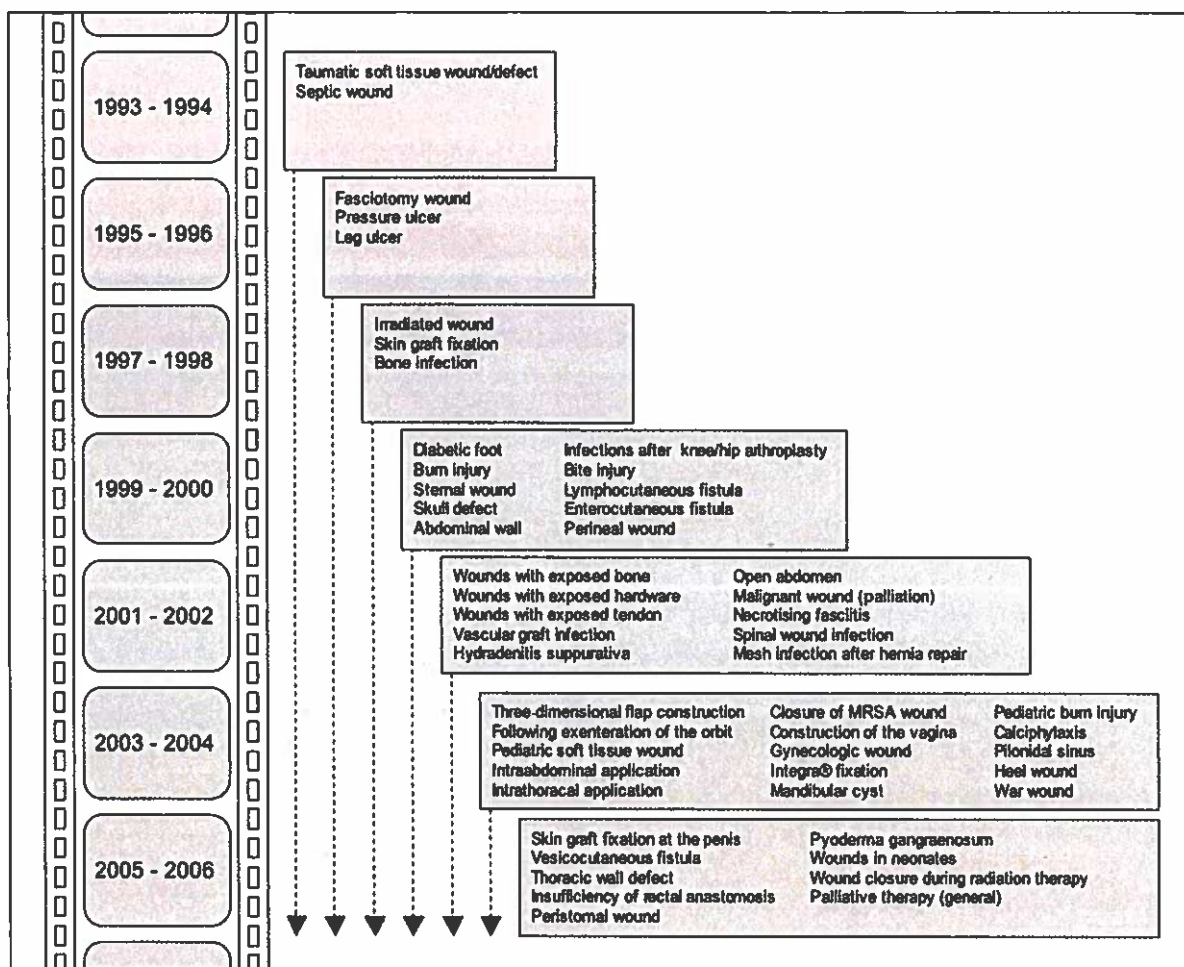


Fig. A2.3 Development of the spectrum of indications from 1993 to 2006. The assigned time is based on the date of publication.

series or case reports (evidence 4 and 5 levels; Table A2.3). About 10% cannot be assigned an evidence level. This leaves only 27 published articles with an evidence level higher than 4.

Development of the Range of Indications

The first experiences with vacuum therapy as it is used today have been made from 1987 onwards when traumatic soft tissue defects and acute and septic wounds were treated with this method. Publications followed in the early 1990s. Very soon, the range of indications was extended to chronic wounds (leg ulcers, decubitus ulcers; see also Fig. A.2.3). Since the year 2000, there has been a marked extension of the range of indications including

severe dermatological syndromes and problematic wounds in vascular surgery as well as an increasing use in plastic surgery. In visceral surgery, entero- and lymphocutaneous fistulas and open abdomens are treated with vacuum therapy. In trauma surgery, the range of indications has been extended to implant infections in the fields of endoprosthetics and spinal surgery. In the last two years, burns (burns of the hand, fixation of skin substitutes) have found to be an ideal indication for vacuum therapy. In visceral and thoracic surgery, vacuum therapy is not only used on the body surface for the management of septic wounds or defect regions but also when there are problematic conditions deep in the body cavity (bronchial stump insufficiency, pancreatic trauma).

Discussion

An analysis of the 550 *peer-reviewed* citations reveals certain characteristics of this literature. Today, vacuum therapy is used in a wide variety of medical and surgical disciplines including trauma surgery, general surgery, visceral and thoracic surgery, plastic surgery, paediatric surgery, maxillofacial surgery as well as urology, gynaecology and dermatology. Only 13 years ago, this treatment method was used almost exclusively for traumatic soft tissue wounds. The almost exponential increase in the number of indications in the various disciplines is also reflected in the marked increase in publications, with the number of publications doubling approximately every two years.

This trend is not only found in the United States but also in Europe and Australasia. This increased extension of the indications for the use of the method is described in detail in publications from the United States, Germany, the United Kingdom, Austria, the Netherlands and Switzerland.

Quality of the Publications (EbM Criteria)

Evidence-based medicine means the conscientious and judicious application of the best current state of knowledge (evidence) from clinical research to the care of individual patients¹¹. In assessing the current state of knowledge, one finds that case reports and case series dominate the literature (~ 85%). Retrospective studies and randomized controlled trials (RCTs) are the exception, and the majority of RCTs involve only a small number of patients. However, the small number of studies with a high evidence level is not a problem specific to the wound care method discussed here. Prospective randomized studies in surgery are rare^{2,3}. In trauma surgery, the rate is approximately 3% of all publications. For visceral surgery, the value is only negligibly higher. An even smaller number was found by the research group of Kiter et al. in the analysis of 36,203 articles in nine renowned journals, which revealed that the proportion of RCTs and meta-analyses was only 1.85% and 0.03%, respectively⁸.

This situation is also evident in an estimate of the proportion of high-quality studies in the available literature on wound care in general. It is not until the very recent past that a marked increase in the proportion of studies with a high evidence level has been seen. The last five years have determined this trend. Nevertheless,

according to our own research, the proportion of RCTs and meta-analyses in this field is only approximately 0.69% in 2002, for example.

We did not investigate how many publications that were initially considered to be of high quality meet EbM quality standards. In an analysis of 44 prospective randomized studies on the therapy of radius fractures, for example, none fulfilled the required criteria. Another critical investigation of meta-analyses of prospective randomized studies (highest evidence level) showed that even the quality of meta-analyses was limited. The investigation found that only 30% of these meta-analyses actually complied with all the analysis criteria stipulated for a correct analysis¹.

Substantial deficiencies are even found in Cochrane reviews that are performed according to the strictest quality guidelines (Cochrane Handbook). For instance, an experimental study evaluating the first 53 Cochrane reviews (Cochrane Database of Systematic Reviews, Issue 4, 1998) showed that major problems with the method or content were found in almost one third of all Cochrane reviews. In almost one fifth of all reviews, the scientific evidence was not consistent with the conclusion. In even more cases, the methodological procedure was inadequately employed or described (in 23%)¹⁰.

One reason for this situation is a gap between clinical practice, on the one hand, and scientific findings and EbM requirements, on the other. Clinicians who use a new treatment method and find it effective will usually publish case reports or observational studies reflecting the treatment success on the basis of their experiences. They will focus attention on an exact description of the method and potential risks and benefits. EbM principles will play only a minor role in their work.

Only very rarely will clinicians find the time and support to conduct an RCT study with all the additional tasks involved (ethics committee application, biometry, etc.) and at the same time perform their daily routine work. The fact that many "renowned" journals have published these research reports to date reflects acceptance of this relatively low evidence level. It is thus explainable and understandable that approximately 85% of the international *peer-reviewed* literature on vacuum therapy consists of case descriptions.

The necessity of Evidence-based Medicine must not lead to a form of dogmatic authoritarianism that rejects any studies with an evidence level lower than 1 or 2. The

popular belief that only RCTs provide trustworthy results and that results of studies with a lower evidence level misdirect lines of decision does a disservice not only to the patient but also to the health professional.

One should be open to studies with a lower evidence level. In a practice-oriented EbM concept, clinical experience should be integrated into the decision process. This is the only way of coping with a situation in which one must assume that many questions arising in the routine use of vacuum therapy cannot be answered with

RCTs (one generally assumes that approximately 30-40% of the everyday activities in a surgical department cannot be assessed on the basis of randomized controlled trials^{3,17}).

There is a clear trend that theoretical aspects of EbM must be taken into account when clinical, scientific and health economic questions are addressed. The above considerations reflect the arrangement of this book:

- Part A offers a description of the scientific basis of vacuum therapy and a number of safety aspects.
- Part B focuses on the indications for use. We attempted to integrate modern criteria of EbM into the individual descriptions. Whenever possible, we drew attention to higher quality studies published in the literature.
- Nevertheless, there are still many conditions that have been described only in individual case descriptions. In order not to appear authoritarian and dogmatic, we did not strictly comply with the rules of Evidence-based Medicine in these cases. Part C offers a collection of interesting case reports.

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Part A / Chapter 3

Indications and Contraindications

C. Willy

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Vacuum therapy is indicated in patients with large soft tissue defects, in initially and post-operatively infected wounds after surgical debridement, and for skin graft fixation. It has become the method of choice for sternal wound infections and a practicable alternative to other methods for the temporary closure of the open abdomen. As far as chronic wounds are concerned, vacuum therapy has proved successful in treating decubitus ulcers, ulcerus cruris and above all diabetic foot syndrome. Some authors also consider several other conditions such as burns, enterocutaneous fistulas and lymphocutaneous fistulas to be indications.

Acute bleeding and the risk of bleeding are clear contraindications. The use of vacuum therapy over exposed vessels and neoplastic tissue remains controversial. However, individual cases in which vacuum therapy was successfully used have led to the realisation that this technique can also be effective for these indications.

Since the first clinical applications, the spectrum of indications for vacuum therapy has continuously expanded. The decision to use vacuum therapy for some of the conditions described below depends on different effects of this therapy, which are mentioned as well.

Acute Wounds

In the case of acute wounds, which are usually caused by trauma or surgery, vacuum therapy is primarily used for temporary coverage and/or wound preparation until definitive wound closure by secondary suture or plastic surgery (split skin grafts, flap grafts, etc.) is possible. It should be emphasised that vacuum therapy is by no means a substitute for surgical debridement¹⁰.

Indications for vacuum therapy are:

- Soft-tissue defects where primary suture is unacceptable or impossible, e.g. degloving injuries, lacerations, contusions, fasciotomy wounds for compartment syndrome, contaminated war wounds, etc.
- Initially and postoperatively infected wounds after surgical debridement (e.g. abscesses, animal bites, necrotising fasciitis, pilonidal sinus, hydradenitis suppurativa, impaired wound healing, periprosthetic infections after implantation of endoprostheses, vascular graft infections, mesh infections after hernia repair, osteomyelitis after debridement, peristomal wounds, etc.).
- Soft-tissue wounds with exposed bradytrophic tissue, such as bones and tendons, or metal implants. In these cases, vacuum therapy is primarily used to enhance granulation tissue formation even under the most unfavourable nutritive conditions.
- Burns. Vacuum therapy is particularly useful for the treatment of burn injuries because it has an antioedematous effect and promotes microcirculation. In addition, it is effective in covering the wound safely and hygienically and encouraging the fixation of split skin grafts and Integra® artificial skin.
- Fixation of skin grafts (mesh-grafts) until the graft has taken (4-6 days). In these special cases, vacuum therapy is used for the secure fixation of a split skin graft to the wound. The soft foam helps gently press the graft onto the wound and thus ensures full contact between the graft and the underlying wound bed, irrespective of the wound contours and the formation of pockets.
- Coverage of skin graft donor sites.
- Preparation of pedicle and free flap grafts.
- Temporary closure of the open abdomen. Vacuum therapy allows abdominal wounds to be temporarily covered in a clean and hygienic manner. In addition, it promotes wound contraction.
- Vacuum therapy is also increasingly being used for the treatment of postoperative intraabdominal and intrathoracic infections.
- Vacuum-assisted closure of infected wounds after debridement. Vacuum therapy has been effective in helping control methicillin-resistant *Staphylococcus aureus* (MRSA) infections.

Acute and Subacute Wounds

Vacuum therapy serves different purposes in the treatment of acute and subacute wounds, which usually take four to eight weeks to close. In the treatment of sternal wound infections, for instance, it is primarily used as a method of covering wounds temporarily and preparing the wound until definitive wound closure by secondary suture or plastic surgery (split skin grafts, flap grafts, etc.) is possible. In addition, it helps stabilise the thoracic wall. Vacuum therapy is also effective in the treatment of the fistulas listed below. In these cases, the application of gentle pressure on the outlet of the fistula and the hygienic removal of wound exudate are likely to benefit wound healing. Here again, however, vacuum therapy is no substitute for surgical debridement:

- Sternal wound infections (after sternotomy)
- Entero-cutaneous and vesico-cutaneous fistulas
- Lymphocutaneous fistulas
- Rectal anastomotic leaks

Chronic Wounds

In the management of chronic wounds that have been present for many weeks or even months, the main purpose of vacuum therapy is to prepare the wound bed (cleansing and new granulation tissue formation) until definitive wound closure by secondary suture or plastic surgery (split skin grafts, flap grafts, etc.) is possible or to promote spontaneous epithelialisation, in which case vacuum therapy is supported by modern methods of moist wound management. Especially in the case of pressure sores and diabetic foot syndrome, however, radical debridement must precede vacuum therapy so that, in

other words, “chronic” wounds are converted to “acute” wounds.

Indications are:

- Pressure ulcers
- Leg ulcers (both venous and arterial in origin)
- Chronically impaired wound healing (e.g. diabetic foot syndrome)
- Preparation and protection of wounds in the case of extensive factitial dermatitis, wound closure during radiation therapy
- Radiation ulcers

Contraindications

The following contraindications of vacuum therapy were established during the consensus conference held in 2003 by the German Society for Wound Healing and Wound Management (DGfW) and the Austrian Wound Association (AWA)⁴⁵:

- Clotting disorders (risk of bleeding) and acute mild to moderate bleeding in the wound region after injury / debridement
- Exposed vessels and vascular anastomoses, which might be altered or damaged by vacuum therapy
- Necrotic wound bed
- Untreated osteomyelitis
- Neoplastic tissue in the wound area

Risk of Bleeding

If there is manifest bleeding or a risk of bleeding, negative pressure must not be applied to the wound. In these cases, suction could result in a continuous removal of blood and thus in significant blood loss⁴⁴. Commercially available negative pressure systems (VAC^{TS} and VAC^{Freedom}), however, are fitted with a collection canister with a volume of 300-500 ml and also have an audio-visual alarm to alert the provider or patient if the canister is full. Blood loss can thus be prevented in time.

Exposed Vessels and Vascular Prostheses

Recent practical experience and theoretical knowledge have shown that the use or non-use of vacuum therapy for the treatment of exposed vessels and vascular anastomoses should be reconsidered and discussed. Over the

last few years (2001-2006), there has been an increasing number of publications by different authors who investigated the use of vacuum therapy in infected inguinal wounds after vascular surgery^{1,2,6,8,9,11,12}. In some cases, pieces of foam were placed directly into the infected wound over the exposed vessel or the vascular anastomosis and neither compromised circulation nor caused any other complications. These issues are dealt with in more detail in Chapter 20 of Part B.

Necrotic Wound Bed

Necrotic tissue acts as a barrier to new tissue growth. The use of vacuum therapy must therefore be preceded by radical debridement.

Untreated Osteomyelitis

Due to the deep extension of a potential osteomyelitic focus, simple surface treatment is unlikely to be successful, even if direct contact between the dressing and the bone is ensured. In this case, treatment must include the radical removal of the focus of infection. In addition, instillation therapy is another option to be considered in these cases (see Part A, Chapter 5)⁴⁵.

Malignant Wounds

Vacuum therapy is known to promote tissue growth and is therefore used for the purpose of improving tissue perfusion and enhancing granulation tissue formation. As a consequence, it should not be used in the presence of malignant neoplastic tissue³.

The above-mentioned consensus paper and many other publications in the literature as well as our own experience suggest, however, that vacuum therapy can be useful as a purely palliative measure in inoperable cases, e.g. patients with a gangrenous tumour or with a malignant cutaneous metastatic wound (Fig. A3.1)^{3,13}.

Particularly in patients with tumours that are not completely resectable or with ulcerating lesions or highly exudative wounds, vacuum therapy should not be strictly regarded as contraindicated. When used as a purely palliative measure, it allows wounds to be covered in a hygienic and clean manner and at the same time is more comfortable and less painful for the patient without restricting any remaining mobility. In special cases, the presence of malignant tissue in the wound bed can thus be considered an indication for vacuum therapy.



Fig. A3.1 A malignant cutaneous metastatic wound on the medio-dorsal side of the right thigh. An unfavourable prognosis, the presence of metastases in various locations and a highly infiltrative growth pattern made local excision impossible. Initially, very painful dressing changes had to be performed almost every three to four hours because of the heavily exuding wound. As a result, the patient became nearly immobile. "Palliative" vacuum therapy led to a considerable reduction in the number of dressing changes and improved mobilisation (The picture was kindly provided by Dr. R. Schiener, Department of Dermatology, Military Hospital Ulm, Germany).

Comment

This chapter was intended to provide a general overview of the indications and contraindications for vacuum therapy. Further details are available in the various chapters of Parts B and C. Table A3.1 gives a summary of the indications for vacuum therapy and specifies the number of references that were found for each indication, the highest level of evidence available and the number of patients treated for each indication. In addition, the editor has given his subjective assessment of the usefulness of vacuum therapy for the various indications. These assessments are intended as a basis for discussion only.

Table A3.1 Literature overview: value of vacuum therapy for the individual indications (subjective assignment by the author)

Indication	Number of References	Highest Level of EbM	Number of Patients	Assessment
Skin graft fixation	31	1b	> 1000	method of choice
Sternal wound infections	48	4	770	method of choice
Integra® fixation	5	1b	17	method of choice
Vascular infections/vascular prosthesis infection	10	4	86	method of choice
Leg ulcers	8	4	57	method of choice for securing split skin grafts
Fasciotomy wounds	6	3b	76	method of choice for contaminated wounds
Mesh infections after hernia repair	3	5	2	method of choice
Diabetic foot syndrome	24	1b	352	firmly integrated in the treatment algorithm
Instillation vacuum therapy	8	4	58	one of the most promising modifications of vacuum therapy
Soft-tissue infections	52	2b	> 1000	suitable method
Temporary closure of the open abdomen	21	3b	249	suitable method
Abdominal wall wounds	11	4	21	suitable method
Exposed bone, tendons, implants	6	4	107	suitable method
Rectal anastomotic leaks	2	4	64	suitable method
Necrotising fasciitis	7	5	7	suitable method
Spinal wound infections	4	4	24	suitable method
Hydradenitis suppurativa	2	4	7	suitable method
Pyoderma gangraenosum	2	5	2	suitable method
Burns	10	1b	39	promising method for hand burns
Stage III and IV decubitus ulcers	21	1a	> 1000	superior to other conservative methods in inoperable cases
Postoperative intraabdominal and intra-thoracic infections	6	4	16	interesting option
Enterocutaneous fistulas	8	4	261	interesting option
Heel wounds	2	5	2	interesting option
Radiation ulcers	3	5	2	interesting option
Lymphocutaneous fistulas	3	4	7	interesting option
Bite injuries	2	5	2	interesting option
Pilonidal sinus	5	4	58	treatment alternative
Closure of MRSA wounds	2	4	47	interesting option
Thoracic wall defects	2	4	12	interesting option
Vesicocutaneous fistulas	1	5	1	interesting option
Home care	4	4	42	suitable method
Cost-effectiveness	7	4	> 1000	Calculated in USA and Germany

The references cited in this table are not included in the list of references below.

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Part A / Chapter 4

Technical Basis – Vacuum Sources / Foams

C. Willy and B. Friemert

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Over 30 different pre-shaped and ready-made foams made from two different materials (polyvinyl alcohol and polyurethane) are currently available for vacuum therapy. Special dressing systems have been developed for particular indications (treatment of open abdomen, heel ulcer, burns on the hand). Various devices are available for use as vacuum sources (storage-battery operated systems, systems which are suitable for software-controlled drug application, etc.).

Vacuum therapy can be performed using foams of various shapes, sizes and materials. Today, the multitude of ready-made manufactured foams permits a differentiated use of the material so that it can be adapted to the individual wound. Over 30 different foams are currently available. The different foams are presented below, followed by a description of the currently available vacuum sources.

At present, the majority of foams constituting the currently available product range come from one manufacturer, who has functionally coordinated foams, adhesive drapes, suction tubes and the suction-generating vacuum sources. This has facilitated development of special dressing systems for particular indications. Against the background of 10 years of experience, a complete product package has been developed that can be considered mature in terms of handling and safety functions (alert on loss of suction, overfilling and blockage). However, drainage systems (e.g. Redon drainage, drainage container with hand pump) and wall suction are still used, as are further electronically controlled suction systems and other manufacturers' foam materials.

In view of this, when relevant, other manufacturers' products are also listed in order to present an overall and objective picture of the equipment required for vacuum therapy. For the same reason, the firms' brand names are only mentioned where this serves the purpose of maintaining a better overview for the reader. Because a complete listing of all available vacuum sources does not really provide any additional help for the user, these products are only described by using individual suction generators as examples. This restriction also appears to make sense because these vacuum sources involve safety risks for the patient. Any known functional differences between the products are discussed at the end of this chapter; differences with regard to safety risks that may exist are discussed in Part A, Chapter 8 "Side-Effects and Risks of Vacuum Therapy".

Foam Materials

Two different foam materials are currently available: polyvinyl alcohol (PVA, the so-called "white foam") and polyurethane (PU, the so-called "black foam"; Fig. A4.1). A brief description of the physical difference between the two materials and the resulting consequences is given below:

The foams have different properties with regard to pore size and stability. Due to the in-growth of the newly formed granulation tissue into the pores, the polyurethane (PU) foam (hydrophobic, open pore structure, pore size 400 - 2000 μm , soft, black) forms a fairly strong mechanical bond with the wound tissue after approximately three to four days; this can also be observed in surgery when artificial skin such as Epigard® is used. The foam should therefore be changed after two to three days, at the latest. Experience has shown that this recommended period applies to healthy tissue under optimal perfusion conditions (e.g. young patient with large soft-tissue defect after fasciotomy); when there is a more unfavourable nutritive situation, the PU foam can be left in place for an extra one or two days.

Polyvinyl alcohol, the material used for the slightly firmer and less pliable white foam (pore size 700 - 1500 μm), does not form a firm bond due to its material and pore size and can be left in the wound for up to seven days without any tendency to adhesion. It is thus particularly suitable for wounds in which the foam can be left for a prolonged period without being changed (clean wound) or wounds where adhesion must be avoided (e.g. after mesh-graft). However, the above-mentioned periods of application of the two foam materials are appropriate only in the case of clean wounds. A shorter period should be chosen when wound conditions are unfavourable (in case of second look, in infections, or if repeated necrosectomy or debridement are necessary).

No clear rationale for the choice of a white or black foam could be found in the *peer-reviewed* literature. There is no study to date which, for example, compares new granulation tissue formation on the basis of the same initial diagnostic findings and the same tissue of origin. There is also no information on differences in secretion performance or different bacterial clearance effects.

Wild et al. are of the opinion that it is beneficial to change to a PVA dressing as soon as the area of the granulation tissue exceeds 65%¹. They justify this recommendation based on the fact that there is a comparatively greater in-growth of granulation tissue into the pores of the PU foam. They take the view that continuation of therapy with a PU foam at this stage of wound healing would lead to microbleeding from lacerated granulation tissue and pain when the foam is changed. They argue for the use of a PU foam in wounds from which small tissue debris needs to be removed together with the wound exudate. The research group of

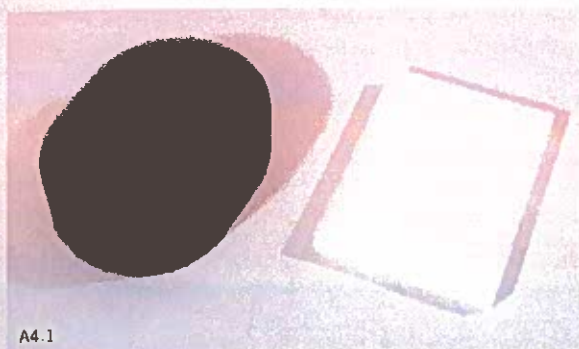


Fig. A4.1 The two different foam materials: polyurethane (PU) foam (left) and polyvinyl alcohol (PVA) foam (right).

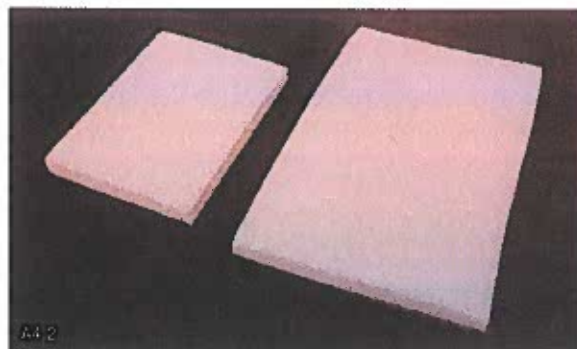


Fig. A4.2 The white polyvinyl alcohol foam (10 x 7.5 x 1 cm and 10 x 15 x 1 cm; available in sizes of up to 20 x 25 cm).



Fig. A4.3 PVA foam with drainage tubes (old version).

Fleischmann, however, reported that, in their experience, the PVA foam has proven very successful in terms of its wound cleansing potential².

In this connection, one should refer to the results of the pressure measurements in the various foam materials as given in Chapter 7 "Experimental Basis II". Here, it appears that, with the PVA foam, suction values of 150-200 mmHg are transmitted only to a limited extent beyond a distance of 15 cm from the *trac-pad connector*, so that higher suction strengths generated by the vacuum source (e.g. 900 mmHg of an empty Redon drainage system) evidently have no additional positive effect. With the PU foam, on the other hand, the transmission of suction is about 1:1, even over greater distances.

Another difference between the materials is that the soft black foam adapts to a very uneven wound bed with a greater contact zone than the firmer white foam.

Basic Equipment

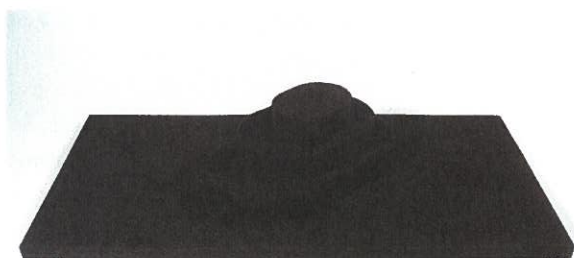
PVA Foams

The polyvinyl alcohol foams are available in rectangular shape (Fig. A4.2; sizes: 10 x 7.5 x 1 cm and 15 x 10 x 1 cm [KCI] and 5 x 5 cm to 20 x 25 cm [Velo]). Until a few years ago, all PVA foams were fitted with one to two drainage tubes (depending on the foam size) by the manufacturer (Fig. A4.3). These drainage tubes were brought out through the wound or through the skin outside the wound and then connected to the suction generator (usually to a collecting reservoir with a negative pressure of 900 mmHg, ca., e.g. Redon system). The rationale for the often very close, parallel insertion of the two drainage tubes was the observation that suction performance was adequate only within close proximity to the drainage tube (< 7 cm; personal communication from W. Fleischmann).

The fact, mentioned above, that a reduction in the suction transmission rate was observed in the PVA foam with increasing suction strength above values of 150-200 mmHg may explain this circumstance. Further extrapolation leads to the assumption that suction values of approximately 900 mmHg might result in marked reduction in the transmission of suction such that the suction may actually only be effective in the immediate vicinity of the tube that transmits the suction. With suction strengths of less than 150 mmHg, there is no such restriction and the transmission of suction is almost 1:1, even over a distance of 50 cm. In view of this, the *trac-pad connector* guarantees a very good transmission of suction even when a PVA foam is used. For this situation, the PVA foam is now also supplied without incorporated drainage tubes.

PU Foams

The polyurethane foams were initially produced in four different sizes (Fig. A4.4). They can be adapted to the individual wound geometry with scissors or a scalpel.



A4.4

Fig. A4.4 The black polyurethane foam (PU; examples in the sizes 10 x 7.5 x 3.3 cm, 18 x 12.5 x 3.3 cm, 26 x 15 x 3.3 cm and 60 x 30 x 1.5 cm). PU foams are available from only one manufacturer worldwide.

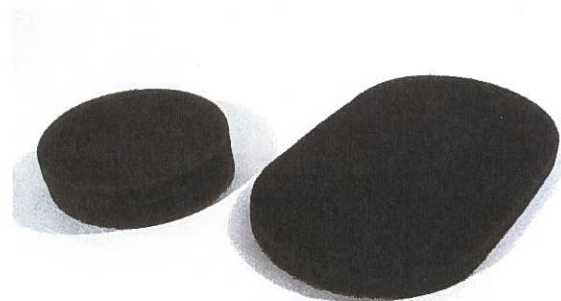


A4.6

The foam thickness of 3.3 cm allows three-dimensional adaptation to the wound (Figs. A4.6 and A4.7). If the wounds are not deep enough for these relatively thick foams, the foam can be sliced in half, lengthwise, by the user. With this method, it is also possible to use a small foam for dressing a larger wound.

A "second generation" of PU foams is now available. These foams have perforations along four oval or circular lines in the foam. This allows the user to comfortably adapt the foam to the wound with less effort and without having to cut the material, just by tearing off the outer layers (Fig. A4.5). Therefore, the perforations providing easy customization of dressing length and width make these foams particularly suitable for the home care setting.

The newest modifications of PU dressing contains elemental silver (10%) as a sustained release formulation. Micro-bonded metallic silver is uniformly distributed throughout the dressing, providing continuous delivery of silver, even after sizing, resulting possibly in anti-infectious effects.



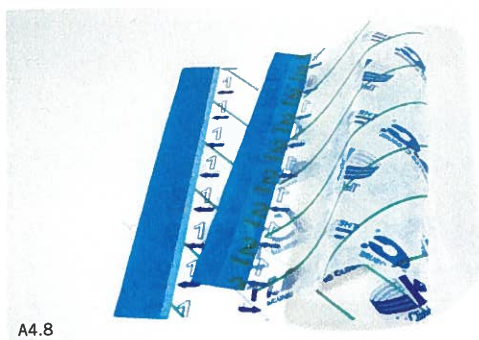
A4.5

Fig. A4.5 PU foams offering the capability to adapt to wound geometry with minimal effort and without scissors or scalpel, just by removing the outer layers along the perforation lines (examples in the sizes 12.7 x 12.7 x 3.2 cm and 26 x 15 x 1.6 cm).



A4.7

Figs. A4.6 / A4.7 Sacral decubitus of an 80-year-old bedridden patient with a necrosis-related drop in the wound level in the cranial corner of the wound, located in the left paravertebral region. Cutting the foam to fit the shape of the wound ensures an even contact of the foam despite the uneven depth of the wound; it was thus possible to completely fill the pocket.



A4.8

Fig. A4.8 Adhesive drape for sealing the wound (30.5 x 26 cm).



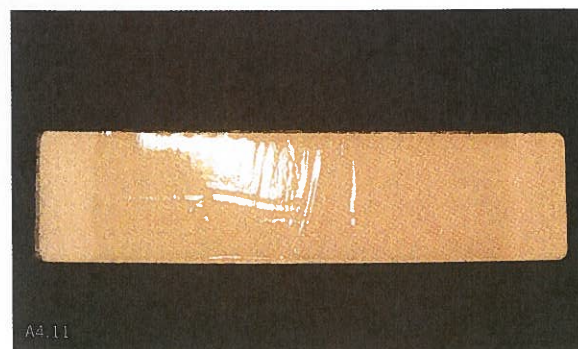
A4.9

Fig. A4.9 Trac-pad connector for transmission of suction.



A4.10

Fig. A4.10 The four measuring channels within the wall of the drainage tube.



A4.11

Fig. A4.11 Double-sided adhesive gel strip for secure fixation of the adhesive drape.

Adhesive drapes and the Trac-Pad Connector

A water vapour-permeable, breathable and transparent adhesive drape is used to seal the wound (Fig. A4.8).

The transmission of suction between the foam that has been placed in the wound and the vacuum source can then, in principle, take place via several routes:

1. Via drainage tubes inserted into the foam by the user or the manufacturer and brought out directly from the wound or transcutaneously through a separate drainage channel beside the wound for subsequent connection to the drainage system of the vacuum source. This was the prevalent technique until the late 1990s. At that time, the tube in the foam was almost always connected to a Redon drainage system. In many cases, it was difficult to make the site air-tight as the drainage tube that was brought out from the wound and ran across the skin could not always be fully integrated in its entire circumference into the dressing with the aid of the drape. This problem, however, could often be solved with measures such as adhesive paste or a sandwich technique (see also Section D), but it meant more time and effort.
2. Via a suction connector that is equipped with an adhesive pad (Fig. A4.9). This can be attached to any desired part of the sealed wound. The user must cut a small hole in the adhesive drape before the adhesive pad is attached to the sealed wound.

As regards the practicability, the suction connector appears to be the more comfortable and safer solution (Fig. A4.9). Within the wall of each of the two drainage tubes that are connected to the suction connector and the container, there are four small pressure measuring channels (Fig. A4.10) that are used for the control circuit of the suction control and the alarm function. This type of pressure control led to the name *trac-pad connector* ("therapeutic regulated accurate care", T.R.A.C.), which was created for the suction connector by the manufacturer.

A double-sided adhesive, sterile hydrogel strip 3 cm wide and 14 cm in length can be used for a secure fixation of the adhesive drape in regions where there is only slight lateral overlapping of the drape (perianal region, perineum) or to achieve air-tightness in the immediate vicinity of an external fixation (Fig. A4.11).

Y-Connectors, Sealing Plug

The sealing plug provides a hygienically sound seal for the container tube (Fig. A4.12). Y-connectors allow the connection of two *trac-pad connector* tubes to the tube of a single vacuum source (Figs. A4.13 and A4.14).

If, for example, two vacuum therapy dressings are applied to different parts of the body, they can be supplied by a single vacuum source.



Fig. A4.12 Sealing plug for the container tube.



Fig. A4.13 Y-tubing.



Fig. A4.14 Y-connector.

Special Dressings

Vacuum Therapy Glove Dressing Kit

When there are extensive degloving injuries or partial-thickness burn injuries of the hand, this "glove" allows an uncomplicated complete embedding of the hand in the polyurethane foam package consisting of a bottom half with a moulded depression for the hand with individual fingers and a top half consisting of a flat foam. After the hand has been placed inside the glove, a sealing bag (like a plastic bag) is pulled over it and fixed on the forearm. The dressing allows the complete coverage of the hand and fingers with the foam (Figs. A4.15-A4.17).



Fig. A4.15 The bottom half of the vacuum therapy glove dressing and the moulded depression for the fingers.



Fig. A4.16 Both halves of the vacuum therapy glove.



Fig. A4.17 The hand is embedded in a glove dressing which is not yet under suction. It is covered with a transparent sealing bag that is fixed on the forearm with incorporated strips of adhesive tape.



A4.18

Fig. A4.18 The part of the abdominal foam that is placed on the abdominal organs consists of a foam that has been encapsulated in a double-layered film. Numerous perforations in the non-adherent layer ensure that negative pressure is built up.

Abdominal Dressing System for Vacuum Therapy

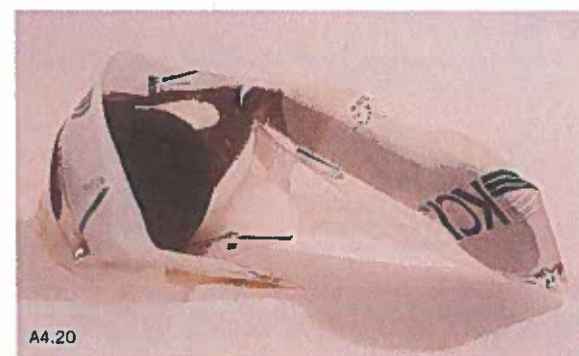
The abdominal dressing for vacuum therapy is suitable for the temporary closure of the open abdomen with exposed viscera. It consists of two parts:

1. A foam that is sealed in a double-layered drape. This can be placed directly on the intestine or other organs. The lateral skirt of the drape extends approximately 25 cm beyond the foam and needs to be spread as smoothly as possible into the four quadrants laterally and craniocaudally. Both layers of the drape are manufactured with numerous perforations in order to ensure the transmission of suction (Fig. A4.18).
2. A second foam, which has a longitudinally oval shape. A special feature of this part of the dressing is its onion skin-like arrangement. By tearing off the first or second outer ring, a foam is obtained for the closure of the dehiscant abdominal wall wound that fits the wound without any further cutting to shape (Figs. A4.18 and A4.19).



A4.19

Fig. A4.19 The second foam, which is placed on the bottom foam. It is adapted to the size of the abdominal wall wound by removing individual layers.



A4.20

Fig. A4.20 Heel foam. A second diverging foam ensures the positioning of the *trac-pad* outside the wound.

Heel Dressing Kit for Vacuum Therapy

Use of a conventionally shaped foam for the closure of a heel ulcer or a wound that is located on the heel has the disadvantage that the relatively rigid suction connector (*trac-pad*) usually exerts punctual pressure on the wound due to the supine position of the patient. The heel foam, which is specially shaped for this situation, includes an additional second foam that extends from the heel wound along the side of the foot to the meta-

tarsus. The *trac-pad connector* can be positioned outside the load zone so that it is not pushed into the wound. Consequently, no unfavourable shearing and frictional forces are exerted at the heel wound when the patient moves, and leaks occur less often (Fig. A4.20)^{13,4}.



Fig. A4.21 Possible suction source: Redon drainage system.



Fig. A4.22 Possible suction source: drainage container and hand pump.

Vacuum sources for Vacuum Therapy

A variety of vacuum sources for the generation of the suction required for vacuum therapy are now available. In some situations, high-vacuum drainage containers (e.g. Redon drainage systems) that have been used since the early phase of vacuum therapy remain in use (Fig. A4.21). Usually, these drainage systems initially generate a suction strength of approximately 900 mmHg, although this decreases as the container is filled. The drainage container with an integrated hand pump that even allows the patient on the ward to easily restore the vacuum in the event of a loss of suction constitutes a further development (Fig. A4.22). This added function is useful since small leaks frequently cannot be prevented when the wound is sealed. In these cases, loss of suction leads to unnecessarily frequent changes of the conventional Redon drainage container.

Today, dedicated vacuum sources are enjoying increasingly broad use. These are commercially available and can be obtained from different companies, including the leading manufacturer of vacuum therapy foams (the so-called "therapy units") Figs. A4.23 - A4.28).

All therapy and safety functions are integrated into both systems of this manufacturer (VAC^{ATS} and VAC^{Freedom}): the suction strength and suction mode can be selected as described above (between 50 and 200 mmHg); loss of suction and overfilling of the container result in the staff being alerted. While a 500 and 1000 ml collecting reservoir (container; Fig. A4.23) can be inserted into the VAC^{ATS} vacuum pump system, a container with a capacity of 300 ml (Figs. A4.24 and A4.25) is integrated in the smaller, storage-battery operated VAC^{Freedom} therapy unit. With its greater portability, this smaller and lighter system, which can easily be worn on a strap over the patient's shoulder or around the neck, is particularly suitable for outpatient therapy and unusual transport conditions (e.g. return to home country after trauma suffered at vacation location).

Some first-generation therapy units remain in use today (Fig. A4.26). These units also have an integrated suction range and alarm function. However, these older devices have the disadvantage that, compared to systems of the new generation, there is no capacity to compensate small yet significant leaks in the drape. Even small leaks that are detected by the system trigger the alarm and cause the suction function to be switched off. Newer systems "tolerate" small leaks and compensate for them by building up a slightly higher suction. With the aid of an integrated measuring and control circuit (the T.R.A.C. technology), the current VAC^{ATS} therapy unit automatically increases the set suction of 125 mmHg to a suction of 150 mmHg, for example. When higher suction values are required, this system also triggers the alarm function. In many cases, it is only this possibility of compensation that makes vacuum therapy feasible in anatomically unfavourable locations where small leaks cannot be avoided.

Instillation therapy will constitute an extension of the therapeutic spectrum of vacuum therapy (see also Part A, Chapter 5). The programmable therapy unit (VAC^{instill}), which is now available in Europe too, will enable the automatic control of the instillation of topical wound solutions (Figs. A4.27 and A4.28).

With the software-controlled VAC^{instill} vacuum source, it is possible to automatically control the set duration of instillation, the time for which the instilled solution is allowed to remain in the wound to take effect and the desired frequency of the vacuum therapy per day (Fig. A4.28).

Electronically controlled therapy units are not the only systems that are used for vacuum therapy.



Fig. A4.23 Vacuum source (therapy unit, VAC¹³), container volume 500 ml, alarm function for loss of suction, blockage and overfilling of the container. Unit can be operated with a storage battery (four hours). An available 1000ml canister minimizes canister changes.

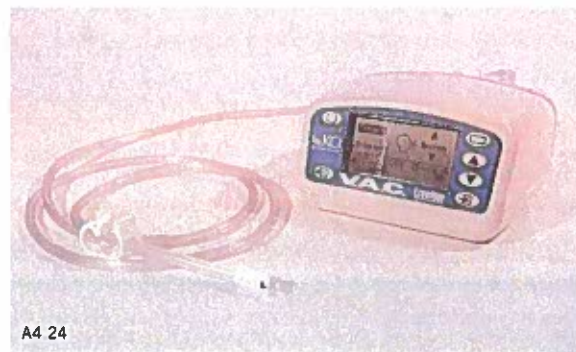


Fig. A4.24 Storage-battery operated therapy unit (VAC¹⁴). The lightweight unit can be comfortably worn on a strap. Container volume 300 ml, alarm function for loss of suction, blockage and overfilling of the container. Unit can be operated with a storage battery (12 hours).

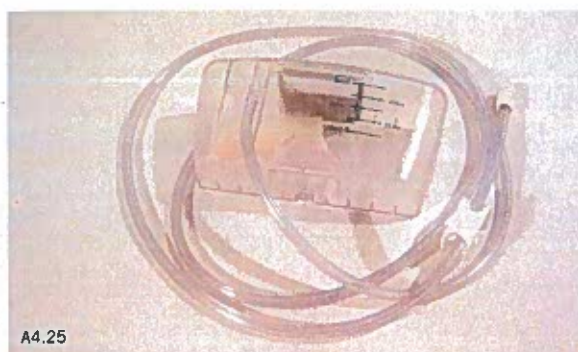


Fig. A4.25 Container for the VAC¹⁴ vacuum therapy unit with a capacity of 300 ml.



Fig. A4.26 First generation vacuum pump (therapy unit), which already was provided with an alarm function for loss of suction, blockage and overfilling of the container.



Fig. A4.27 Vacuum therapy unit with the possibility of automatic, software-controlled instillation of antiseptic or antibiotic solutions.

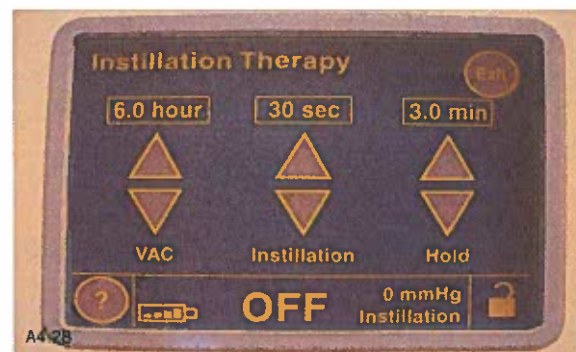


Fig. A4.28 Image of display with the setting options for the automatic instillation system VAC¹⁴.

After sealing of the wound, it is possible, in principle, to create the vacuum in the wound with other suction generators. The use of wall suction, which is usually available in the inpatient setting, is widespread. Other electronic pump systems are also sometimes used

(Figs. A4.30-31). Any known differences with regard to safety risks that may exist between the commercially available vacuum sources are discussed in Part A, Chapter 8 "Side-Effects and Risks of Vacuum Therapy".



Fig. A4.29 Connection of a collecting reservoir and a pressure control unit to the wall suction vacuum source installed in the hospital room. This system limits patient mobility. There is no alarm function and no capacity to use the "therapeutic regulated accurate care" (TRAC) feedback system.

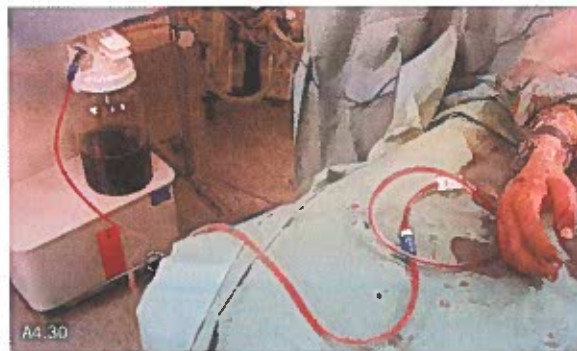


Fig. A4.30 Improvisation with the operating theatre suction system. There is no storage battery function, no alarm function and no possibility to use the "therapeutic regulated accurate care" (TRAC) feedback system.

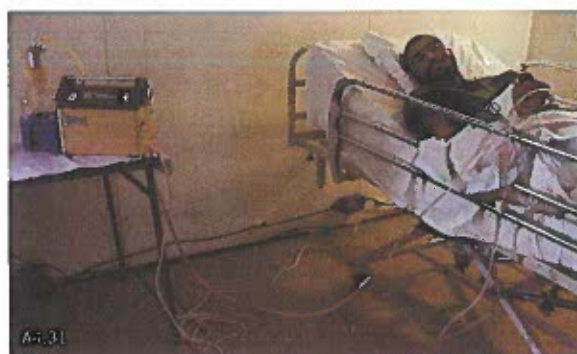


Fig. A4.31 Improvisation with a mobile suction system on the ward. There is no storage battery function, no audible and visual alarms and no possibility to use the "therapeutic regulated accurate care" (TRAC) feedback system.

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The diversity of the foams available today allows them to be used in an increasingly differentiated manner, such that optimum adaptation to the individual indication is possible in most instances. In certain cases, custom-made foams are available for a specific indication or location (open abdomen, hand, heel). Although almost the entire range of foams are supplied by a single manufacturer, the user can choose from various technical solutions for the suction generators. These differ greatly in their user-friendliness and in their practicability under inpatient and outpatient conditions. Major differences exist with regard to the capacity to detect malfunctions and alert the user (alarm function). Only one manufacturer offers systems with an integrated alarm function for loss of suction and over-filling of the container.

Part A / Chapter 5

Vacuum Instillation Therapy

W. Fleischmann

(in collaboration with C. Willy)

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Own Experiences with Instillation Therapy	36
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Instillation therapy is a further development and modification of conventional vacuum therapy for the complementary treatment of acute and chronic wound infections after initial surgery. It involves the instillation of the chosen drug in dissolved form into the foam situated in the wound via a second tube. Depending on the particular situation, the drug is normally permitted to remain in the wound for approximately 5-30 minutes in order to allow it to take effect. In this way, it comes into contact with the potential pathogen(s) over the entire area between the foam and the wound surface. Instillation therapy has been used clinically since 1996. Since 1999, refinements in equipment have provided the option of automatically controlled instillation therapy. This permits constantly controlled instillation (e.g. every three hours) without burdening either the patient or the nursing staff. To date, experiences have been made with antiseptic and antibiotic solutions, sometimes in combination with local anaesthetics.

There are currently eight *peer-reviewed* articles that have been published on the subject of "instillation therapy" (1998-2006; four article EbM level 4 and four articles have EbM level 5).

Introduction

Vacuum therapy has been successfully used for the treatment of acute wound infections after surgical wound debridement^{10,12,14,15,25,32,38,39}. Experimental studies have shown that vacuum therapy produces a beneficial shift in the species composition of the bacterial flora and a significant reduction in the bacterial concentration on the contaminated wound surface^{3,23,33}.

Nevertheless, clinical outcomes of infected or contaminated wounds have been observed that, clinically, were either not controlled or not satisfactorily controlled despite the vacuum therapy. In our own domain, we were expecting optimisation in terms of the method for these situations very soon after the introduction of vacuum therapy. The stated objective of this modification of the principle of vacuum therapy was to provide the capacity for an intermittent application of antibacterial solutions as an adjunct to the known effects of the therapy. It was proposed that, by taking advantage of the large area of contact between the foam and the wound surface, there could be even distribution of the antibacterial solution over the entire wound surface. It was hoped that the introduction of instillation therapy as an additional vacuum therapy option would increase the effectiveness and safety of the therapy in the treatment of infected wounds^{13,22}.

Time Sequence and Mode of Action of Instillation Therapy

Instillation therapy is performed during vacuum therapy by instilling the desired solution into the foam via a dedicated tube system and then, after a set time during which the drug is left to take effect and no suction is applied, removing the solution by suction (continuation of the actual vacuum therapy). In principle, this alternation between vacuum therapy and instillation periods can be repeated as often as desired. The instillation should in fact be performed several times a day for sufficient antimicrobial effect.

In order to enhance practicability in clinical routine, an electronic control unit was integrated into the existing commercial vacuum therapy unit, leading to the development of the automatic instillation system (VAC^{Instill})^{13,22}. As a result of this automation, it is now possible to perform the individual therapy phases according to a controlled time sequence:

In the first phase (instillation phase), which lasts for approximately 10-20 seconds, depending on the size of the wound, the vacuum line closes, the instillation line opens and the instillation fluid drips by gravity through the first tubing to saturate the foam and bathe the wound. During instillation, pressure values above the atmospheric ambient pressure are eventually reached in the foam and in the wound region. The wound thus unfolds and its surfaces are then completely in contact with the drug solution. During the first instillation, the absorption of the inflowing liquid by the foam and the expansion of the foam are monitored through the transparent drape. The time required for this phase is entered in the automatic instillation system.

After the closure of the instillation line, the in- and outflow remain blocked in the subsequent second phase, the drug action phase. Even with ambulatory patients, there is no movement of fluid in the tubes. The drug solution has unhindered access to the unfolded wound surface, even in deep and piercing wounds. The duration of the active phase is dependent on the pharmacokinetics of the drugs used and the sensitivity of the pathogens (usually 5-30 minutes).

When the third phase – the vacuum phase – begins, the original negative pressure is restored. At the same time, the drug solution is removed by suction together with the wound exudate and the wound detritus. The duration of the vacuum phase is dependent on the clinical assessment of the virulence of the infection and the associated toxin production, and on the viscosity of the wound exudates that affect the porosity of the foam. This phase takes between 30 minutes and several hours; the standard setting is one to three hours.

Each instillation cycle basically corresponds to a normal dressing change. However, with the automated instillation system (VAC^{Instill}), which is available for use today, the number of “dressing changes” is practically unlimited, so that an uninterrupted intensive and effective wound management becomes possible. For both patient and therapist, the number of time-consuming and often painful dressing changes is substantially reduced. Instillation therapy thus appears to be a patient-friendly and cost-effective form of treatment for acute and chronic, infected wounds. Above all, it is the automation of the therapy unit that ensures the safety, effectiveness and treatment comfort of the procedure. A time switch controls the function of the two valves that

are responsible for opening and closing the instillation and vacuum lines. Any malfunction triggers an alarm signal. All events are automatically documented in the background.

Instillation therapy should not be confused with the irrigation-suction drainage described by Willenegger³⁵ in which a continuous directional flow of liquid is generated that naturally takes the shortest route along a pressure gradient between the inflow via the infusion line and the outlet via the drainage tube. With irrigation-suction drainage, it has been found that dead spaces are created in the neighbourhood of these "irrigation routes". These dead spaces can no longer be reached by the irrigation solution after a few irrigation-suction cycles and may thus persist as septic "islands". With instillation therapy the wound is, ideally, completely filled by the foam so that the creation of dead spaces is unlikely.

On the vacuum side, the therapy unit contains an integrated collecting reservoir for the instillation fluid that is removed by suction. Different sizes are available, as required. The option of mains or battery operation enables the transport of the patient without interruption of the therapy and promotes patient mobility. The unit is comfortably operated via a touch screen. The various functions of the automatic instillation system, such as the level of vacuum and the duration of the instillation, drug action and vacuum phases, can easily be selected and set with the fingertip. The electronic control system allows for many different settings. The instillation phase, for instance, can be set at between one second and two minutes, the drug action phase at between one second and one hour and the vacuum phase at between one minute and 12 hours.

Indications for Vacuum Instillation Therapy

Current experience in the application of instillation therapy includes the following indications for its use
13,16,18,19,22,26,36,37.

- Septic wounds after initial surgical debridement (acute infections, particularly postoperative infections, are considered the most favourable indications for the instillation technique).
- Infection in the region of the implant bed (in many cases, sepsis was achieved even without removing the osteosynthesis material).

- Uncomplicated wounds (instillation therapy can regenerate the porosity of the foam, which preserves the effectiveness of the seal and extends the intervals for vacuum dressing changes. With aseptic wounds, Ringer's solution can be used for instillation).
- Osteitis, osteomyelitis, empyema (chronic soft-tissue and bone infections after surgical removal of the septic focus).
- Painful wounds (postoperative or infection-related conditions of pain occasionally require the instillation of local anaesthetics; this can also make sense when a painful PU dressing change is anticipated).

Wound Management and Setting up the Instillation Therapy System

Non-viable tissue barriers protect infective agents against the antibacterial effect of the instilled antiseptic and impede effective detoxification during the vacuum phase. Extensive surgical wound debridement for the removal of necrotic and atrophic tissue and fibrinous wound layers is thus a prerequisite for successful instillation therapy.

With surface wounds or widely gaping wounds, the black polyurethane (PU) or the white polyvinyl alcohol (PVA) foam can be used. After the wound has been sealed with the adhesive drape, at least two suction connectors – one for the instillation and the other for the vacuum – must be attached. (Fig. A5.1).

With deep wounds that lie beneath healthy skin or viable muscle layers (e.g. postoperative infection), we prefer the white PVA foam. Due to the effects of the vacuum, it becomes a thin, hydroactive membrane with a thickness of two millimeters and closely approximates the wound surfaces. The formation of iatrogenic cavities, as occurs with wound packing, is thus counteracted and a pressure-related disturbance of tissue perfusion is avoided. The skin should be fixed to the foam under tension in order to reduce the size of the wound and prevent retraction of the wound edges. However, a "monitoring window", through which the foam remains visible, should always be left. This provides visual evidence that the wound is passing through the three phases of instillation vacuum therapy in the correct manner. After sealing the superficial wound, two *trac-pad connectors* are attached (one for the instillation tube and the other for the container tube).

With deep wounds, the PVA foam with incorporated drainage tubes can be used. The tubes serve the purpose of exudate removal and creation of the partial vacuum. With the aid of an additional, separately inserted drainage tube (12-16 Charrière; without suction connector), the instillation fluid can be located at the deepest part of the wound or the particular wound compartment. In this modification, the drainage tubes are brought out through the wound or, if necessary, through the skin (see Fig. A5.2). Finally, the wound region is sealed air- and watertight with the common adhesive drape. If a "deep drainage" tube is brought out through the wound, it will then be necessary to seal in the drainage tube between two layers of adhesive film in order to achieve a sufficient leak-tightness (sandwich technique, Figs. A5.3 and A5.4). If the fluid accumulates between the foam

and the bulging drape, the pressure or the instillation time must be reduced. If the installed fluid is not fully removed during the vacuum phase, the system is blocked and requires changing.

Own Experiences with Instillation Therapy

In the Department of Trauma and Reconstructive Surgery of Bietigheim-Bissingen Hospital, instillation therapy has been used since early 1996^{13,22}. Since 1999, the electronically controlled automatic instillation system (VAC^{Instill}), which allows the automation of fluid instillation in any desired duration, has been used for the therapy. To date, over 500 patients have been treated with this method. The spectrum of indications currently includes soft tissue, bone and joint infections (in all cases,



Fig. A5.1 Chronic osteitis of the right femur. Two *trac-pads* are used for the instillation therapy. The instillation side (infusion bottle, left VAC^{Instill} valve, left *trac-pad*) is on the left and the vacuum side (right *trac-pad*, right VAC^{Instill} valve, canister) is on the right. Center of picture: VAC^{Instill} therapy unit.



Fig. A5.3 The instillation and vacuum tubes are sealed in between the adhesive layers of two sheets of adhesive drape and thus fixed with an air- and watertight seal (sandwich technique).

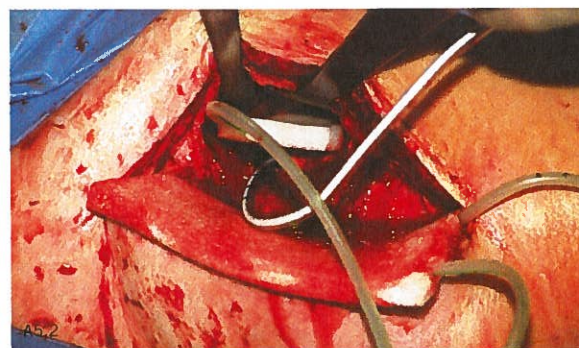


Fig. A5.2 Septic Girdlestone situation of the right hip. Preparation for instillation therapy: carefully chosen placement of the PVA foam with, in this case, integrated drainage tubes, so that complete contact is made with the entire wound surface. The separately inserted installation tube is visible below the upper foam. Its perforated end lies in the deepest part of the wound.

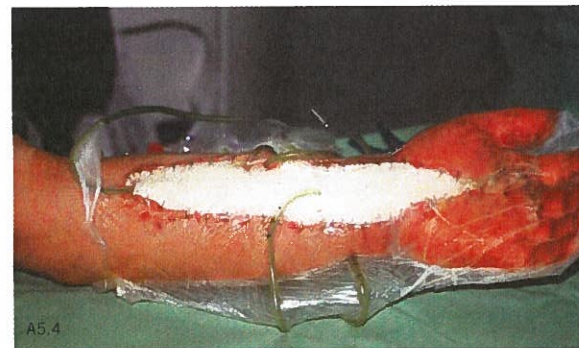


Fig. A5.4 Phlegmon of the left forearm. The instillation tube runs through the superficial foam into the depth of the wound.

the septic focus was first removed according to the general principles of surgery):

- Acute infection after osteosynthesis
- Acute infection after total hip joint replacement
- Contaminated open fractures
- Chronic femoral osteitis
- Chronic osteitis after removal of a total hip prosthesis
- Isolated soft-tissue infections (abdominal wall abscess after ileus and closure of disrupted abdomen with prolene mesh, phlegmonous inflammation of the flexor compartments of the lower leg)
- Acute purulent bursitis
- Ulcus cruris
- Diabetic gangrene of the forefoot

The most common pathogens in the observed patient population were *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The usual instillation fluids, which are used, are:

- Nebacetrin® (antibiotic; per gram dry substance: neomycin sulphate 325,000 IU (aminoglycoside), bacitracin 25,000 IU (polypeptide complex from *Bacillus subtilis* and *Bacillus licheniformis* cultures) in 100 ml NaCl solution; Yamanouchi Pharma; left to take effect for 30 minutes)
- Lavasept® (antiseptic; polihexanide 400 mg, macrogol 4000, 20 mg in 1000 ml Ringer's lactate; Fresenius AG; left to take effect for 30 minutes)

Some authors alternated daily Nebacetrin® and Lavasept® 0.4% (n=5, in septic hip and knee wounds following arthroplasty, PVA foam, instillation time 15 sec, active phase 10-20 minutes, approx. every two hours for 15 days, dressing change every 4-5 days)¹⁸. Other authors used only Lavasept® 0.2% (n=3, in septic hip and knee wounds following arthroplasty, PVA foam, instillation time - 40 sec, active phase 15 minutes, approx. every two to six hours for four to six days)¹⁹.

In most cases, the implant, e.g. the osteosynthesis material, the endoprosthesis or the abdominal wall mesh could be left in place in acute infection situations. Apart from a few exceptions, healing of the wound could even be achieved in patients with chronic infection. For instance, in patients who were treated with vacuum instillation during a Girdlestone situation (after explantation

of the total hip prosthesis due to infection), reimplantation of the total hip prosthesis was possible after a short time, usually only two weeks in the majority of cases.

Drugs for Instillation Therapy

According to our own experiences with well over 500 patients treated to date, the antibiotic Nebacetrin® (neomycin sulphate / bacitracin, Yamanouchi Pharma) and the antiseptics Lavanid® (polihexanide, Serag-Wiessner) or Lavasept® (Fresenius AG)^{13,22,36} have proved successful for this purpose. No pharmacologically and toxicologically relevant interactions between the foam material and these drugs that have been used in instillation therapy have been described to date, and there are no reports of absorption-related reductions in effectiveness.

Based on the presentations in the literature, it is also possible to instill other topical solutions during vacuum therapy:

- Ringer's lactate for "regeneration", i.e. rinsing of the foam. This can extend the changing interval of two to three days, which mainly applies to the black PU foam, in particular cases. However, the instillation of Ringer's lactate also results in a reduction in bacterial wound contamination even without the addition of further antiseptics or antibiotics¹⁶.
- Local anaesthetics to reduce the discomfort of dressing changes if anaesthesia is not possible. They can also be instilled for pain reduction if vacuum therapy is painful, when a reduction in suction has not provided relief, or in cases of persistent, irritating itching. The instillation of 25 ml lidocaine 1% in 250 ml NaCl or 25 ml lidocaine 2% in 500 ml NaCl, left to take effect for five minutes, every three hours for seven days, has proved successful^{36,37}.
- Streptokinase for the promotion and increase of fibrinolysis; dose: dry substance Varidase® 125,000 IU per 50 ml NaCl³¹.
- Antibiotics such as vancomycin were successfully used in a case of ORSA (oxacillin resistance; 1 g vancomycin per 250 ml NaCl, left to take effect for five minutes, every three hours for three days)^{36,37}.
- Also topical application of other antibiotics like gentamicin (80 mg dissolved in 500 ml NaCl, sometimes in combination with a cephalosporine like cefazolin 500 mg in 500 ml NaCl) or tobramycin (80 mg dissolved in 500 ml NaCl) were successfully used³⁶.

- In isolated cases, the antibiotic substance was instilled together with a local anaesthetic^{36,37}.
- Further topical wound solutions are silver nitrate solutions ($\leq 0.5\%$) and acetic acid solutions ($\leq 3\%$; recommended in our experiences for *pseudomonas* infections).

Several aspects of wound irrigation ("manual" intraoperative or postoperative flushing of the wound) with antibiotics and antiseptics are critically discussed below against the background of the existing literature on the subject. This appears necessary as our own positive experiences are not always in accord with reports in the literature.

However, there is agreement on the fact that the depth of tissue penetration by instilled drugs and the extent of their absorption are dependent on the biochemical properties, the wound perfusion and the molecular weight of the drug in question. It seems obvious that, when drugs with a low depth of penetration and rate of absorption are chosen, the therapeutic effect is limited to the surface. This explains why favourable results have mainly been achieved with acute infections. Hence, the earlier the systematic treatment begins, the greater the chances that instillation therapy will be successful. Some substances should only be used with caution in vacuum instillation therapy. Although some of the critical comments below are only based on individual observations and there have been positive experiences with these substances elsewhere, we want to point out potential sources of danger or possible complications that may arise when these substances are used.

Hydrogen Peroxide (H_2O_2)

There are reports in the literature of serious complications after wound irrigation (no vacuum therapy) with hydrogen peroxide. The absorption of minute gas bubbles led to small gas embolisms in three patients who developed a shock and coma situation, pulmonary oedema, and pneumocephalus in the region of the posterior cranial fossa which compressed the basal ganglia, respectively^{4,6,38}. In the latter case, the complication had occurred in a 40-year-old male directly after irrigation of an infected intervertebral space (H_2O_2 is unsuitable for instillation). Additionally, H_2O_2 destroys the porous structure of the black PU foam. Therefore, and due the effervescence of the solution upon contact, vacuum dressings are contraindicated for use with hydrogen peroxide.

Furthermore, solutions that are alcohol based or contain alcohol are also contraindicated due to their potential adverse effects on skin with extended tissue contact. Vacuum instillation therapy is intended for use with saline solutions in a physiologic pH range that are topical wound treatment solutions.

Neomycin Sulphate

Even though no complications occurred in connection with the Nebacetin® instillations in our own domain, it should be mentioned that overdose, which has been reported in the literature, can lead to irreversible side-effects due to the oto- and nephrotoxicity. For instance, positive systemic neomycin levels were detected after intraoperative irrigations following a hip prosthesis replacement and another research group observed progressive ototoxic effects even after the instillation had been discontinued^{21,34}.

Over a period of almost a decade, the author has observed no resistance problems due to the local application of the antibiotic Nebacetin®. Although it is being discussed that the local application of an antibiotic contributes to the sensitisation of the patient and the development of resistances, this is not confirmed by patient follow-up. One should also take into account that antibiotic carriers have been placed in septic wounds in infection situations for decades (Septopal® chains, Sulmycin® foam) and the healing outcome was positively influenced by the topical application of antibiotics^{20,24}.

Nebacetin®, which contains a combination of different active substances, was chosen by the author as a suitable drug for instillation because, unlike many other antibiotics that can potentially be used for instillation therapy, it has a long half-life and only a slight photosensitivity. It also appears to be advantageous that Nebacetin® does not form a bond with the PVA foam material.

Bacitracin®

It must be taken into account that there are isolated reports in the literature ($n = 4$) of anaphylactic reactions during irrigation (mediastinum, knee joint) with Bacitracin^{2,5,11}. Allergy testing should therefore be ordered before it is used⁹.

Lavasept®

The existing reports ($n = > 1600$ patients) document a reduction in the incidence of infection and good tolera-

bility when prophylactic intraoperative irrigation is performed with Lavasept[®]. No joint irrigations should be performed because of chondrotoxicity.

Polyvinyl Pyrrolidone

For safety reasons, only well-tolerated drugs with little or, preferably, no absorption should be used. So far, no polyvinyl pyrrolidone solutions have been used in our own domain. Besides, there was a report in the literature of a fatality after continuous irrigation of a septic wound following hip surgery⁷. On the other hand, the reports of follow-ups after wound irrigation in almost 1500 patients do not mention any complications due to absorption^{1,8,17,27,30}.

Instillation therapy is an effective variant of vacuum therapy for the treatment of wound infections. The correct indication is of crucial importance for the therapeutic result. The low penetration depth of most topical drugs that can be used leads to limitations. The best treatment results are achieved with acute inflammations where there is no deep tissue penetration of the pathogens. Chronic inflammations with deeper bacterial infiltrates require surgical decontamination during which the infected tissue is removed as completely as possible before instillation therapy is performed. The possibility of instilling Ringer's lactate ("regeneration of the foam") to extend the changing interval when PU foam is used also seems to represent an interesting option.

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Part A / Chapter 6

Experimental Basis I

– Review of the Literature

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The aim of this overview is to present the current state of knowledge on the physiological effects of vacuum therapy. On reviewing the literature, one is struck by the fact that, despite numerous inconsistencies with other results, a small number of research findings are repeatedly cited to explain the effects of vacuum therapy. Scientific studies conducted to date do not answer many questions regarding the functional mechanisms and effects of vacuum therapy. Although some surprising findings emerge in the analysis of all available publications, numerous questions remain unanswered. This scientifically unsatisfactory but nevertheless fascinating situation stands in sharp contrast to the confirmation of vacuum therapy's clinical effectiveness reported in a great many studies, observational reports and case descriptions.

"The physiological and molecular biological mechanisms by which VAC therapy accelerates wound healing are to a large extent unknown."

Wackenfors, 2004⁶⁹

Reasons primarily given for the generally acknowledged success of vacuum therapy included induction of granulation tissue and the reduction of the wound area. These effects were even observed in wounds in bradytrophic tissue as well as over bone and even over metal implants. These favourable effects have been ascribed to:

- Improved blood flow in the tissue at the wound edges. It is stated that an increase in the local blood flow by up to 400% is induced^{6,33,44,50,68,76}
- Reduction of the microbial load^{9,11,27,44,47,72}
- Reduction of interstitial fluid^{43,44}
- The effects of the mechanical forces that act on the affected cells and are thought to lead to stimulation of cell proliferation^{26,36,37,44,56,71}

Since its first description in the early 1990's, these effects of vacuum therapy have consistently been cited in reports of the high clinical importance and the excellent results of this method. However, the citations refer to only a few isolated studies in which today's knowledge of the principles of action of vacuum therapy was acquired.

Against this background, the aim of the overview is to provide a detailed presentation and discussion of our present knowledge based on these studies. It should provide the vacuum therapy user with a general idea of the current state of the scientific basis of this clinically successful therapy. The overview also presents identified

research deficits and possible scientific study approaches and should contribute to maximizing the potential of vacuum therapy. Thus, a method that is already successful today can become even more effective in the future by taking advantage of further technical developments.

Material and Methods

Literature Search

Publications referenced in the European Tissue Repair Society's monograph published on the occasion of the *Topical Negative Pressure (TNP) Focus Group Meeting* (London, 2003) and the publications of the abstract volume of the *Second World Union of Wound Healing Societies (WUWHS) Meeting* (Paris, 2004) have been added to the results of the search presented in Part A, Chapter 2 "Literature on the Subject of Vacuum Therapy".

Procedure for Presentation and Assessment of Studies

For each of the following subject areas, studies are presented in the chronological order of their publication:

1. Change in perfusion as a result of vacuum therapy
2. Immunology (bactericidal property of the wound exudate, decontamination, bacterial clearance)
3. Cell proliferation, growth factors, speed of wound healing, new granulation tissue formation, epithelialization
4. Pressure and suction relationships – measuring results and effect on the wound healing rate
5. Systemic effects

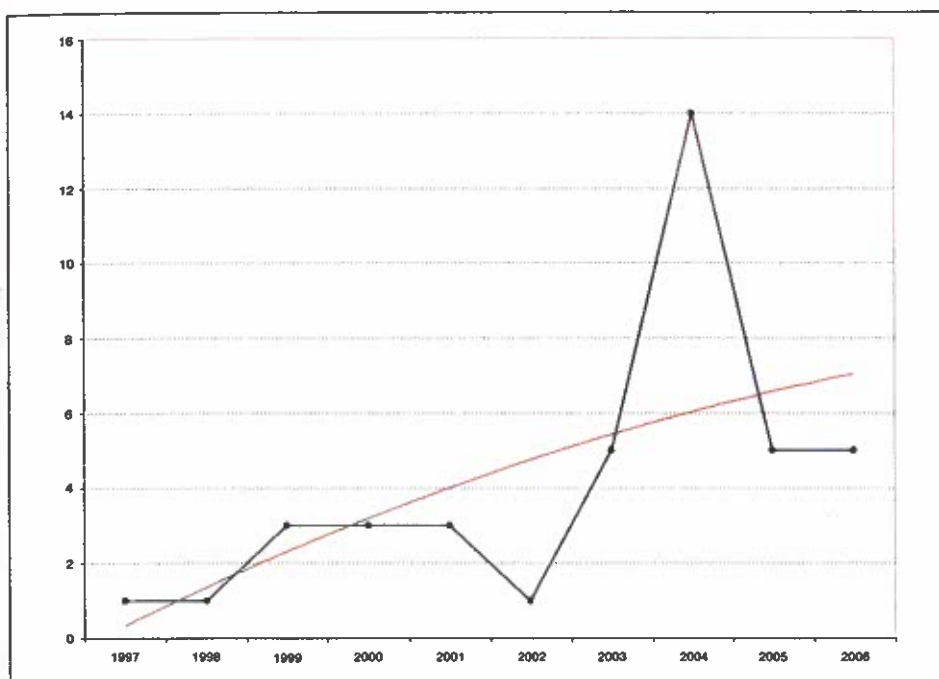


Fig. A6.1 Number of publications per annum in which the scientific background of vacuum therapy was investigated (red line: trend). It has to be taken into account, that the year 2006 is not yet complete (the search was last updated on 30 June, 2006)

A detailed presentation of the individual studies will be given according to the same pattern for each of these subject areas: title – type of publication – contents – conclusion by the authors – comments or considerations, if any, in connection with the overview.

Results

Number of Publications

To date, several thousand journal articles, congress reports, abstracts, letters, editorials and posters have been published both nationally and internationally on the subject of “vacuum therapy”. The analysis of the literature shows that the majority of the available reports in the print media must be regarded as congress reports, expressions of opinion or experience reports and that they did not undergo a *peer review* process in most cases. Since the introduction of vacuum therapy, 550 publications have been published that fulfil the criteria mentioned in Part A Chapter 2. These include 41 publications (30 full papers, 10 abstracts, one discussion) that give a background of the mechanism of action of vacuum therapy (Fig. A6.1).

Change in Perfusion as a Result of Vacuum Therapy

① Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W (1997) Vacuum-assisted closure: A new method for wound control and treatment: Animal studies and basic foundation. *Ann Plast Surg* 38:553-562⁴⁴.

Type of Publication

Full paper

Contents

In a series of animal experiments (species: pig, $n = 5$), laser Doppler flowmetry was performed in the subcutaneous tissue and at the wound edge (excision wound with a diameter of 2.5 cm) during vacuum therapy (suction strength: 0-400 mmHg in increments of 25 mmHg); continuous and intermittent therapy (cycles: 1-10 minutes ON and 1-5 minutes OFF). The blood flow in subcutaneous tissue and muscle initially increased by up to factor of 4 (suction strength 125 mmHg). At suction strengths of 400 mmHg and above, perfusion decreased to below baseline levels. Five to seven minutes after the start of continuous vacuum therapy (125 mmHg), a reduction of this increased blood flow to

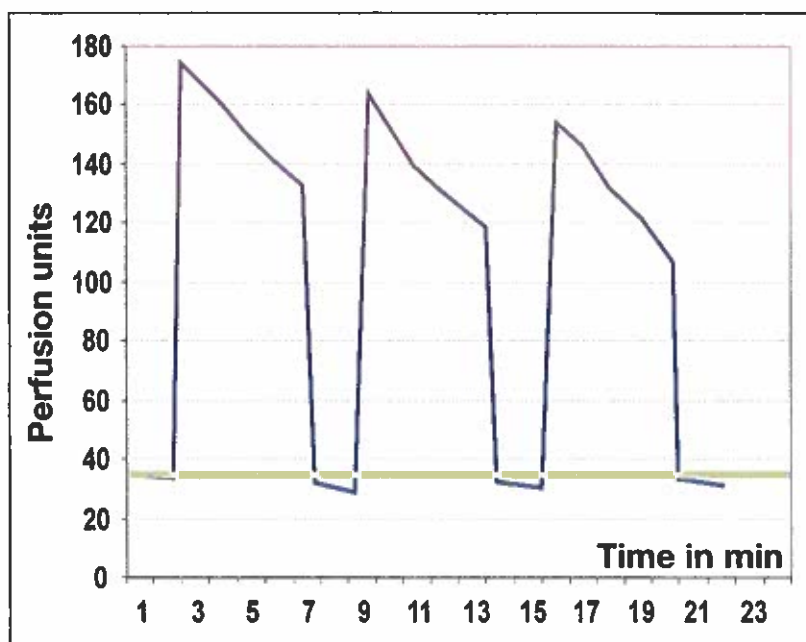


Fig. A6.2 Perfusion values measured by Doppler flowmetry in subcutaneous tissue and at the wound edge during intermittent suction of 125 mmHg with a suction cycle of five minutes ON/two minutes OFF (n = 5; species: pig). An increase to up to four-fold baseline levels is found during suction and a decrease to values below baseline is found during the OFF periods. The green line represents the baseline (modified according to Morykwas et al. ⁴¹).

baseline values was observed. The intermittent suction resulted in an increased blood flow during the ON phase and in a decrease in flow values to baseline levels in the OFF phase. The increase in flow values was reduced when the OFF period was less than two minutes; OFF periods of more than two minutes had no positive or negative effect on perfusion.

Conclusions by the Authors

Vacuum therapy results in an increase in local functional perfusion. Due to the reduced blood flow after application of suction for more than five to seven minutes and a reduction in the increase when OFF periods are less than two minutes, the suction cycle of five minutes ON/two minutes OFF is the most suitable cycle (Fig. A6.2). According to the authors, the increased perfusion leads to a reduction in bacterial contamination.

Considerations in Connection with the Overview

The authors of this paper are the first to describe the use of vacuum therapy in the North American area. The paper is the most frequently cited publication in the literature on vacuum therapy.

② Rejzek A, Weyer F (1998) The use of the V.A.C.™ system in the therapy of ulcer cruris and diabetic gangrene. *Acta Chir Austriaca* Supplement No. 150:12-13⁵⁰.

Type of Publication

Extended abstract in a supplement volume

Contents

Using a laser Doppler technique, the capillary blood flow was measured transcutaneously in patients (n = 7, ulcer cruris) during continuous and intermittent vacuum therapy (two minutes ON, two minutes OFF). An increase of at least 50% in capillary blood flow was established during continuous suction (suction strength not stated) and a wavelike pattern was found during intermittent suction.

Conclusions by the Authors

A moderate suction effect increases the perfusion and oxygenation of the tissue.

Considerations in Connection with the Overview

Changes in oxygenation are not measured. Upon closer examination of the curve (Fig. A6.3), there is no homogeneous response of perfusion under the foam: when suction was applied, the perfusion initially increased but then decreased again on two occasions, while in one cycle it remained constant, and only once did it increase. A general increase in flow during suction cannot be convincingly derived from the graph presented by the authors. After the suction was switched off, an increase in perfusion was observed in three cycles and constant flow

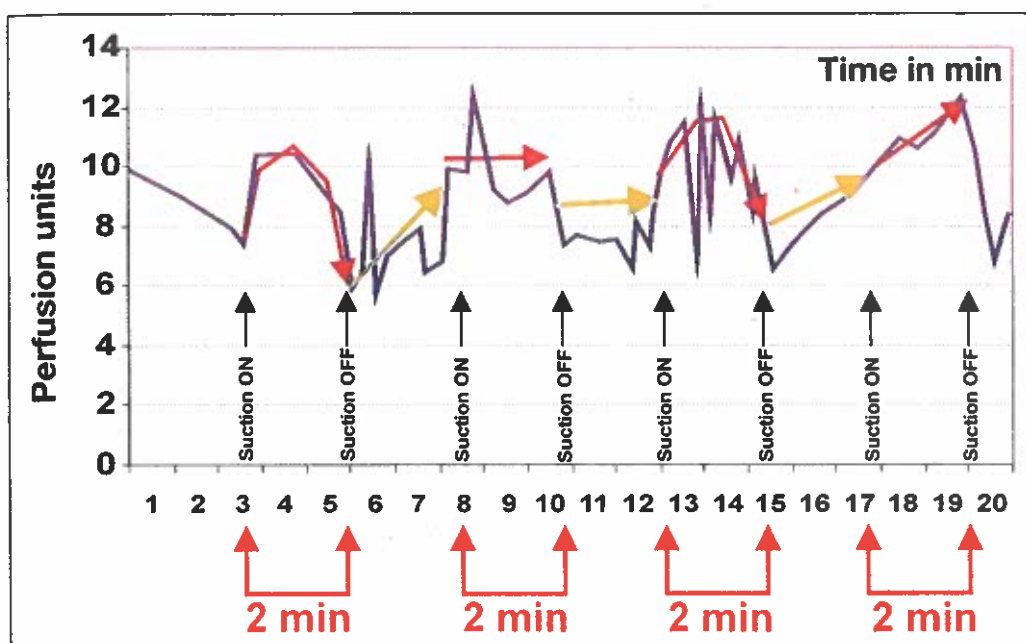


Fig. A6.3 Perfusion values measured by Doppler flowmetry in human wound tissue during intermittent suction with application of four suction cycles of two minutes ON/two minutes OFF ($n = 7$ patients, ulcerations on lower extremity). An inhomogeneous perfusion behavior can be shown. During application of suction (red line), the perfusion initially increased but then decreased on two occasions, while, in one cycle, it remained constant, and only once did it increase permanently for the suction interval of two minutes. After the suction was switched off (green arrows), there was an increase in perfusion on three occasions and constant flow behavior in one cycle. Similarly, no homogeneous response of perfusion can be seen in this time interval (modified according to Rejzek et al. ¹⁹).

behaviour was observed on one occasion. Similarly, no homogeneous response of perfusion can be seen in this time interval.

③ Banwell PE, Jones S, Evison D (2000). Dermal microvascular blood flow in experimental partial thickness burns: the effect of topical sub-atmospheric pressure. *J Burn Care Rehabil* 21: 161⁶

Type of Publication

Abstract, no full paper has been published so far.

Contents

In a randomised animal study, second-degree contact burn wounds ($n = 32$ pigs) showed significantly ($p < 0.001$) increased blood flow (Doppler flowmetry at times 0, 24, 48 and 72 h after application of vacuum therapy for 48 h and 72 h (125 mmHg suction, mode not stated), respectively, compared to a foam dressing without suction (FWS) and to conventional silver sulfadiazine dressing (SSD). The number of tangential ex-

cisions that were performed to regain healthy tissue was significantly lower after vacuum therapy (72 h after trauma; 6.25 ± 0.7 versus SSD: 13.0 ± 0.7 versus FWS 14.88 ± 0.7).

Conclusions by the Author

When applied to burns that do not affect all dermal layers, vacuum therapy reduces dermal ischaemia.

④ Kamolz LP, Andel H, Haslik W, Winter W, Meissl G, Frey M (2004): Use of subatmospheric pressure therapy to prevent burn wound progression in human: first experiences. *Burns* 30: 253-258¹³

Type of Publication

Full paper

Contents

In an initial experience report, the authors report on a perfusion measurement (ICG video angiography after application of indocyanine green, qualitative assessment

of the images and quantitative determination of the mean pixel intensity [MPI] in percent of a defined standard region) in seven patients with second-degree partial thickness burns of both hands which were treated within six hours after the injury. In wounds treated with vacuum therapy (the more severely burnt side was chosen; suction mode: continuous, suction strength: 125 mmHg, vacuum therapy foam glove in intrinsic-plus position) the examination on Days 1 and 3 revealed hyperperfusion as compared to the contralateral hand (treated with silver sulfadiazine). Oedema development and the degree of recapillarization were clinically assessed. On the hands treated with vacuum therapy, there was no decrease in perfusion as demonstrated by ICG video angiography (baseline $52.7\% \pm 12.0\%$, Day 1: $50.4\% \pm 12.4\%$, Day 2: $51.3\% \pm 10.8\%$, Day 3: $51.6\% \pm 15.1\%$) in contrast to the hands treated with SSD where a significant decrease ($p = 0.004$, $p = 0.001$ and $p = 0.008$ respectively) in perfusion was found on Days 1, 2 and 3: baseline $55.7\% \pm 8.8\%$, Day 1: $44.0\% \pm 6.3\%$, Day 2: $42.7\% \pm 6.7\%$, Day 3: $44.8\% \pm 6.6\%$. The differences between the two groups are significant for Days 2 and 3 ($p = 0.001$ and $p = 0.006$). The diffusion time to maximum mean pixel intensity (MPI) was $1.7 \text{ s} \pm 2.2 \text{ s}$ shorter at baseline (n.s.) in the SSD group, however it was longer on the subsequent days (Day 1: by $3.4 \text{ s} \pm 8.2 \text{ s}$ [n.s.], Day 2: by $3.8 \text{ s} \pm 6.1 \text{ s}$ [n.s.], Day 3: by $5.2 \text{ s} \pm 6.9 \text{ s}$ [$p = 0.013$]). Clinically, a reduction in oedema of up to 500 ml was observed during the therapy period.

Conclusions by the Author

Vacuum therapy has a favourable effect on dermal perfusion and leads to a reduction in oedema development. In addition, it induces hyperperfusion in second degree burn wounds. The therapy should begin within six hours and be performed for at least 48 hours to reduce oedema development within the initial 48 hours.

Comment

Similar results were presented by the research group of Schrank et al. in 2004 (Schrank C, Mayr M, Overesch M, Molnar J, Henkel VDG, Muhlbauer W and Ninkovic M (2004): Results of vacuum therapy (V.A.C.) of superficial and deep dermal burns. *Zentralbl Chir* 129 Suppl 1: P59-61). However, as the information was only qualitative and not quantitative, no detailed presentation will be given here.

5 Zöch G (2004) VAC-therapy and laser-induced fluorescence of indocyanine-green (IC-view), an assessment of wound perfusion in diabetic foot syndrome. In: Banwell P, Téot L (ed): Topical Negative Pressure (TNP) Focus Group Meeting (Proceedings European Tissue Repair Society). *TXP Communications*: 232⁷⁶

Type of Publication

Extended abstract

Contents

Perfusion before and after vacuum therapy was evaluated by ICG video angiography after application of indocyanine green in $n = 10$ patients with diabetic foot syndrome. The measurement revealed an increase in perfusion of 31% (6-62.5%) and 15% (1.5-38%) in the wound bed and the wound edge, respectively.

Conclusions by the Author

IC-View enables the quantification of the improvement in perfusion due to vacuum therapy.

6 Wackenfors A, Sjogren J, Algotsson L, Gustafsson R, Ingemansson R, Malmjö M (2004) The effect of vacuum-assisted closure therapy on the pig femoral artery vasomotor responses. *Wound Repair Regen* 12:244-251⁶⁸

Type of Publication

Full paper

Contents

In an animal study (species: pig; $n = 7$), the vasodilatation and vasoconstriction of isolated ring segments of the femoral artery were investigated after continuous 12-hour vacuum therapy (continuous suction, 125 mmHg) of an inguinal wound and compared with the results in the contralateral wound (control, a foam was placed in the wound and the wound was sealed, no suction). There was no macroscopically detectable difference. The vasoconstriction which was induced by endothelin-1 (ET-1 = endothelin type A receptor agonist) and the endothelin type B receptor agonist sarafotoxin 6c was significantly increased after vacuum therapy (ET-1: $325\% \pm 3\%$ versus $181\% \pm 2\%$ [$p < 0.01$]; S6c: $69\% \pm 1\%$ versus $30\% \pm 1\%$ [$p < 0.01$]; no effect on vasoconstriction induced by norepinephrine, phenylephrine or angiotensin II).

The vasodilatation induced by acetylcholine which is dependent on the endothelium was significantly increased by vacuum therapy (mediated by NO, prostaglandin and the endothelium-derived hyperpolarising factor which were significantly elevated after vacuum therapy).

Conclusions by the Author

Vacuum therapy over a period of 12 hours increases the vasoconstriction mediated by endothelin type A and type B receptors. This can be compensated by an endothelium-dependent vasodilatation.

7 De Lange MY, Nicolai JPA (2004) The influence of subatmospheric pressure on tissue oxygenation and temperature. *Abstract volume IInd WUWHS Meeting*, Paris 2004: 51¹⁷

Type of Publication

Abstract

Contents

Vacuum therapy (125 mmHg) was used on nine patients with wound-healing impairments after median laparotomy. The tissue oxygen partial pressure and the temperature were measured in subcutaneous tissue at a depth of 1 cm and a distance of 1 cm from the wound edge, using a polarographic measuring technique (Licox), before vacuum therapy was started and then over a period of 48 hours. The temperature and the tissue oxygen partial pressure did not show any significant changes.

Conclusions by the Author

Vacuum therapy has no effect on tissue oxygenation.

8 Wackenfors A, Sjogren J, Gustafsson, R, Algotsson L, Ingemansson, R and Malmjsjo M (2004) Effects of vacuum-assisted closure therapy on inguinal wound edge microvascular blood flow. *Wound Repair Regen* 12:600-606⁶⁹

Type of Publication

Full paper

Contents

Laser Doppler flowmetry using deep fibre-optic probes in 10 cm deep inguinal wounds (at a distance of 0.5 to

4.5 cm from the wound, increments of 0.5 cm) treated with vacuum therapy (50-200 mmHg, increments of 25 mmHg; animal study [species: pig; n = 7]). Analysis of the effects of intermittent suction at 125 mmHg and ON periods of between one and 15 minutes (at a distance of 0.5 cm from the wound). There is an increase in perfusion at a distance of 3 cm from the wound in subcutaneous tissue (+ 77 ± 46%) and at a distance of 1.5 cm in muscle tissue (+ 11 ± 8%; both at 50 mmHg). Hypoperfusion within this tissue in close proximity to the wound; with higher suction, the hypoperfused area increases more markedly in subcutaneous tissue (1.8 cm at 50 mmHg and 2.5 cm at 200 mmHg) than in muscle tissue. No effect on the blood flow when the distance is 3.5 cm or greater. During the ON periods, the blood flow increases by 40-50%; no further increase after a duration of over 10 min.

Conclusions by the Author

Vacuum therapy affects the microcirculatory blood flow. Particularly in subcutaneous tissue, the suction should not be set too high in order that perfusion near the wound is not excessively restricted. Intermittent therapy leads to an increase in the blood flow and prevents a persistent tissue ischemia.

9 Wackenfors, A., R. Gustafsson, J. Sjogren, L. Algotsson, R. Ingemansson and M. Malmjsjo (2005) Blood flow responses in the peristernal thoracic wall during vacuum-assisted closure therapy. *Ann Thorac Surg* 79(5): 1724-30; discussion 1730-1.⁷⁰

Type of Publication

Full paper

Contents

Microvascular blood flow was examined in the muscular and subcutaneous tissue by laser doppler velocimetry in an uninfected porcine sternotomy wound model (n = 19 pigs) to investigate the effects of negative pressure on peristernal soft tissue blood flow and metabolism (wound fluid pH, partial pressures of oxygen and carbon dioxide, bicarbonate, and lactate; after 0, 30, and 60 minutes of continuous negative pressure (-50 to -200 mm Hg); at different distances from the wound edge). Close to the wound edge, relative hypoperfusion was observed. The hypoperfused zone was larger at high nega-

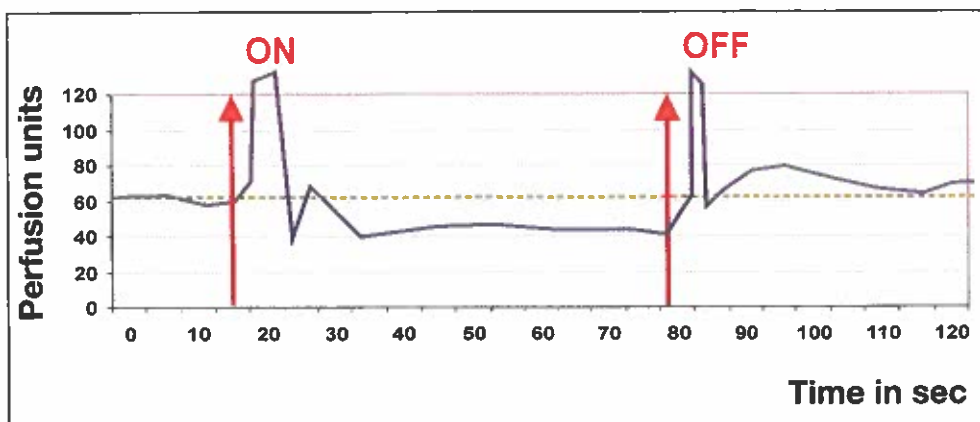


Fig. A6.4 Perfusion values measured by Doppler flowmetry in inguinal wounds (pig, $n = 7$) before, during and after vacuum therapy (applied for approx. 1 min; suction: 125 mmHg), measured in subcutaneous tissue at a distance of 0.5 cm from the wound edge; baseline perfusion is shown as a broken green line. Perfusion decreases during application of suction; after the suction is switched off (time = red arrow) there is an increase in perfusion (modified according to Wackenfors et al.⁶⁵).

tive pressures and was especially prominent in subcutaneous tissue; increase in the microvascular blood flow a few centimeters from the wound edge. Wound fluid partial pressure of oxygen and lactate levels were increased after 60 min of vacuum-assisted closure therapy.

Conclusions by the Authors

The change in microvascular blood flow is dependent on the pressure applied, the distance from the wound edge, and the tissue type. It may be beneficial to tailor the negative pressure used for vacuum-assisted closure therapy according to the wound tissue composition.

Considerations in Connection with the Overview

Similar, in principle, to results published 2004⁶⁶.

⑩ Timmers, M. S., S. Le Cessie, P. Banwell and G. N. Jukema (2005) The effects of varying degrees of pressure delivered by negative-pressure wound therapy on skin perfusion. *Ann Plast Surg* 55(6): 665-71.⁶²

Type of Publication

Full paper

Contents

Prospective, randomized study evaluating the response of cutaneous blood flow (CBF) in healthy intact forearm

skin ($n = 10$) to varying vacuum therapy negative pressures and both foam types (PU, PVA). Continuous negative pressure was used in the range of 25-500 mmHg. Skin blood flow was measured with noninvasive laser Doppler probes incorporated into the foam. Significant increase in CBF was found with both foams up to negative pressure of 300 mmHg, with over 5-fold increase (mean: 5.57; SD: 3.32) with the PU foam and nearly 3-fold increase (mean: 2.87; SD: 1.29) with the PVA foam.

Conclusions by the Authors

Comparison of blood flow baseline *versus* negative pressure of 300 mmHg showed a statistically significant difference ($P < 0.001$). No decrease in blood flow below baseline was observed during the experiments.

⑪ Chen, S. Z., J. Li, X. Y. Li and L. S. Xu (2005) Effects of vacuum-assisted closure on wound microcirculation: an experimental study. *Asian J Surg* 28(3): 211-7.¹³

Type of Publication

Full paper

Contents

Round full-thickness skin defects (2 cm in diameter, 32 Japanese large-ear white rabbits, dorsal left ear:

experimental group (vacuum-assisted closure; -5, -10, -15 and -20 kPa, lasting for 20 minutes, intervals 10 minutes), right ear: control group [petrolatum gauze]) were made to study blood flow on skin wounds. Microcirculation microscope and image pattern analysis were used to observe the variation in wound microcirculation through a detective window. Vacuum therapy promoted capillary blood flow velocity, increased capillary calibre and blood volume.

Conclusions by the Authors

By increasing capillary calibre and blood volume and by stimulating angiogenesis, vacuum therapy could improve blood circulation in wounds. By narrowing endothelial spaces and by restoring the integrity of capillary basement membranes, vacuum therapy could decrease the permeability of blood vessels and wound oedema.

⑫ Jungius, K. P., B. K. Chilla, L. Labler, N. Teodorovic and B. Marincek (2006) Non-Invasive Assessment of the Perfusion of Wounds Using Power Doppler Imaging: Vacuum Assisted Closure® versus Direct Wound Closure. *Ultraschall Med.*³²

Type of Publication

Full paper

Contents

Power Doppler ultrasound was carried out under standardised conditions in 15 VAC-treated and 10 primarily closed wounds to assess the perfusion in wounds treated by vacuum assisted closure compared to primary wound closure. All wounds showed a significant increase in perfusion when compared to the intraindividual reference area ($p < 0.0001$). In VAC-treated wounds, a markedly increased perfusion was measured compared to the wounds closed primarily ($p < 0.0001$). Perfusion decreased during treatment, but in two VAC-treated wounds, an initial increase in perfusion was observed. Both these wounds were grossly infected.

Conclusions by the Authors

Power Doppler ultrasound allows the quantification of the differences in wound perfusion.

Immunology (Bactericidal Property of the Wound Exudate, Decontamination, Inflammatory Reaction of the Body)

① Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W (1997) Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. *Ann Plast Surg* 38:553-562⁴⁴

Type of Publication

Full paper

Contents

In an animal study (species: pig; $n = 5$), the decontamination (bacterial clearance) during vacuum therapy (125 mmHg, suction mode not stated) and moist wound management (NaCl pads) was investigated and compared intraindividually over a period of two weeks (biopsy). This involved the inoculation of 10^8 bacteria of two species (human *Staphylococcus aureus* [RP12], $n = 3$; porcine *Staphylococcus epidermidis* [SR5], $n = 2$) in 1 ml NaCl into two wounds with an approximate size of 2.5 cm. In the controls the highest value was reached on Day 5 and a value $< 10^5$ bacteria per gram of tissue was, on average, not reached until after 11 days, while under vacuum therapy the degree of contamination decreased to below 10^5 bacteria per gram of tissue between Day 4 and Day 5 ($p < 0.01$ versus controls).

Conclusions by the Author

The lower bacterial load in the wound is considered to be due to the increased perfusion.

② Bischoff M, Kinzl L, Frei P, Trautmann M (2000) Bactericidal activity of wound fluid in traumatic wounds treated by vacuum sealing. *Zentralblatt. Chir* 125, Suppl. 1:83⁹

Type of Publication

Abstract; the thesis *Kinetics of cefuroxime and bactericidal activity of blood serum and wound exudate under the influence of vacuum sealing* by Patrick Frei (1999), on which the abstract is based, has been also taken into account in this presentation.

Contents

The antibacterial action of wound exudate was investigated in two groups. Group A: patients with open fractures who were given the antibiotic cefuroxime systemically; Group B: patients with closed fractures and severe soft-tissue damage who were treated with vacuum therapy without the administration of antibiotics. The analysis of the antibacterial action of the wound exudate showed a high bactericidal activity against test bacteria (*Staph. aureus*, *Staph. epidermidis* and *E. coli*) in Group A (n = 12; approx. 93% of samples; value has been taken from the thesis). The wound exudate of Group B without systemic administration of cefuroxime also showed a high antibacterial activity (n = 12; approx. 66% of samples; value has been taken from the thesis).

Conclusions by the Author

The findings demonstrated the decontamination properties of vacuum sealing.

Considerations in Connection with the Overview

By the term "decontamination property" the authors do not mean the property of bacterial load reduction in the wound but rather the bactericidal activity of the wound exudate. This elucidates a further interesting aspect.

③ Buttenschön K, Fleischmann W, Haupt U, Kinzl L, Buttenschön DC (2001) The influence of vacuum-assisted closure on inflammatory tissue reactions in the postoperative course of ankle fracture. *Foot Ankle Surg* 7:165-173¹¹

Type of Publication

Full paper

Contents

A controlled, randomized study was conducted to investigate whether vacuum therapy has an effect on acute systemic inflammatory response. In 35 patients who had suffered an ankle joint fracture (types B and C; surgery within six hours after trauma), the wound was either primarily closed or treated with vacuum therapy. During the pre- and postoperative periods (until 96 hours after surgery), the following parameters were determined in the plasma of the systemic circulation: endotoxin, interleukin 6 (IL-6), C-reactive protein (CRP), haptoglobin, transferrin, orosomucoid, 6-keto-prostaglandin (6KPG),

alpha-1-antitrypsin and complement C3 and C4. The study shows that only the endotoxin plasma concentration increased from 0.05 ± 0.01 EU/ml to 0.11 ± 0.03 EU/ml 0.5 h after the end of surgery in patients with primary wound closure, while there was no such increase in patients who received vacuum therapy (from 0.06 ± 0.02 EU/ml to 0.07 ± 0.02 EU/ml; $p < 0.05$ versus primary suture). There were no differences at the other times, after 12, 24, 48 and 96 hours.

Conclusions by the Authors

Vacuum therapy has limited systemic effects. As the size of the foam was only 2 x 10 cm, more intense systemic effects might be detectable with larger wounds.

Considerations in Connection with the Overview

It cannot be reliably assessed to what extent the endotoxin values, which are acquired with a time-consuming method, are a marker for an existing systemic effect of vacuum therapy.

④ Gouttefangeas C, Eberle M, Ruck P, Stark M, Muller JE, Becker HD, Rammensee HG, Pinocy J (2001) Functional T lymphocytes infiltrate implanted polyvinyl alcohol foams during surgical wound closure therapy. *Clin Exp Immunol* 124:398-405²⁷

Type of Publication

Full paper

Contents

In 15 patients with acute and chronic infected wounds, the degree of infiltration by white blood cells and their function were investigated (histological, immunohistological and flow cytometric analysis of T-lymphocytes [CD3, CD4, CD56, CD57, CD8] and macrophages [CD68]) in the polyvinyl alcohol (PVA) foam at the time of the first dressing change, 5-8 days after the initial implantation. The histochemical analysis revealed mainly neutrophilic granulocytes, isolated macrophages and predominantly activated T-lymphocytes (particularly CD4⁺, CD8⁺ and NK cells; the composition of this population did not correspond to that of the blood T-lymphocytes of healthy donors). The functional analysis revealed a changed behavior of the T-cells; due to the antigen contact (bacteria) there was a state of non-responsiveness in two cases.

Conclusions by the Authors

There is only a minor degree of infiltration of the PVA foam by functionally active T-cells as compared to granulocytes. The CD4⁺ portion of the T-lymphocytes is influenced by the antigens that exist in the wound. The infiltration of the foam with T-cells and their activation could be promoted by integrating stimulating factors such as chemokins in the tube.

- 5 Moues CM, Vos MC, van den Bemd GJ, Stijnen T, Hovius SE (2004) Bacterial load in relation to vacuum-assisted closure wound therapy: a prospective randomized trial. *Wound Repair Regen* 12:11-17⁴⁷

Type of Publication

Full paper

Contents

In a randomized, controlled study, the effect of vacuum therapy on the bacterial load of open contaminated wounds (decubitus, posttraumatic, diabetes mellitus, vascular diseases, osteomyelitis) was investigated and compared to conventional moist wound management (quantification of the number of colonies/gram of tissue with the aid of an average of 4.5 tissue biopsies). Twenty-nine wounds were treated with vacuum therapy (group A, PVA foam, 125 mmHg) and 25 were treated with conventional moist pads (group B, 0.9% NaCl or 0.2% nitrofurazone solution or 1% acetic acid solution or 2% sodium hypochlorite solution, depending on the contamination of the wound, necrosis and bacterial species). No significant quantitative decrease in the bacterial load was found in either of the two groups. Group A: A significant reduction in gram-negative bacteria ($p < 0.05$; not found in group B) and a significant increase in the gram-positive bacterium *Staphylococcus aureus* ($p < 0.05$; not found in group B) were demonstrated as compared to the initial situation (no significant difference between group A and B, no change in enteric bacteria and anaerobes). At the end of the observation period, the bacterial count was above the critical limit of 10^5 bacteria/gram of tissue in 42% of cases in both groups.

Conclusions by the Authors

Vacuum therapy has the same effect on the reduction of the bacterial load as conventional methods of treatment, however, the latter involved the application of antiseptic

agents. A shift in the species composition of the bacterial population with a (slight) increase in the contamination with *Staph. aureus* could have a positive effect on wound healing.

- 6 Weed T, Ratliff C, Drake DB (2004) Quantifying bacterial bioburden during negative pressure wound therapy: does the wound VAC enhance bacterial clearance? *Ann Plast Surg* 52:276-279; discussion 279-280⁷²

Type of Publication

Full paper

Contents

The effect of vacuum therapy (dressing change every 3-5 days) and the degree of bacterial load of acute ($n = 23$) and chronic ($n = 2$) wounds (in colonies/gram of tissue; average of 10.5 wound smears) were investigated in a retrospective study of the medical records of 25 patients (1999-2003, 21 outpatients). A significant increase in bacterial contamination was observed in the course of vacuum therapy (*versus* baseline). The analysis of the bacterial load during vacuum therapy revealed an overall trend to an increase in bacteria: the load increased in 43% of cases, remained constant in 35% and decreased in 22%. The degree of bacterial colonisation was unrelated to the success or failure of vacuum therapy. Wounds with $> 10^6$ bacteria/gram of tissue healed without problems while some wounds did not heal despite a lower bacterial load ($< 10^5$ bacteria/gram of tissue).

Conclusions by the Authors

There is no general decrease in the bacterial load. The results are inconsistent with the findings of the study conducted by Morykwas et al. (1997). Despite the increase in the bacterial load that was observed in some of the cases, there is no apparent effect on wound healing overall. The idea that bacterial load is a critical element for wound healing must be reconsidered. It remains doubtful whether more frequent dressing changes would have had a more favorable effect on the degree of bacterial clearance.

7 Adams TST, Herrick S, McGrouther DA (2004) VAC-therapy alters the number and distribution of neutrophils in acute dermal wounds. In: Banwell P, Téot L (ed): Topical Negative Pressure (TNP) Focus Group Meeting (Proceedings European Tissue Repair Society). *TXP Communications*: 212¹

Type of Publication

Extended abstract

Contents

In a comparative study involving tissue biopsies in n = 6 split skin donor sites and n = 6 burn wounds after 48-hour vacuum therapy or conventional therapy (control: areas not treated with vacuum therapy), immunohistochemical analysis revealed that the number of neutrophilic granulocytes in the wound bed (tissue biopsies) was significantly reduced as a result of vacuum therapy.

Conclusions by the Authors

Vacuum therapy has an effect on the cellular wound environment during wound healing.

8 Banwell P, Herrick S, Tyler M, Roberts A, McGrouther D (2004) Topical negative pressure (TNP) attenuates burn depth progression in humans via selective modulation of neutrophil extravasation. In: Banwell P, Téot L (ed): Topical Negative Pressure (TNP) Focus Group Meeting (Proceedings European Tissue Repair Society). *TXP Communications*: 214¹

Type of Publication

Extended abstract

Contents

In a prospective study involving n = 34 second-degree burn wounds, the burn depth and the profile of immunologically competent cells were investigated and compared in an immunohistochemical analysis after 48-hour vacuum therapy (n = 16; 125 mmHg, continuous) and without therapy (control, n = 18). Superficial wounds in the control group showed only minimal depth progression while there was a progression of $27.2 \pm 4.8\%$ in deeper wounds. Compared to the control, wounds in the vacuum therapy group showed a significant reduction in the depth progression of $3.8\% \pm 2.2\%$. The immunohistochemical analysis revealed a significant reduction in

the extravasation of neutrophils in the burn wound (no change in the macrophage and lymphocyte counts).

Conclusions by the Authors

Vacuum therapy reduces the depth progression of the burn wound and modulates neutrophil response to the trauma.

9 Kilpadi, D. V., C. E. Bower, C. C. Reade, P. J. Robinson, Y. S. Sun, R. Zeri, L. W. Nifong and W. A. Wooden (2006). Effect of Vacuum Assisted Closure Therapy on early systemic cytokine levels in a swine model. *Wound Repair Regen* 14(2): 210-5.³⁴

Type of Publication

Full paper

Contents

Investigation of the effect of vacuum therapy on the systemic distribution of the inflammatory cytokines interleukin IL-6, IL-8, IL-10, and TGF- β 1 on 12 pigs (given one full-thickness excisional wound, using electrocautery; n=6 pigs treated by vacuum therapy (125 mmHg, continuous mode), n=6 pigs treated by saline-moistened gauze). Serum samples were collected immediately after wound creation, and hourly for four hours (ELISA). During the initial four hours of treatment, vacuum therapy resulted in earlier and greater peaking of IL-10 and maintenance of IL-6 levels compared with saline-moistened gauze controls (both at p < 0.05). No other treatment-based differences were detected.

10 Chen, S. Z., D. Y. Cao, J. Q. Li and S. Y. Tang (2005) Effect of vacuum-assisted closure on the expression of proto-oncogenes and its significance during wound healing. *Zhonghua Zheng Xing Wai Ke Za Zhi* 21(3): 197-200.¹²

Type of Publication

Abstract in English, full paper in Chinese

Contents

Examination of the variations in expression of proto-oncogenes c-myc, c-jun and Bcl-2 in pig wound model with acute full-thickness skin defect and human chronic wounds by immunohistochemistry (numbers of

expressive positive cells, labelling index). After the wound was created, the expression of c-myc, c-jun and Bcl-2 rapidly and obviously increased, the distribution of the positive cells also became enlarged, but the amount of expression decreased rapidly after the expressive peak was reached. In the successive 12 days, expression of c-myc, c-jun and Bcl-2 in the vacuum therapy group was constantly higher than that of the control group. In human chronic wounds too, the expression and the labelling index became increased after vacuum therapy.

Conclusions by the Authors

Vacuum therapy could rapidly start the healing course of the pig's acute skin wound and human chronic wound, decrease apoptosis of the reparative cells, so as to accelerate wound healing.

⑪ Greene, A. K., M. Puder, R. Roy, D. Arsenault, S. Kwei, M. A. Moses and D. P. Orgill (2006) Microdeformational wound therapy: effects on angiogenesis and matrix metalloproteinases in chronic wounds of 3 debilitated patients. *Ann Plast Surg* 56(4): 418-22.²⁴

Type of Publication

Full paper

Contents

Microvessel density and matrix metalloproteinase (MMP) activity were determined by immunohistochemistry and zymography (n=3, chronic wounds). Microvessel density of vacuum therapy-treated wounds was 4.5% ($\pm$ 0.8) compared with areas not covered by foam 1.6% ($\pm$ 0.1; p=0.05; during the first week of treatment) and 2.7% ($\pm$ 0.3) compared with untreated tissue 1.3% ($\pm$ 0.1; p=0.03) during the second treatment week. MMP-9/NGAL (neutrophil gelatinase-associated lipocalin), MMP-9, latent MMP-2, and active MMP-2 were reduced by 15%-76% in vacuum therapy-treated wounds.

Conclusions by the Authors

Vacuum therapy provides a favorable wound-healing environment by increasing angiogenesis and decreasing MMP activity in chronic wounds.

Rate of Wound Healing, New Granulation Tissue Formation, Growth Factors

① Morykwas MJ, Argenta LC, Shelton-Brown EI, McGuirt W (1997) Vacuum-assisted closure: a new method for wound control and treatment: animal studies and basic foundation. *Ann Plast Surg* 38:553-562⁴⁴

Type of Publication

Full paper

Contents

This randomized animal study (species: pig; n = 10) analysed the rate of granulation tissue formation during vacuum therapy (suction: 125 mmHg) versus a control group (moist wound management with NaCl pads) and compared the two therapy modes "continuous" and "intermittent" (cycle: five minutes ON / two minutes OFF). It was found that continuous application resulted in an average increase in new granulation tissue formation of $63.3 \pm 26.1\%$ while intermittent application of suction resulted in an average increase of $103.4 \pm 35.3\%$ (p < 0.01 versus control). There was a significant difference between each vacuum group and the control group.

Conclusions by the Authors

The application of vacuum therapy leads to an improvement in the wound healing condition. Intermittent application of suction results in a higher rate of new tissue formation than continuous suction.

② Genecov DG, Schneider AM, Morykwas MJ, Parker D, White WL, Argenta LC (1998) A controlled subatmospheric pressure dressing increases the rate of skin graft donor site reepithelialisation. *Ann Plast Surg* 40:219-225²⁶

Type of Publication

Full paper

Contents

In a randomized animal study (species: pig; n = 4), the granulation and epithelialisation power of vacuum therapy (suction: 125 mmHg) was compared intraindividually with an occlusive dressing (three split skin grafts of different thicknesses (0.25 mm, 0.30 mm and 0.35 mm)

taken from the left side and three taken from the right side of the back). A histological examination and assessment of epithelialisation was carried out after 2, 4, 7, 9 and 11 days. The same question was addressed in an additional human study. Two split skin grafts of the same size were taken from each of 10 patients, followed by the application of vacuum therapy or an occlusive dressing (film). Results of the animal study: on the second day no reepithelialisation on the control side, after vacuum therapy continuous epithelial layer in all three layer thicknesses, isolated islands of *stratum corneum* at some sites. On the 4th day beginning reepithelialisation on the control side, however, separation of the epithelium from the underlying structures in some cases; after vacuum therapy relatively mature epithelial layer with partial detachment from the substratum. In the human study, epithelialisation on the vacuum therapy side in seven out of ten patients with faster reepithelialisation compared to the control side, no difference in two patients and slower reepithelialisation in one patient; overall significantly faster epithelialisation ($p \leq 0.013$).

Conclusions by the Authors

Vacuum therapy accelerates the rate of epithelialisation of split skin donor sites.

- ③ Walgenbach, K. J. and G. B. Stark (2000). Induction of angiogenesis following vacuum sealing. *J Wound Healing* 13: 9-10⁷¹

Type of Publication

Full paper

Contents

The degree of angiogenesis was analyzed immunohistochemically (antibodies to endothelial cell component CD 31, CD 105 [protein of proliferating endothelial cells]) in tissue samples (three from the wound edge and three from the wound bed) of eight patients after five-day vacuum therapy (suction: 150 mmHg). The endothelial proliferation index (EPI) was calculated as the ratio of proliferating endothelial cells to total number of endothelial cells. The analysis shows an increase in the number of capillaries to 200% compared with the control (wound bed before the start of therapy), EPI: 0.76 ± 0.14 in the wound area *versus* 0.42 ± 0.11 in the wound edge ($p < 0.05$).

Conclusions by the Authors

The study reveals an increased proliferation activity of endothelial cells in the newly formed granulation tissue after the application of vacuum therapy.

- ④ Kopp J, Hoff C, Rosenberg B, von Buelow S, Kilpadi DV, Schroeder W, Pallua N, Horch RE (2003) Application of VAC therapy upregulates growth factor levels in neuropathic diabetic foot ulcers. *Wound Repair Regen* 11, 5:0.007³⁶

Type of Publication

Abstract

Contents

Randomized controlled study to analyse the growth factors (TGF β 1, VEGF and PDGF, after 0, 2, 4, 6 and 8 days) in the wound exudate (collection with the Trengove technique) of patients (n = 30) whose neuropathic diabetic foot ulcers were treated with vacuum therapy (group A) or a conventional hydrocolloid dressing (group B). The growth factor levels increased in both groups, however, in the vacuum therapy group they increased by factor of 2.5 (PDGF) and factor of 3-4 (VEGF and TGF β 1,) compared to group B.

Conclusions by the Authors

Vacuum therapy leads to increased levels of the growth factors TGF β 1, VEGF and PDGF in the wound exudate of patients with diabetic foot syndrome.

- ⑤ Kremers L, Kearns M, Hammon D, Scott CA, Daniel L (2003) Involvement of mitogen activated proteases kinases in wound healing during subatmospheric pressure therapy. *Wound Repair Regen* 11, 5: 0.009³⁷

Type of Publication

Abstract

Contents

In an *in vitro* experiment in fibroblast cell lines, the intracellular phosphorylation of p38 mitogen activated protein kinase and its transcription factor c-JUN73 were measured after a stretching stimulus (5% [n = 4] or 10% [n = 2] biaxially, 5 min stretch/2 min relax for 24, 48 and 72 h; western blot, control cells without stretching).

After 24 hours: no significant difference for p38 and cJUN73 levels as compared to non-stimulated cells; after 48 hours with 5% stimulation: significantly increased concentration levels for p38, after 72 h: significantly increased levels of phosphorylated cJUN 73 (with 10% stimulation, this was the case after only 24/48 hours).

Conclusions by the Authors

As the phosphorylation process of p38 and cJUN73 is associated with cell growth and division, the results can contribute to the identification of the mechanisms by which vacuum therapy induces new tissue formation.

Considerations in Connection with the Overview

The authors did not work on a model in which the stretching stimulus is produced by vacuum therapy (subatmospheric pressure therapy). They rather assume that vacuum therapy produces a stretching stimulus. However, it needs to be discussed whether the stimulus acting on the cell during vacuum therapy is a pure stretching stimulus.

- 6 Shi B, Chen SZ, Zhang P, Li JQ (2003) Effects of vacuum-assisted closure (VAC) on the expressions of MMP-1, 2, 13 in human granulation wound. *Zhonghua Zheng Xing Wai Ke Za Zhi* 19:279-281¹⁶

Type of Publication

Abstract in English, full paper in Chinese

Contents

Concentrations of matrix metalloproteinases (MMP)-1, -2, -13 (RT-PCR technique) in chronic wounds of five patients after vacuum therapy (no details of suction strength) on Days 0, 1, 4 and 7: MMP-1 and -13 mRNA showed a marked decrease while MMP-2 mRNA showed a trend of decrease.

Conclusions by the Authors

The application of vacuum therapy can promote wound healing via reduced expression of MMP-1, -2, -13 mRNA and hence reduced degradation of collagen and gelatin.

Considerations in Connection with the Overview

There is no comparison with alternative wound treatment methods.

- 7 Miller Q, Bird E, Bird K, Meschter C, Moulton MJ (2004) Effect of subatmospheric pressure on the acute healing wound. *Curr Surg* 61:205-208⁴³

Type of Publication

Full paper

Contents

In an animal study (species: pig; n = 9), the effects of vacuum therapy (group A, 125 mmHg) were investigated in comparison with moist wound management (group B, changes twice daily) and a transparent occlusive dressing (group C, no change) in 3 x 2 wounds with a diameter of 2.4 cm each, which were assessed on Days 4, 7 and 9 (histopathologically: mature or immature granulation tissue, amount of necrotic suppurative scab, proliferating cell nuclear antigen (PCNA) and collagen deposition). Wounds in group B had significantly less necrotic suppurative scab than group A and C ($p < 0.05$). In comparison with group C, there were elevated levels of immature collagen in the two groups A and B on Day 9. There were no other differences.

Conclusions by the Authors

Under these study conditions, there is no indication that acute wounds heal faster as a result of vacuum therapy.

- 8 Argenta A, Simpson J, Morykwas M (2004) Vertical growth "tunnels" in dressings for use with topical negative pressure. In: Banwell P, Téot L (ed): Topical Negative Pressure (TNP) Focus Group Meeting (Proceedings European Tissue Repair Society). *TXP Communications*. 213³

Type of Publication

Extended abstract

Contents

The study investigates the formation of growth "tunnels" in dressings with different pore sizes. The pore depths were measured in sponge cuboids (2 x 2 cm) of various heights (from 1 mm to 20 mm) while suction was applied. It was found that the larger the pore is initially, the further the granulation tissue will grow in terms of depth under vacuum conditions.

⑨ Saxena V, Hwang CW, Huang S, Eichbaum Q, Ingber D, Orgill DP (2004). Vacuum-assisted closure: microdeformations of wounds and cell proliferation. *Plast Reconstr Surg* 114(5): 1086-96; discussion 1097-1098⁴⁴

Type of Publication

Full paper

Contents

With the aid of the finite elements method, the authors developed a computer model, taking into account the suction strength, tissue firmness, tissue compressibility, pore diameter and pore volume, in order to investigate microdeformations on the wound surface. For the validation of their own results, a comparison was made with histological sections ($n = 4$ wounds after four to seven days of vacuum therapy). During application of the vacuum, cell stretching of 5-20% was calculated using the model. The precalculated microdeformations of the tissue were also found in histological studies.

Conclusions by the Authors

The hypothesis is formulated that the applied vacuum leads to stretching of the individual cell. By analogy to *in vitro* studies, in which similar amounts of cell stretching led to a proliferation of the tissue, it is assumed that the cellular microdeformation during vacuum therapy constitutes the most important factor that has a positive effect on wound healing.

Pressure and Suction Relationships, Effects of Different Suction Strengths on Wound Healing

① Maier D, Becker U, Kinzl L, Bischoff M (2000) Physical basics of vacuum sealing. *Zentralbl. Chir* 125, Suppl.1: 82⁴¹

Type of Publication

Abstract

Contents

A flow rate measurement (NaCl 0.9%, 5% Glc and wound exudate), determination of pressure values and scanning electron microscopic analysis were performed in PVA and PU foams. The analysis showed that there was no longer any appreciable increase in the flow rate when the applied suction was 300 mmHg or higher. Higher nega-

tive pressure values increased the risk of blockage. The NaCl flow was higher in the PU foam than in the PVA foam. The pressure measurements ruled out a negative pressure on the cells. Overall, the pressure on the wound surface was found to be positive. This positive pressure did not exceed 26 mmHg even when high suction was applied with a Redon drainage system (-700 to -900 mmHg, approx.). The optoelectronic analysis revealed an average pore size of 0.2 mm under strong suction (0.7-1.5 mm without suction). As far as could be assessed, there was no evidence of any collapse of the pores.

Conclusions by the Authors

The pressure measurements ruled out a negative pressure on the cells. Overall, the pressure on the wound surface was found to be positive.

Considerations in Connection with the Overview

It has not been stated in which type of wounds the experiment was conducted (in the thesis on which the publication is based, *Investigations on the physical basics of vacuum sealing* by D. Maier (2002), these measurements were investigated in models (foam on wood, foam on grapefruit).

② Morykwas MJ, Faler BJ, Pearce DJ, Argenta LC (2001) Effects of varying levels of subatmospheric pressure on the rate of granulation tissue formation in experimental wounds in swine. *Ann Plast Surg* 47:547-555⁴⁵

Type of Publication

Full paper

Contents

This animal study (species: pig; $n = 12$) investigated the rate of granulation tissue formation during vacuum therapy at various suction strengths (25, 125 and 500 mmHg) over a period of eight days. For this purpose, four wounds with a diameter of 4 cm extending down to the fascia were created on the back of each animal and dressing changes were performed every two days. Within eight days, complete closure of the wound ($= 100\%$) was observed at 125 mmHg while only $21.2 \pm 6.7\%$ of the wound had closed at 25 mmHg and only $5.9 \pm 13.8\%$ ($p < 0.0001$) at 500 mmHg. In an additional experiment under the same conditions but with a 2-mm hole in the drape, an enlargement of the wound by $97.2 \pm 8.6\%$ was

found at a suction of 125 mmHg on the eight day (even by the second day, the wound had enlarged by > 50%).

Conclusions by the Authors

The application of suction is most effective at a pressure of around 125 mmHg. Air leaks lead to a considerable negative effect on wound healing. Uncontrolled suction must thus be avoided.

③ Isago T, Nozaki M, Kikuchi Y, Honda T, Nakazawa H (2003) Effects of different negative pressures on reduction of wounds in negative pressure dressings. *J Dermatol* 30(8): 596-601³⁰

Type of Publication

Abstract

Contents

Animal study (species: Wister rats; n = 50) for the analysis of the speed of wound healing in five groups treated with different suction strengths: 0, 25, 50, 75 and 125 mmHg (continuous application of suction) over a period of two weeks. After one week, all four groups with suction (25, 50, 75 and 125 mmHg) were found to have a significantly ($p < 0.05$) smaller wound area than the group without suction. After two weeks, the wounds treated with suctions of 50, 75 and 125 mmHg were significantly ($p < 0.05$) smaller than wounds treated with a suction of 25 mmHg.

Conclusions by the Authors

A reduction of the suction strength from 125 to 50 mmHg (e.g. for pain reduction) has no detrimental effect on the speed of wound healing. Wound healing is not stimulated by the effect of increased blood flow, as assumed by Morykwas, but by the elimination of interstitial fluid and by the exertion of mechanical forces on the wound edges.

Systemic Effects

① Morykwas MJ, Howell H, Bleyer AJ, Molnar JA, Argenta LC (2002) The effect of externally applied subatmospheric pressure on serum myoglobin levels after a prolonged crush/ischemia injury. *J Trauma* 53:537-40⁴⁶

Type of Publication

Full paper

Contents

This animal study (species: rabbit; n = 8) involved a comparative investigation of the degree of systemic infiltration of myoglobin in crush syndrome during vacuum therapy with two different suction strengths (group A: 125 mmHg, continuous suction; group B: 0 mmHg).

Conclusions by the Authors

The prevention of systemic infiltration of myoglobin is possible.

② Kremers L, Wanner M, Argenta JA, Webb K, Argenta LC, Morykwas MJ (2003) Effects of subatmospheric pressure on PGI₂ and TBX-βA₂ and control of visceral blood flow post burn. *Wound Repair Regen* 11 (5):0.008³⁸

Type of Publication

Abstract

Contents

In an animal study (species: pig; n = 54 wounds in six animals), the visceral blood flow was measured after a 15% burn of the skin with and without vacuum therapy of the burn wounds (flow rate in superior mesenteric artery, measurement of prostacyclin PGI₂ and thromboxane TBX-βA₂ in the renal, splenic and jugular veins; 30-180 min after trauma). In comparison with animals treated with vacuum therapy, mesenteric blood flow decreased by 35% ($p < 0.01$). In the vacuum therapy group, the concentration of the vasoconstrictor TbX-βA₂ in the renal artery decreased significantly after 30 to 90 min. Systemically and in the splenic vein, there was a significant increase in the concentration of the vasodilator PGI₂ in this group between 60 and 120 min after trauma.

Conclusions by the Team of Authors

Vacuum therapy can lessen the burn-induced reduction of visceral blood flow.

③ Bower CE, Kilpadi DV, Clifton C, Zeri R, Wooden WA (2004) Effect of negative pressure wound therapy on systemic cytokine levels in swine, *Abstractband II, WUWHS Meeting*, Paris 2004: Z032 auf Seite 169¹⁰

Type of Publication

Abstract

Contents

This animal study (species: pig; n = 12) involved a comparative investigation of the degree of systemic infiltration of interleukin 6, 8 and 10 and TGF- β (ELISA) after full-thickness skin excision in 2 groups (group A: n = 6, vacuum therapy, no details of suction strength and therapy mode; group B: n = 6, moist wound management) over a period starting before the wound was created and ending four hours after the creation of the wound. In group A, IL-10 had a significantly ($p < 0.1$) higher systemic level 1 h after creation of the wound.

Conclusions by the Team of Authors

IL-10 inhibits the inflammatory reaction. Vacuum therapy contributes to the reduction of the inflammatory reaction.

Discussion

The aim of this overview is to present the current state of knowledge on the physiological effects of vacuum therapy. On reviewing the literature, one is struck by the fact that, despite numerous inconsistencies with other results, a small number of research findings are repeatedly cited to explain the effects of vacuum therapy. Scientific studies conducted to date do not answer many questions regarding the functional mechanisms and effects of vacuum therapy. Although some surprising findings emerge in the analysis of all available publications, numerous questions remain unanswered. This scientifically unsatisfactory but nevertheless fascinating situation stands in sharp contrast to the confirmation of vacuum therapy's clinical effectiveness reported in a great many studies, observational studies and case descriptions.

Not all scientific publications could be integrated in the analysis. Some were omitted because, although they presented interesting results on effects of vacuum therapy, no comparison was made with other forms of wound management. Consequently, the physiological effects of the therapy observed in these cases could

not be reliably related to intrinsic effects of vacuum therapy.

Change in Perfusion as a Result of Vacuum Therapy

The listed articles on the subject area of perfusion are evaluated below ^{6,13,17,32,34,44,50,62,68,70,76}.

Morykwas and co-workers compared the "continuous" and "intermittent" therapy modes (cycle of 5 minutes ON/2 minutes OFF) and found that continuous application of suction resulted in an average increase in new granulation tissue formation of approximately 60%, while intermittent application of suction resulted in an average increase of approximately 100%. In both cases, new granulation tissue formation was significantly increased compared to controls (moist wound management, this result has not been presented in any way). The research group points out that there is no positive effect on perfusion when a continuous suction of 125 mmHg is applied. After an initial increase in perfusion, the increased blood flow decreases permanently to baseline levels or even below baseline after only 10 minutes, reaching a state of normo- or hypoperfusion. This decrease had also been observed by Jungius et al (2006) in vacuum therapy-treated wounds after an initial markedly increased perfusion compared to primarily closed wounds³².

With suction ranging to approximately 400 mmHg, the same group of authors described a decrease in perfusion to below baseline (this would constitute hypoperfusion = ischaemia). When intermittent suction is applied, the repeated generation of suction leads to recurring hyperperfusion and, when suction has stopped, to normoperfusion as the perfusion values decrease to baseline levels.

Based on these results, the research group suggests that vacuum therapy increases perfusion in the wound and thus contributes to wound healing – a conclusion that has been cited in almost every subsequent publication. It is interesting, however, that this formulation (1997) is derived from only one of many constellations of its underlying animal experiment: the combination of suction at 125 mmHg and intermittent suction mode. According to the experiments, other combinations (suction of 125 mmHg and continuous suction mode) lead to hypoperfusion, yet they enable formation of new granulation tissue that is over 60% higher than controls. What is more, the period of 1990 to 1998, during which continuous suction of 900 mmHg (Redon drainage

system) was usually applied in many countries, saw the "triumphant advance" of vacuum therapy due to the clinical successes. However, according to Morykwas et al., it is precisely this combination of parameters that leads to persistent hypoperfusion of the tissue adjacent to the wound.

This raises the following questions:

- Does hypo- or hyperperfusion of the wound tissue occur during vacuum therapy?
- Is an increase in perfusion in the area adjacent to the wound really necessary for accelerated wound healing?

Laser Doppler flow measurements were performed in some other studies^{32,50,62,69}. Although there are some inconsistencies, it still appears possible to derive a general hypothesis regarding the perfusion situation during vacuum therapy. While a homogeneous response to the increase in suction to 125 mmHg was observed by Morykwas et al. (increase in perfusion and decrease to baseline levels within the first 10 minutes; Fig. A6.2), Rejzek et al. found more inhomogeneous curve patterns (Fig. A6.3)⁶⁰; they observed different responses to identical influences and demonstrated that an increase in suction led to both an increase and a decrease, but also to a constant pattern of perfusion. The question whether these differences, observed using the same measuring method, relate to methodical differences between the two studies (animal experiment in five pigs / human experiment in seven patients; artificial, uncomplicated acute wound after skin excision / ulcer cruris; subcutaneous measurement / measurement in the wound edge and transcutaneous measurement) cannot be answered. Unfortunately, the two publications do not indicate to what extent the laser Doppler flow measurements were validated according to the guidelines of the Standardization Group of the European Society of Contact Dermatitis (1993)⁸. On the whole, a direct increase in flow after application of suction cannot be reliably derived from the diagrams presented by the two groups of authors.

The presumed increase in perfusion would result in an improved oxygenation of the wound edges. However, the research group of Lange et al. was unable to demonstrate any changes in tissue oxygen partial pressure during vacuum therapy with the polarographic measuring technique¹⁷. Studies by Banwell and Kamolz^{6,33} and Schrank et al.³⁵ also do not demonstrate that vacuum therapy is associated with an increase in flow: these

research groups found indications that vacuum therapy is advantageous in the early stage therapy of burn wounds (> 24 hours after initiation of therapy) for the nutritive perfusion status of the tissue. However, one must bear in mind that vacuum therapy exerts compression on the tissue which, after a burn, usually responds with increased swelling. The compression is even more pronounced when the commercially available vacuum therapy hand dressing kit is used: antioedematous compression is mechanically generated due to the exertion of circumferential pressure, possibly preventing development of oedema. The improvement of nutritive perfusion due to vacuum therapy is more likely the result of an indirect antioedematous effect that promotes perfusion. However, a different explanation is also conceivable. In these studies, perfusion was not measured until the compressive vacuum therapy dressing had been removed. As the dressing exerts a more or less strong pressure on the tissue, depending on the intensity of the applied suction, the reported increased perfusion could simply be the result of reactive hyperemia. The measurement result after removal of the dressing is no proof that perfusion is also increased when the vacuum therapy dressing is in place. This explanation has also to be taken into account when interpreting the results of Chen et al. (2005)¹³. They observed increasing capillary calibre and blood volume "during" vacuum therapy by analysing the wound bed microcirculation by means of microscope and image pattern analysis.

Assessing inguinal and peristernal wounds in the most recent studies addressing this question, the research group of Wackenfors et al. (2004, 2005)^{69,70} showed, that, when a suction of 50-200 mmHg is applied, depending on the subatmospheric pressure used, ischemia occurs in the subcutaneous and muscle tissue directly adjacent to the wound edge (1.0 - 2.6 cm *versus* 0.5 - 1.7 cm) while there is hyperperfusion at a distance of 3.0 - 3.5 cm (subcutaneous tissue) *versus* 1.5 - 2.5 cm (muscle) and no changes at all in baseline levels at a distance of approximately 3.5 cm (muscle) and 4.5 cm (subcutaneous tissue). Thus, the hypoperfused volume increases under the influence of higher pressure values and is dependent on the tissue, e.g. the ischemic area, measured from the peri-sternal wound edge, expands from 0.5 cm at 50 mmHg to 1.4 cm at 200 mmHg (muscle tissue) and from 1.0 cm at 50 mmHg to 2.6 cm at 200 mmHg (subcutaneous tissue).

In muscle, the area of hypoperfused tissue is much smaller. The explanation for this finding may be that subcutaneous tissue more easily collapses during pressure, which results in a large zone of hypoperfusion proximal to the wound.

In contrast to these data of Wackenfors et al, the group of Timmers, Banwell and Jukema (2005)⁴² showed a significant increase in cutaneous blood flow (CBF) using vacuum "therapy" on the intact skin of healthy volunteers as measured by noninvasive laser Doppler probes embedded in the foam. These results were found with both foam types up to a negative pressure of 300 mmHg, with an over five-fold increase with the PU foam and a nearly three-fold increase with the PVA foam (*versus* baseline). They could not demonstrate any decrease in blood flow below baseline during the experiments in spite of using only continuous negative pressure application and no hypoperfused soft tissue area. Thus, their results are also inconsistent with the data of Morykwas and Jungius. One explanation for their data is that Timmers et al. studied the perfusion of intact forearm skin with underlying well-perfused intact subcutaneous tissue while Wackenfors et al., Morykwas et al. and Jungius et al. analysed blood flow in acute wounds. Considering the different experimental settings it can be assumed that CBF analysis is not clinically relevant.

Reviewing all studies discussed here, it can be postulated that the pressure applied during vacuum therapy has a negative effect on the microcirculatory blood flow in the upper layer of the wound tissue. In soft tissue, particularly in subcutaneous tissue, it is possible for ischemic states to occur. Adjacent to this hypoperfused zone, there is a small tissue area of increased blood flow. The data suggest that, in order to generate granulation tissue, the intermittent suction mode should be chosen when vacuum therapy is applied. The background for this is the demonstration by Morykwas et al. of the significantly more extensive granulation tissue and the markedly increased blood flow in the OFF interval. This increased blood flow was confirmed by the research groups led by Rejzek and Wackenfors. As a practical consequence of this recommendation, suction systems that allow such intermittent therapy should be used.

Which ON and OFF Intervals Should be Chosen for Intermittent Mode?

Because of the decrease in blood flow when suction is

applied for longer than 5-7 minutes and because of a reduction in the increase in perfusion when OFF times are less than two minutes, Morykwas et al. recommended a cycle of five minutes ON / two minutes OFF. Wackenfors et al. also investigated the perfusion response to ON and OFF periods of different duration. The measuring site they chose was the immediate vicinity of the wound – i.e. the tissue volume that would be subjected to ischemia at a suction of 125 mmHg. They found that the increase in blood flow, which is probably due to hyperemia, was not dependent on the duration of vacuum therapy: in all cases involving an ON phase of 1-15 minutes there was an increase of 40-50% of the baseline blood flow. However, the duration of the increase in perfusion was dependent on the duration of the ON period and ranged from 6.3 to 11 minutes. Nevertheless, contrary to Morykwas' findings, a longer duration of the ON period did not lead to a reduction of perfusion in the ON cycle.

The question of which ON and OFF periods are the most favourable can only be decided on the basis of theoretical considerations as there are no clinical studies that address this question. However, this entails the problem that we do not know at this point which mechanical effects vacuum therapy really aims to achieve and, in particular, for how long these different effects should act on the wound. However, it would be safe to say that a setting between five minutes ON / two minutes OFF and 10 minutes ON / 10 minutes OFF can be recommended at the present time.

Decontamination, Increased Bacterial Clearance, Immunological Effects

Another effect of vacuum therapy that is thought to be beneficial for wound healing is the reduction of the bacterial load in the wound. Although the reduction of the wound infection rate and the degree of bacterial clearance as a result of vacuum therapy were described as a secondary endpoint of the study in several publications^{18,19}, there are only two studies on this subject, dating to 1997 (Morykwas et al.)⁴⁴ and 2004 (Moues et al.)⁴⁷, in which the results of vacuum therapy were investigated in comparison with conventional therapy. In an experiment in pigs, Morykwas et al. investigated the degree of bacterial clearance in acute artificial wounds after inoculation of gram-positive cocci⁴⁴. Moues et al. analysed the clearance of a total of 50 different bacterial species⁴⁷ in human wounds of different ages and origins (total n = 54). Although the study by Morykwas et al. was only con-

ducted in five animals (two were inoculated with *Staphylococcus aureus* and three with *Staphylococcus epidermidis*), the positive effect of vacuum therapy on the reduction of the bacterial load of the wound appears to be proven. The favourable result can thus be assumed at least for acute, artificially created and infected wounds under optimal healing conditions.

The results of the research group of Moues et al., however, appear to be contradictory. Although they also show a reduction in the number of colonies/gram of wound tissue (as determined with the aid of biopsies), the favorable result of the reduction of the bacterial load is limited to gram-negative bacteria. Contrary to Morykwas et al., the study occasionally demonstrates an increase in gram-positive staphylococci in the tissue during vacuum therapy. Unfortunately, the two patient groups that were compared in the Moues study are so inhomogeneous in terms of age and origin of the wounds that, strictly speaking, no exact comparison of the two groups is possible from a critical point of view. What is more, some two to three-fifths of the patients in both groups of the Moues study were treated with antibiotics, which could result in bacterial selection. Also, there is no information on the possibly different degrees of contamination in the individual wounds at the beginning of the treatment and the proportion of acute and chronic wounds. Nevertheless, this study illustrates that vacuum therapy does not always produce a quantitative reduction of the bacterial load in contaminated human wounds. It is even possible that an increase in the bacterial count will develop for individual species. This observation is also confirmed in the retrospective study by Weed et al. (2004)⁷² in which the bacterial load was analysed before, during and after vacuum therapy. Here, there was an overall trend toward increase in the bacterial count, increasing in 43%, while remaining constant in 35% and decreasing in only 22% of cases. However, it must be emphasised that the degree of bacterial colonisation was unrelated to the success or failure of vacuum therapy. Wound healing without problems, even in wounds with bacterial contamination, could be observed in all three studies. Wounds with $> 10^6$ bacteria / gram of tissue healed without problems while some wounds did not heal despite a low bacterial load ($< 10^3$ bacteria / gram of tissue). Thus, the question arises whether the bacterial load that remains under vacuum therapy (or other procedures) really must always be considered to be a critical element for wound healing. It also remains doubtful whether

more frequent dressing changes would have had a more favourable effect on the degree of bacterial clearance.

On the whole, it appears likely that acute, purely superficially contaminated wounds (as in the model of the Morykwas study) can be decontaminated more easily by the application of vacuum therapy than chronic wounds which are also contaminated in the deeper layers. In this connection, the interesting question arises to what extent the continuous removal of wound exudate during vacuum therapy exerts the decisive effect on the bacterial clearance in acute wounds with a purely superficial contamination. In this case, it could hold true that the bacterial clearance which is achieved with vacuum therapy would be less pronounced in drier, non-exudative wounds. Vacuum instillation therapy according to the research group of Fleischmann et al.²³ would then be indicated in these wounds because of its capacity to instill antibiotic and antiseptic solutions.

A few other publications provide some insight into the pathophysiology of local and systemic immunological effects of vacuum therapy. An accumulation of activated T-lymphocytes could be demonstrated in the vacuum therapy foam²⁷. This finding could indicate that the sponge should not be regarded as immunologically inert under therapy: due to the accumulation of immunologically competent cells, immunologically relevant reactions could take place at the interface between foam and tissue. On the other hand, the number of granulocytes in the wound is reduced¹⁶. According to the study by Buttenschoen et al., vacuum therapy does not seem to have a major effect on whole-body inflammation¹¹. No relevant changes could be demonstrated for the parameter interleukin-6 which is considered a highly sensitive marker for inflammatory whole-body reactions. Additionally, they could not prove conclusively at the present time to what degree the endotoxin values, which are acquired with a time-consuming method, are a marker for a potential systemic effect of vacuum therapy.

Two further studies give no further insights into one part of the cytokine network influenced by vacuum therapy^{34,39}. Kilpadi et al. (2005)³⁴, assessing systemic IL-6, -8, -10 and TGF- β levels during the first four hours after wound creation showed only significant differences of IL-10 levels between animals treated with vacuum therapy and those treated with saline-moistened gauze. IL-10 levels in vacuum therapy-treated wounds peaked earlier and, when the aggregate four-hour period was considered, vacuum therapy-treated animals

had significantly higher levels of IL-10. These results were based on data normalized to baseline by subtracting the baseline values (before wound creation) in each animal from subsequent measurement. It is interesting that, calculating with the non-normalized data, this significant difference is lost due to doubled IL-10 baseline levels in the vacuum therapy group (9.2 ± 5.6 pg/ml *versus* 4.5 ± 1.9 pg/ml in saline-moistened gauze-treated group). Unfortunately the authors did not discuss this point. Labler et al. (2006) investigated systemic and exudate cytokine levels in comparison of human soft tissue wounds treated with vacuum therapy and Epigard® between the second and the fifth day after trauma. After the period of vacuum therapy they observed significantly increased IL-6, IL-8 and VEGF levels when analysing the wound exudate expressed from the foam. There were no differences in IL-10 levels. The authors give no information about the distribution of the injured patients into the two different treatment groups and no data about the initial cytokine levels. Thus, it is not possible to say how clinically relevant their data are.

Against this background, it is not clear whether there are influences caused by the vacuum therapy on the extent of (anti-)inflammatory reactions during the wound healing process. However, it can be assumed that the new modification of vacuum therapy, i.e. vacuum instillation therapy, markedly alters the immunological condition of the whole wound-dressing system. Using a *trac-pad connector* for instillation of the topical wound solution, the foam will be completely rinsed out. All foam "contents", such as cytokines, immunologically relevant cells (activated T-lymphocytes, bacterial species) are flushed back into the wound. Then, in the negative pressure therapy period, the instilled fluid is drawn back to the canister. If an additional tube, located at the deepest point of the wound, is used, only the recurrent outflow will change the foam content. However, in both situations, vacuum instillation therapy will induce immunological effects by diminishing molecule and cell concentrations at both the wound surface and the foam compared to the "traditional" vacuum therapy.

Pressure and Suction Relationships, Effects of Different Suction Strengths on Wound Healing

Overall, the studies give a reliable indication that there are also positive pressures at the interface between foam and wound surface ("under" the foam)^{41,67,74}. In *in vitro* experiments on solid surfaces (tabletop), the spectrum of

measured pressure values ranged from negative values at the level of the applied suction to positive values of up to 80 mmHg (at a suction of 200 mmHg; see also Part A, Chapter 7 "Experimental Basis II - Pressure Values under Vacuum Therapy Foams - An *in vitro* and *in vivo* Investigation"). Likewise, a spectrum of pressure values of -6 mmHg to 15 mmHg (the latter value at a suction strength of 200 mmHg) was found on the surface of bovine muscle and at a depth of 1-3 mm in the human muscle⁷⁴. One thus has to assume that, at least in some parts of the foam/wound interface, the application of vacuum therapy is associated with positive pressure values.

To date, the effects of different suction strengths on wound healing have been analysed in two studies (Morykwas et al. and Isago et al.)^{30,41}. These researchers investigated wound healing and new granulation tissue formation at 25, 125 and 500 mmHg (Morykwas et al.) and at 25, 50, 75 and 150 mmHg (Isago et al.). The two studies concur that a suction of around 25 mmHg is more unfavourable than a suction strength of around 125 mmHg. There is only one study for the wound healing outcome of 500 mmHg and one study for the comparison of the suction values of 50-150 mmHg. No significant difference in the wound area was found between the suction strengths of 50, 75 and 125 mmHg. Unfortunately, none of the research groups analysed the suction range of 50-200 mmHg, which is normally used (commercially available vacuum sources) in comparison with the suction of 500 to 900 mmHg, that can be generated by Redon drainage systems.

According to numerous empirical studies describing successful wound healing outcomes using Redon drainage containers as the suction source with a high suction strength (up to 900 mmHg), the principle of vacuum therapy is also successful in this suction range^{20-22,24}. However, the above-mentioned *in vitro* tests suggest that the suction effect is not fully transmitted when higher levels of suction are applied so that increased suction performance cannot be generated. The study of Maier et al., for instance, showed that, when PVA material was used, there was no longer any appreciable increase in the flow rate when the applied suction was 300 mmHg or higher⁴¹. The research group assumed that this was due to alterations in foam and pore geometry at higher suction levels. Further studies^{67,74} also showed that a suction of more than 150 mmHg in PVA foams did not produce any higher suction values than 150 mmHg at the foam/wound interface (see next chapter).

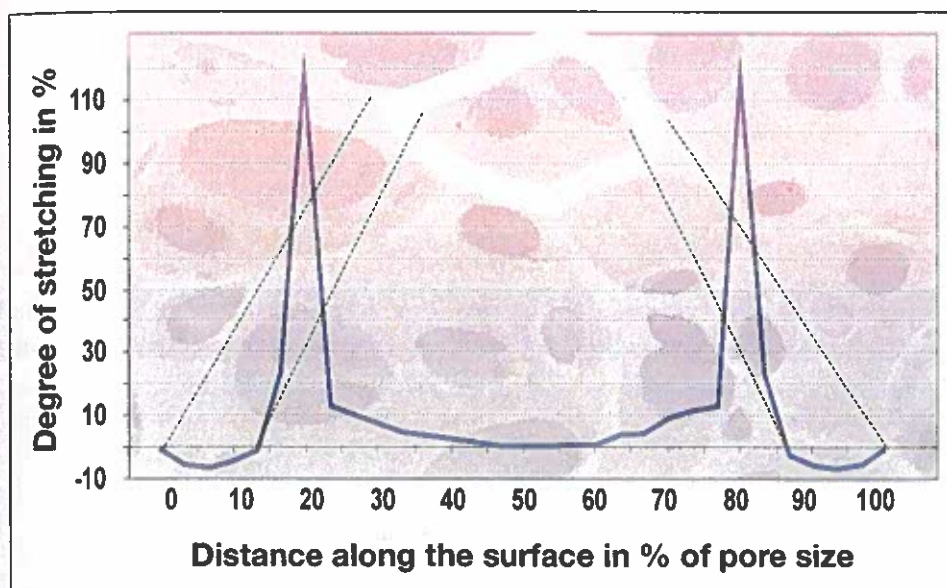


Fig. A6.5 The stretching behaviour of the individual cells in the wound bed during vacuum therapy under the pore wall and under the foam pore, calculated with a computer model using the method of finite elements (modified according to Saxena et al.⁴⁴). The blue graph reflects the degree of microdeformation of the cells concerned. The white ring represents the pore wall and the broken black line represents the projection of the pore wall on the corresponding deformation values.

Based on these observations that higher suction values generate hypoperfused areas of larger volume and that there are no significant differences in wound area reduction between the suction strengths of 50, 75 and 125 mmHg, it may be assumed that a reduction of the usually selected suction strength of 125 mmHg to values below 100 mmHg is at least not detrimental.

Rate of Wound Healing, New Granulation Tissue Formation, Epithelialisation, Cell Proliferation, Growth Factors

The degree of wound healing during vacuum therapy was investigated (*versus* moist wound management) in three comparative animal studies (Morykwas et al., Genecov et al., Miller et al.) and human experiments (Genecov et al.)^{26,42,44}. The studies in pigs compared experimental wounds on the backs of the animals intraindividually in order to create standardized and comparable study conditions. In an additional part of one of the studies that involved human patients, the comparison was made between two split skin donor sites in each individual.

In two of the three studies (total $n = 33$, endpoints: rate of new tissue formation and histopathological assess-

ment of epithelialisation), the results show that the application of vacuum therapy leads to an improvement in wound healing conditions and improves the rate of epithelialisation of split skin donor sites. What is striking, however, is that the rate of new granulation tissue formation in the control group is not mentioned at all in the study of Morykwas et al. Although the research group describes the significantly higher increase in new granulation tissue formation of $63.3 \pm 26.1\%$ and $103.4 \pm 35.3\%$ for continuous and intermittent suction, respectively, as compared to the control group, it fails to mention the values of the control group. The third study ($n = 9$) produced no results that would have indicated faster wound healing as a result of vacuum therapy (criteria: histopathologically mature/immature granulation tissue, amount of necrotic suppurative scab, amount of proliferating cell nuclear antigen [PCNA], collagen deposition). The discrepancy can be explained by the fact that different endpoints were investigated in each of the three studies. However, as all investigated endpoints are parameters for the analysis of wound healing, one would expect the trend of results to go more in the same direction if there is a clearly positive effect of vacuum

therapy. The results must also be qualified by the fact that the findings of all three studies are exclusively based on the investigation of superficial and acute wounds and that the studies involved were mainly animal experiments.

The positive effects of vacuum therapy are attributed to the effects of the vacuum-related mechanical stimulus on cell function, protein synthesis and gene expression with resulting matrix-molecule synthesis and cell proliferation^{44,47,61}. However, this explanation is given as a mere conclusion by analogy to the results of the scientific investigation of the effects of callus distraction and to the *in vitro* tests of cytokine and gene expression of endothelial and smooth muscle cells subjected to mechanical stress. There are in fact hardly any studies in which the cellular effects of vacuum therapy were investigated.

The study by Walgenbach et al. (2000) revealed a proliferation activity of endothelial cells in the newly formed granulation tissue after the application of vacuum therapy⁷¹. There is no analysis in comparison with conventionally treated tissue. Thus, no differences between vacuum therapy and alternative wound treatment methods can be derived.

In analyses of wound exudate samples of patients with neuropathic diabetic foot ulcers, the research group of Kopp et al. (2003) was able to show that some growth factor concentrations increase both during vacuum therapy and under the control treatment (hydrocolloid dressing) – in the vacuum sealing therapy group, they increased by a factor of 2.5 (PDGF) and a factor of 3-4 (VEGF and TGF α) compared to the control group³⁶. It should be noted that there are no currently available data suggesting that wounds with a high endogenous cytokine concentration in the wound exudate have the more favourable healing tendency. However, numerous studies have shown that the exogenous application of the above-mentioned cytokines has a favourable effect on wound healing^{15,25,29,59,63,65}. Assuming that external application really increases the local cytokine concentration in the wound and that this increase in concentration has a positive effect, one can assume that an endogenously generated increase in the concentration could be just as favourable. Consequently, it seems possible that vacuum therapy, which produces a comparatively higher VEGF/PDGF concentration, creates more favourable wound healing conditions (note: there is, in fact, a non-linear interaction in the complex cytokine network^{35,49,60}).

In another study, the concentrations of matrix metal-

loproteinases (MMP)-1,-2 and -13 (collagenases 1, 2 and 3) were analysed in wounds of five patients after vacuum therapy. A marked decrease in the MMP-1 and -13 mRNA concentrations and a slight decrease in the MMP-2 mRNA concentrations were observed⁴⁹. The authors Shi et al. conclude that the application of vacuum therapy promotes wound healing via reduced expression of the MMP-1 (collagenase 1), MMP-2, MMP-13 mRNA and hence reduced degradation of collagen and gelatin. Unfortunately, there is no comparison with alternate wound healing methods so that the observed result cannot be reliably regarded as an effect of vacuum therapy. When comparing the results of this study with those in the literature, the existing view of MMP interaction is not conclusively plausible. The investigation of the change in MMP concentrations in other studies showed that there was an increase in collagenase 1 (peak on Day 7) in wounds which had received moist wound treatment⁴⁸; that acute phase proteins increase the MMP-1 concentration⁷³ and inflammatory reactions increase the MMP-13 concentration³¹; that the MMP-2 concentration⁷⁵ and the MMP-13 concentration⁶⁴ are increased in chronic, non-healing wounds, while another research group finds the opposite for MMP-2¹⁶; that the MMP-1 and -2 concentrations are reduced in fresh burn wounds¹⁴; and that the MMP-1 concentration in tendon cells increases when they have been subjected to traction³. MMP-13 (collagenase 3) is thought to be responsible for the remodelling of the collagen matrix. In the study conducted by Shi et al., this protein showed the most marked decrease in concentration. Against this background, it is not clear why the application of the vacuum sealing technique can promote wound healing via reduced expression of MMP-1, -2 and -13 mRNA and, hence, reduced degradation of collagen and gelatin, as formulated by the authors. Whether these changes are an anti-inflammatory effect, a reduction of the "necessity" for remodelling, a normalization of cell function or the result of the mechanical stimulus can only be investigated in future studies.

A more recent study by Greene et al. (2006) compared matrix metalloproteinase levels (MMP-2 und MMP-9) in vacuum therapy-treated wounds with areas not covered by foam²⁸. They demonstrated that MMP-9/NGAL (neutrophil gelatinase-associated lipocalin), MMP-9, latent MMP-2, and active MMP-2 levels were reduced by 15% - 76% in vacuum therapy-treated wounds. Furthermore, they observed that microvessel density of vacuum

therapy-treated wounds was increased in comparison to areas not covered by foam. Interpreting these data it should be considered that there are no data given for baseline values at the wound bed and the wound edge not covered by foam. In addition, there were only three different chronic wounds without any possibility to estimate the effects of the initial debridement of the wound.

Today, the mechanotransductive stimulus on the wound bed that is exerted by the foam under suction is regarded as an important effect of vacuum therapy. In order to work out the mechanisms operating as a result of the mechanical effects of vacuum therapy, the research group of Kremers et al. (2003) investigated the intracellular concentration of mitogen activated protein kinase after a stretching stimulus (5% biaxially: 5 min stretch/2 min relax)³⁷. In this study, the levels of phosphorylated cJUN73 were increased after 48-72 hours. Indeed, these data are confirmed by the results of Chen et al. (2005)¹², demonstrating that the expression of c-myc, c-jun and Bcl-2 in the vacuum therapy group was consistently higher than the control group during the first 12 days after creation of a full-thickness skin defect in animals and in acute as well as chronic human wounds.

As the phosphorylation process of p38 and cJUN73 is associated with cell growth and cell division, Kremers et al. assumed that the results may contribute to the identification of the mechanisms by which vacuum therapy induces new tissue formation. However, the authors did not work out a model in which the stretching stimulus is produced by vacuum therapy. They merely assume that vacuum therapy produces a stretching stimulus and that their model is thus suitable for explaining the effects of vacuum therapy. The study is based on the assumption that vacuum therapy exerts a five-minute stretching and two-minute relaxing effect⁶⁶. This suction pattern corresponds to the setting for intermittent therapy recommended by Morykwas et al.

However, it remains to be discussed whether the stimulus acting on the cell during vacuum therapy is a pure stretching stimulus. As described above, it is more likely that both positive and negative pressure values are generated on the wound surface. In addition, it must be taken into account that, to date, vacuum therapy has been applied in continuous mode by the majority of users, who, however, achieved clinical success. It is thus difficult to assess what significance the findings that were obtained by Kremers et al. really have for the explanation of the effects of vacuum therapy.

To date, there are no clinical or experimental studies addressing the mechanical effects of vacuum therapy on the affected cell or tissue. The most common view of the principle of action of mechanotransduction on the cell was formulated by Morykwas et al.⁴⁴, who refer to the basic work of the research group led by Sumpio (1987/1988). This research group described the effects of cyclic traction on bovine endothelial cells (10% elongation, 3 cycles/minute) and the cells of the smooth vascular muscles (24% elongation, 3 cycles/minute)^{57,58}. Thymidine absorption, DNA synthesis performance and the rate of cell division were measured. The results show that the tissue traction in the endothelial cells stimulates endothelial cell proliferation (1987) while the proliferation of the smooth muscle cells is inhibited (1988). In their paper, the authors show very impressively how differently various tissue cells respond to the same stimulus. They also show that changes in the strength, frequency and duration of the exerted force and the resultant vector of the particular force on the very same tissue are associated with different cell responses, and that it must even be assumed that these vary from one anatomical location to the next. A general, standard cell response to a particular mechanical stimulus is regarded as unlikely, and, hence, conclusions by analogy to other tissues do not seem to be appropriate.

With regard to the explanation of the cellular effects of vacuum therapy, this exposition from the years 1987/88 helps to understand why the complex mechanism of action exerted by vacuum therapy is not easy to explain. The mechanical effects of the therapy on the tissue differ greatly, depending on the user: The suction strength varies between 50 and 200 mmHg (up to 900 mmHg when using Redon drainages) and the suction mode varies between continuous exertion of force, usually for a period of 48-> 72 hours, and cyclic (intermittent) exertion of force where completely different settings can be chosen for the frequency and duration in each case (ON: from 1-10 minutes; OFF: from 1-10 minutes; for the typically used vacuum therapy unit, this adds up to 700 possible settings!).

The frequently cited explanation of the mechanical effects of vacuum therapy is based on the reviews by Ingber et al. from the year 1991, in which the authors (Harvard Medical School) generally describe the current state of knowledge on the transduction of physical forces into biochemical responses on a cellular level. The conceptual model derived from these data describes how

external forces, such as subatmospheric pressure, act on the cell through the extracellular matrix by means of transmembrane bridges (membrane molecules such as the integrins), thus effecting the release of intracellular second messengers. According to the model, these messengers lead to the immediate activation of immediate early (IE) genes, followed by matrix molecule synthesis and cell proliferation, as described in the papers by Sadoshima (1992, 1993), Vandeburgh (1992) and Bauduin-Legros (1992)^{51-53,66}.

However, the studies of Ingber et al. do not investigate the effects of subatmospheric pressure on the cell. The application of the above-mentioned study results to stretching cell models is merely based on the assumption that vacuum therapy also produces a stretching stimulus.

Against the background of the diversity of cell responses to mechanical stimuli moving in the same direction, as mentioned by Sumpio et al., such a conclusion by analogy may only be drawn very cautiously, if at all. Also, it has not been proven to date that vacuum therapy produces a pure stretching stimulus. Because of the foam architecture, it must rather be assumed that positive pressure values (on the pore wall resting on the tissue) and negative pressure values (in the region of the actual pore) are generated at the same time. To date, there are no studies on the spatial pressure distribution in the mm and μ m ranges. In any case, when developing a model concept of the principle of action of vacuum therapy, one cannot work on the assumption that there is only one single stretching stimulus on cells. Instead of only one type of force acting on the cells, it is much more likely that pressure and/or shear stress (tangential force vector) and/or stretching forces act on the cells.

A somewhat deeper understanding of the heterogeneity of the mechanical forces acting on the cells of the foam/wound interface is conveyed by the results of the research group of Saxena and Orgill⁴⁴. In a computer simulation, they calculated the stretching stimulus that acts on the individual cells in the region of the foam pore wall and the foam pore space. The verification by histological examination revealed that the calculated results were valid. In this way, they were able to demonstrate that the cells in the region of the pore wall are "squeezed" and the cells in the immediate vicinity of the pore wall are stretched greatly, while the cells in the pore space are stretched by approximately 5-20%. In interpreting their results, the authors explain that chemical

stimuli such as soluble growth factors and the attachment to extracellular matrix proteins alone are not sufficient for the proliferation of cells, but that there must also be a mechanical context, which is usually associated with varying states of isometric tension of the cells. According to these authors, this state usually no longer exists in wounds but vacuum therapy can compensate for this lack of mechanical stimuli. They refer to the literature in which stretching stimuli indeed had a proliferative effect^{7,19,21}. In their model, they actually calculated stretching stimuli, as an effect of vacuum therapy, of a magnitude (5-20%), which had been found to be favourable in other studies. However, they did not discuss that, according to their calculations, individual cells experience stretching stimuli of over 110% while other cells are compressed substantially. Assuming that in a cross-section of the pore, only 60% of the cells actually experience a stretching stimulus of 5-20% (see Fig. A6.5), this means that only one-third of all cells within the wound (area = πr^2) experiences a favourable effect. Unfortunately, this circumstance is not discussed. Furthermore, it is necessary to consider that wounds are not simple single-phase linear elastic layers. As Lohman et al. mentioned (2004), this model unfortunately obfuscates the role of fluid shear stresses and electrokinetic streaming potentials (movement of ions in solution) in stimulating responses. Mechanical deformation by external negative pressure wound therapy will also result in fluid flow within the interstices of the matrix⁴⁰. Using vacuum therapy, there are stretching, shearing and electromagnetic effects, probably with certain differences between continuous and intermittent therapy.

Systemic Effects

Besides the above-mentioned local effects, a few studies show that vacuum therapy also has systemic effects. Morykwas et al., for instance, observed that the application of vacuum therapy after severe soft-tissue trauma (crush syndrome) resulted in a substantial reduction in myoglobin infiltration⁴⁶. In conclusion, it may by analogy be assumed that this effect of detoxification can also be applied to other histo- or organotoxic substances. Thus, vacuum therapy could possibly even be used as an emergency measure for the active elimination of toxins such as snake venom. Vacuum therapy also has systemic effects that appear to be completely independent of the local effect. Kremers et al., for instance, showed in an

animal study³⁷ that vacuum therapy lessens the burn-induced reduction of visceral blood flow. This is considered to be due to a decrease in the concentration of the vasoconstrictor TBXA₂ in the renal artery and an increase in the concentration of the vasodilator PGI₂ in the splenic vein. However, it is not discussed by the authors that there are several indications in the literature that a burn trauma is generally more likely to involve splanchnic hyperperfusion⁴.

Conclusions for Clinical Practice

On the basis of numerous observational studies and case descriptions and an increasing number of controlled studies and randomised clinical trials (RCTs), the effectiveness of vacuum therapy can today be regarded as conclusively proven, clinically. The high importance that this therapy has achieved today is founded on the excellent results observed by clinicians. However, although clinical studies have been conducted, there is a considerable deficit of basic pathophysiological research. It is striking that a small number of explanation approaches and recommendations on therapy details are repeatedly cited. However, the most frequently mentioned explanation approaches for the therapy success of vacuum therapy (improvement in perfusion, bacterial clearance and increase in proliferation rate as a result of favourable mechanotransductive effects) have not been conclusively proven by experimental studies.

Nevertheless, the present state of knowledge on the physiological effects of vacuum therapy allows the following statements to be made:

- The foam-under-suction-system generates negative and positive pressure values on the tissue. Information on the heterogeneity of the pressure has, so far, only been investigated in a computer simulation.
- During vacuum therapy, hypoperfusion develops in the tissue directly adjacent to the wound. This is more pronounced in subcutaneous tissue than in muscle tissue.
- The ischemic marginal zone borders on a "shell" with a thickness of approximately 1.0-2.5 cm (subcutaneous tissue, 50 - 200 mmHg) and ~ 0.5-1.5 cm (muscle, 50 - 200 mmHg) while there is hyperperfusion at a distance of ~ 2.5-3.5 cm (subcutaneous tissue) and 1.5-2.5 cm (muscle). Outside this shell, vacuum therapy has no measurable effects.
- No increased tissue oxygenation could be found in the tissue layers close to the wound.
- The reduction of bacterial wound contamination can be achieved in acute and exudative wounds. In a few studies, vacuum therapy produced a shift in the species distribution. What effects this shift ultimately has on wound healing remains to be elucidated.
- It can be derived from animal studies that the intermittent therapy mode is the most favourable for new granulation tissue formation.
- The antioedematous effect of vacuum therapy is undisputed. This can be utilised particularly in burn therapy on extremities.
- Local vacuum therapy can prevent systemic effects of some syndromes (crush syndrome).

While this list shows many approaches for scientific studies, it also reveals research deficits. It would be desirable that the unsettled questions be addressed so that the potential of vacuum therapy, which is already so successful today, can be utilised even more fully in the future, while at the same time systematically advancing the progress of possible further technical developments.

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Part A / Chapter 7

Experimental Basis II – Pressure Values under Vacuum Therapy Foams – An Experimental *in vitro* and *in vivo* Investigation

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The objective of this study was to analyze pressure conditions in the foam-tissue interface zone during application of vacuum therapy. We also focused on the question of whether the applied suction is undiminished over a longer distance as would be required when foams of larger area-size are used and whether there are important differences between the two currently available foam materials, polyurethane (PU) and polyvinyl alcohol (PVA).

The results of the study show that suction is distributed almost undiminished through the foam to the wound surface. This is possible in the suction range of 50-200 mmHg even at distances of over 50 cm using only one *trac-pad connector*. When a PVA foam is used, there is a relevant reduction in suction strength at suction levels of > 150 mmHg that increases in proportion to the distance from the *trac-pad connector*. It was also shown that positive pressures reaching >50 mmHg may develop the uppermost tissue layers. The shape of the wound (whether convex or concave) has a significant effect on the developing pressure conditions.

Introduction

The term "vacuum therapy" implies that a wound is exposed to negative pressure with a therapeutic intention. In actuality, the entire therapy system, when operational, is under negative pressure that is generated by a vacuum source, which acts, in turn, on the canister and the tubing and continues through the *trac-pad connector* into the foam itself. In this model, it is generally assumed that negative pressure must also exist at the wound surface and even extend into the superficial wound tissue. Based on this assumption, it has been concluded that wound secretions and interstitial fluid arising in the wound tissue are continuously removed, resulting in the observed anti-oedematous effect of vacuum therapy.

One study, however, returning data that would be unexpected given the above theoretical considerations, has demonstrated that positive pressures also develop at the wound surface¹. In this study, measurement sensors placed within the foam and at the foam-tissue interface for registering pressure changes showed that a slight positive pressure not exceeding 26 mmHg develops at the wound surface. Still unknown are the pressure conditions that develop in the superficial tissue layers directly subjacent to the foam.

Based on this background, the present *in vitro* and *in vivo* study proposed to analyze the pressure conditions along the foam-tissue border zone and to assess the homogeneity of the distribution of suction at different levels of applied suction in large foams made from the two currently available foam materials (polyurethane [PU] and polyvinyl alcohol [PVA]). Special attention was paid to pressure conditions in tissues immediately subjacent to the wound surface.

The present study addressed the following questions:

1. What suction and pressure conditions exist at the foam-tissue interface (i.e. at the wound surface)?
2. What suction and pressure conditions exist in subjacent tissue?
3. Is there a one-to-one transfer of the vacuum therapy induced suction through the foam in the direction of the tissue?
4. Do these findings apply to large-area foams of up to 50 cm in length?

Material and Methods

Pressure measurement technology and measurement software

Pressure measurements were performed using a multi-channel computer-guided pressure measurement system (ARGUS®, MIPM GmbH, Oskar-von-Miller-Str. 6, 82291 Mammendorf, Germany) that uses a piezoresistive principle for pressure registration⁷. The measurement method is based on changes in specific resistance in certain semiconductors in response to pressure. Pressure measurement probes consist of monocrystalline semiconducting material by which the applied pressure is directly converted to a change in electrical resistance. The sensors used with the applied PC-controlled measurement system are calibrated such that the zero-point voltage and the zero-point drift in the range of 20-40°C is practically zero. The initial signal of the pressure sensor (semiconductor bridge) is on the order of μV . In order to avoid measurement error, very-low-noise input stages with high input resistance are required. These precision operation amplifiers amplify the measurement signal of the pressure sensor into the mV range. The system is capable of measurements in the range of ± 350 mmHg with a resolution of ± 1 mmHg.

A preamplifier and supply module transmit the analog signals of the pressure sensor to the receiver station. For storage, the digitalized measurement data is transmitted across an interface to a PC running measurement software.

Experimental design

The experiments were performed using a total of seven settings, including two experiments that can be described as "pre-experiments" and are intended to serve as a basis for the reader's own thought experiments and five *in vitro/in vivo* pressure measurement experiments. The patient recruited for the study was informed regarding the planned procedure and gave his written informed consent. The study design was submitted to the local ethics commission and approved.

Experiment 1

In vitro: Application of suction at 200 mmHg on intact skin on the volar side of the left forearm of one of the authors (C.W.) for 18 hours ($n = 1$). Photographic documentation of the contact surface was obtained upon

removal of the PU foam and then after 1.5, 6 and 18 hours.

Experiment 2

In vitro: Application of suction of 50, 75, 100, 125, 150, 175 and 200 mmHg (VAC[®]), respectively, together with additional negative pressure of ca. 900 mmHg (Redon drainage container) on cubes of modeling clay with an edge length of 1.5 cm ($n = 1$; Fig. A7.1). The clay cubes were placed on a flat desktop and covered with a foam 8 x 8 cm in size. The sealing drape and the *trac-pad connector* were applied in the usual manner. The duration of the applied suction was 90 minutes. Each of the eight individual experiments was conducted using a PU and a PVA foam (Fig. A7.2).

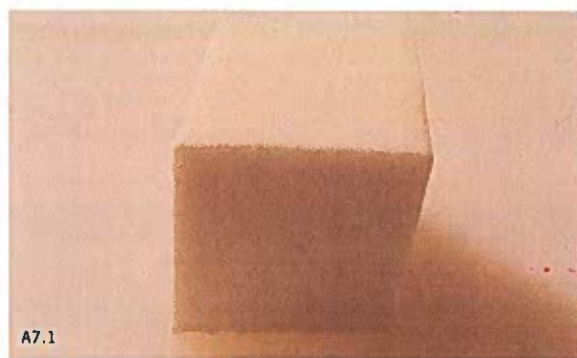


Fig. A7.1 Cube made of modeling clay (edge length approx. 1.5 cm) prior to application of suction through the vacuum therapy foam.



Fig A7.2 Experimental design for demonstration of the effect of suction applied to a cube of modeling clay in relation to the suction strength. Each cube was exposed to suction applied through one of the two types of foams over a period of 90 minutes.

Experiment 3

In vivo: Application of negative pressure of 50 to 200 mmHg (in increments of 25 mmHg, respectively) together with additional suction of ca. 900 mmHg on intact skin on the dorsal side of the left forearm of one of the authors (C.W.) for 15 minutes each ($n = 1$, i.e., one measurement at each pressure level) using foams of different lengths. First, a pressure-measurement probe was inserted to a depth of 0.5 cm into the subcutaneous tissue of the dorsal aspect of the forearm. Three different foam sizes were used to determine the tissue pressure:

1. A foam 5 cm in width and one-quarter forearm circumference (= 7 cm) in length over the tip of the measurement probe.
2. A foam 5 cm in width and one-half forearm circumference (= 14 cm) in length over the tip of the measurement probe.
3. A foam 5 cm in width by 28 cm in length over the tip of the measurement probe that encircled the entire forearm in order to achieve complete closure

of the foam strip (the foam formed a ring around the extremity). This series of experiments was conducted using a PU foam (Fig. A7.3).

In a further experimental session, tissue pressure was measured subcutaneously on the dorsal aspect of the hand of one of the authors (C.W.) during an increase in suction from 50 to 200 mmHg using a circular glove dressing (four measurement series).

Experiment 4

In vitro: Evaluation of pressure conditions on the foam-desktop interface. For this experiment, four measurement probes were applied simultaneously in order to detect heterogeneity in the pressure distribution (Fig. A7.4-A7.6). The unidirectionally oriented measurement window was placed facing the desktop and was conducted using both foam materials (PU and PVA). Each measurement was taken twelve times with intervening release and reapplication of the foam ($n = 12$).



Fig. A7.3 Experimental design for demonstration of the effects of suction on soft tissue in an extremity in relation to the circular extension of the foam (left forearm).



Fig. A7.4 Placement of the four measurement probes on a flat desktop. Fixation of the unidirectionally constructed probe tip using tape strips to prevent unplanned rotation of the probe.



Fig. A7.5 Experimental design with the white PVA foam.

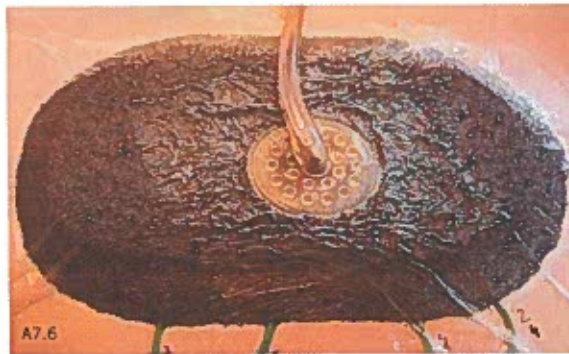
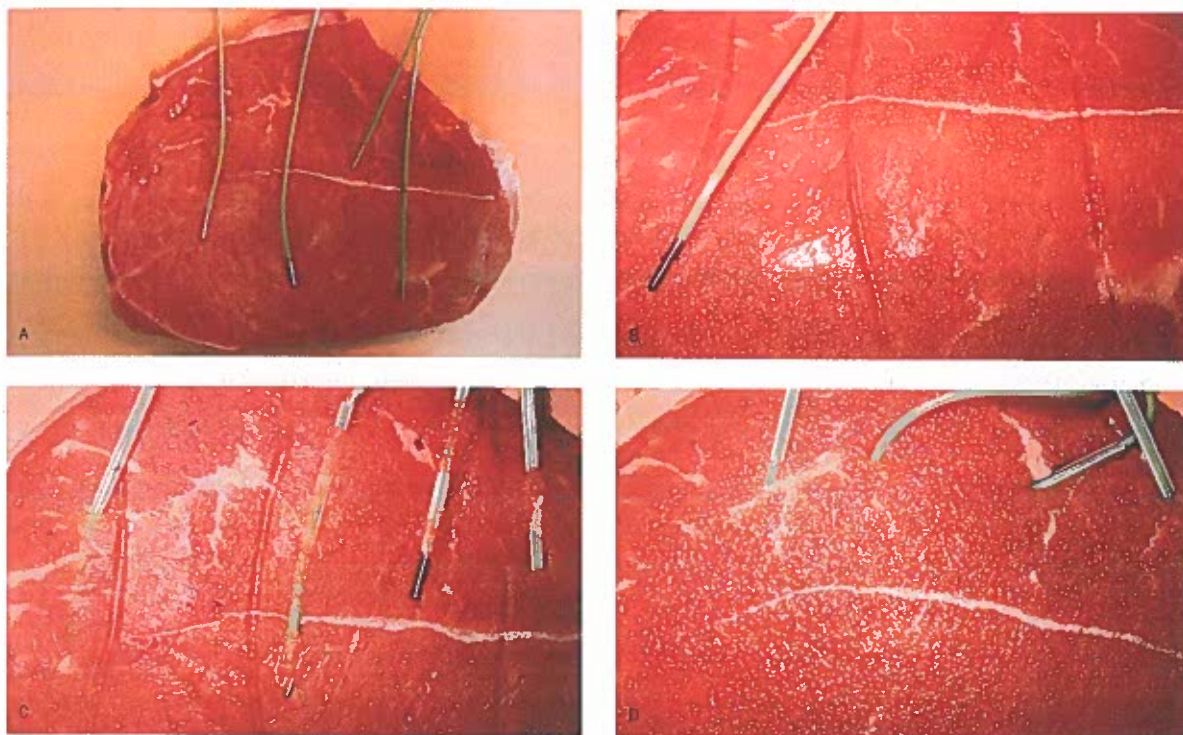
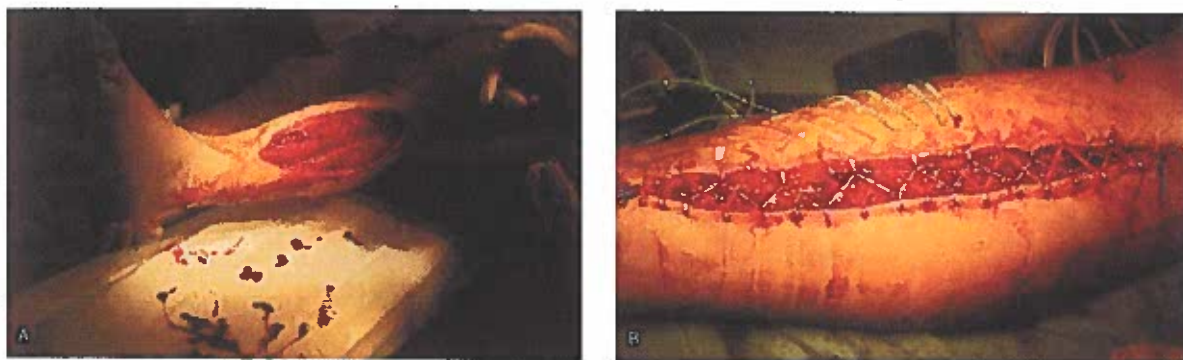


Fig. A7.6 Experimental design with the black PU foam.



Figs. A7.7A-D Placement of the four measurement probes on the surface of the piece of beef (A and B; at 2-3 mm depth [C]; and at 5-8 mm depth [D]). It is remarkable that, following "vacuum therapy" on this non-living tissue, the typical tissue stippling can be seen (the effect therefore appears to be a suction and pressure phenomenon rather than a consequence of the formation of granulation tissue).



Figs. A7.8A+B Open wound on the third day after surgical fasciotomy for compartment decompression (A) and placement of the four green measurement probes in the tissue of the tibialis anterior muscle (B) at 2-3 mm tissue depth; shoelace-technique for support of wound closure planned for the near future (dynamic dermatotraction).

Experiment 5

In vitro: Evaluation of the pressure conditions at the foam/beef interface as well as at tissue depths of 2-3 and 5-8 mm. Four pressure measurement probes were applied simultaneously for this purpose. The unidirectional measurement window was directed toward the surface of the piece of meat (Fig. A7.7A-D). A negative pressure of 50 to 200 mmHg was applied at increments of 25 mmHg. The experiment was performed using both foam materials (PU and PVA). Each measurement was performed a total of eight times with intervening release and re-application of the foam.

Experiment 6

In vivo: Evaluation of the pressure conditions at a tissue depth of 2-3 mm (tibialis anterior muscle). Four pressure measurement probes were applied simultaneously for this purpose (Fig. A7.8A and B). A negative pressure of 50 to 200 mmHg was applied at increments of 25 mmHg. The experiment was performed using both foam materials (PU and PVA). Each measurement was performed eight times with intervening induced loss of suction but without re-application of the foam.

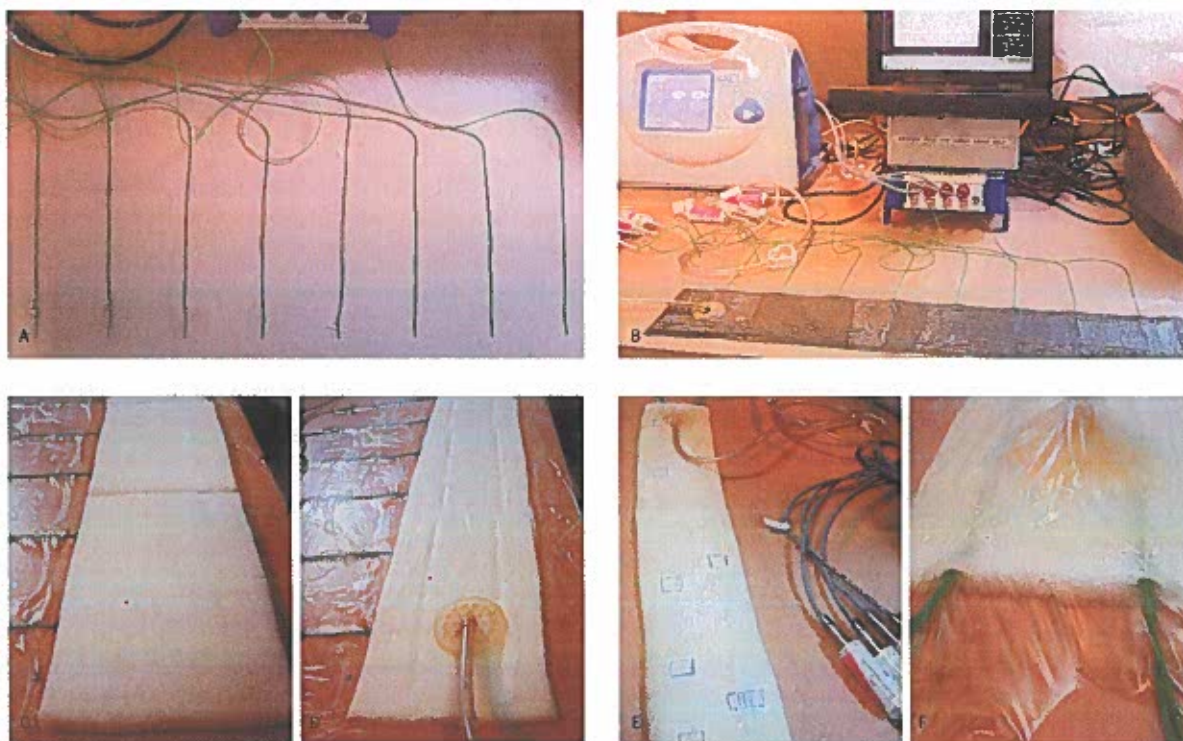


Fig. A7.9A-F Placement of the eight measurement probes on the surface of the work area with orientation of the measurement window toward the desktop (A). B: Application of the 60-cm long PU sponge (interval: 7.5 cm, distance: 3.75-56.25 cm). C: Series of individual 7.5 x 15 cm PVA sponges. D: Series of PVA foams following application of suction with transmission of suction through only one *trac-pad*. E+F: The probes have inserted through the drainage tube holes integrated into the foams. Blue squares (E) mark the location of the measurement catheter tips (= control experiment; equivalent results were documented).

Experiment 7

In vitro: Evaluation of the homogeneity of suction distribution in PU and PVA foams over a distance of 0 to 52.5 cm (eight probes placed simultaneously at intervals of about 7.5 cm). Application of negative pressure of 50-200 mmHg at increments of 25 mmHg. Each measurement was performed eight times with intervening release and re-application of the foam (Fig. A7.9A-F).

Technique of probe implantation, probe localisation

In vitro: Placement of the measurement probes took into consideration that the measurement window constituted only a small portion of probe tip (Fig. A7.10). This made it possible, on the one hand, to orient the measurement window toward the foam in order to directly register pressures developing in the foam and, on the other hand, by turning the probe toward the substratum (desktop or muscle tissue), to measure the suction produced on either the hard, smooth and non-flexible desktop or the soft, flexible simulated wound surface. In

order to prevent inadvertent rotation of the probe and assure that placement of the measurement window (i.e. the direction of measurement) remained correct, the catheter was fixated with a strip of tape about 2 cm proximal to the catheter tip.

In vivo: In order to determine any inhomogeneity in the distribution of suction and a potentially resulting pressure gradient, four measurement probes were implanted under surgical conditions at approx. 1 cm intervals in the *tibialis anterior muscle* three days after fasciotomy for treatment of compartment syndrome of the lower leg. The individual steps of the probe implantation procedure have been described elsewhere⁷. Briefly, following broad disinfection of the skin, four 14-gauge (2.1 mm) PTFE catheters (standard intravenous catheters) were inserted into the skin without additional skin incision at an insertion angle of 30°. The fascia of the *tibialis anterior muscle* was penetrated and the tips of the needles were advanced beneath the wound surface at a depth of ca. 2-3 mm under the wound surface. Then, the probes were

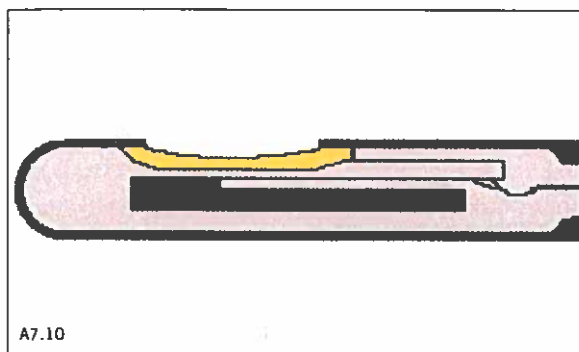


Fig.A7.10 Cross section through the measurement probe tip showing the measurement window oriented in one direction only. The silicon coating of the piezocrystal is represented in yellow. Pressures applied from above onto the crystal can be registered, while pressures applied from below onto the metal housing are not registered.

moistened with sterile 0.9% normal saline solution. The probes were plugged into the PC controlled measurement system by connecting them with the amplifier module after which the software initiated the offset calibration for pressure calibration (software self test and calibration). Following removal of the trochars, the 4-French pressure measurement probes were advanced through the catheter to the level of the needle tip. Finally, the catheters were drawn back over the probe wires and the site of insertion was dressed in sterile fashion. The probe wires were fixated with tape strips without application of pressure to the soft tissue.

Vacuum source

The therapy units VAC^{ATS} or VAC^{Mini} / VAC^{Freedom} were used to generate negative pressure. These vacuum sources are capable of generating a suction strength of 50-200 mmHg. If greater suction was required, a commercially available suction container (Redon drainage) with a pre-existing negative pressure of approximately 900 mmHg was used. Suction was transmitted to the foam using a conventional adhesive-backed *trac-pad connector* following drape sealing of the wound.

Analysis software and statistics

Data was processed using commercially available calculation and statistics software. Parameters were presented as median and 25% and 75% quartiles. The graphic representation showed respective medians, 25% and 75% quartiles, and minimum and maximum values. The dif-

ferences between two samples were considered statistically significant with a $p < 0.05$ (*) or $p < 0.01$ (**) and $p < 0.001$ (***); n.s. = not significant). Calculation of the level of significance was performed using the non-parametric Kruskal-Wallis test for unlinked samples with the Bonferroni correction for multiple tests within the same sample.

Results

Experiment 1

How does intact skin present after 18 hours of vacuum therapy with an applied suction of 200 mmHg?

Erythematous with numerous sites of petechial bleeding secondary to the effects of the applied suction OR pale secondary to reduced perfusion?

Both answers to the question posed in this thought experiment have their rationale. Petechiae might certainly be expected to result from the application of suction at 200 mmHg to both a wound or, in this case, intact skin, resulting in superficial bruising resembling a "love bite". On the other hand, pallor would be an anticipated consequence of reduced perfusion, as might occur secondary to the pressure of the foam that is affixed and placed under suction on the skin.

In general, one sees the sequelae of long-term tissue compression. Immediately after removal of the foam, one observes a pale patch of skin that subsequently becomes erythematous secondary to hyperaemia. Mild hyperaemia persists in the area of foam application even after 18 hours (Fig. A7.11-17).



Fig.A7.11 APU foam is applied to intact skin for 18 hours (200 mmHg, continuous suction mode).



Fig. A7.12 Immediately after removal of the foam and drape. Skin erythema in the vicinity of the foam secondary to the irritation by removal of the adhesive drape. The area of foam application is macroscopically pale with no evidence of petechiae following 18 hours of vacuum "therapy".



Fig A7.13 One minute after removal of the foam and the adhesive drape. Skin erythema surrounding the site of foam application. Note the appearance of small islands of immediate hyperaemia.



Fig. A7.14 Four minutes after removal of the foam and drape. Pronounced erythema of the skin secondary to hyperaemia within the site of foam application. The surrounding erythema has started to resolve.



Fig A7.15 90 minutes after removal of the foam. There is still mild erythema within the site of prior foam application.



Fig. A7.16 Six hours after removal of the foam, there is still slight evidence of mild, persisting erythema within the site of prior foam application with especial demarcation of the peripheral zone.



Fig. A7.17 At 18 hours after removal of the foam, there is still very mild erythema within the site of prior foam application with especial demarcation of the peripheral zone.

Experiment 2

Effects of vacuum therapy for 90 minutes on cubes of modeling clay

All cubes of modeling clay were compressed and flattened, regardless of type of foam and applied pressure (50-200 mmHg and 900 mmHg). High pressures resulted in significantly greater flattening than did lower pressures (because the purpose of the experiment was simply to illustrate the potential tissue compression we offer only a description of the results; see Fig. A7.18).



Fig. A7.18 The cubes of modeling clay are flattened by 90 minutes of vacuum therapy. From left to right: 0 mmHg, 75 mmHg, 200 mmHg of applied suction.

Experiment 3

Effects of circumferential application of vacuum therapy to an extremity

Tissue pressures showed significant growth secondary to circumferential application of the foam on the forearm. While *baseline* values of 1-2 mmHg were registered, tissue pressures increased to 3-4 mmHg with a one-quarter circumferential covering of the forearm to 14-16 mmHg with complete circumferential application of a ring-shaped foam strip. With the glove dressing, pressure values increased from 0 mmHg at *baseline* to 6.75 mmHg (median, at 50 mmHg), 10 mmHg (median, at 100 mmHg), 12.25 mmHg (median, at 150 mmHg) and 14.75 mmHg (median, at 200 mmHg).

Experiment 4

In vitro pressure conditions at the foam/wound interface

Directed the measurement window of the pressure measurement probe toward a smooth, hard surface (desktop) with absence of foam material or soft tissue pressing into the window and onto the pressure sensor, there is nearly a one-to-one transmission of suction through the foam into the desktop (Fig. A7.19). This applies especially for

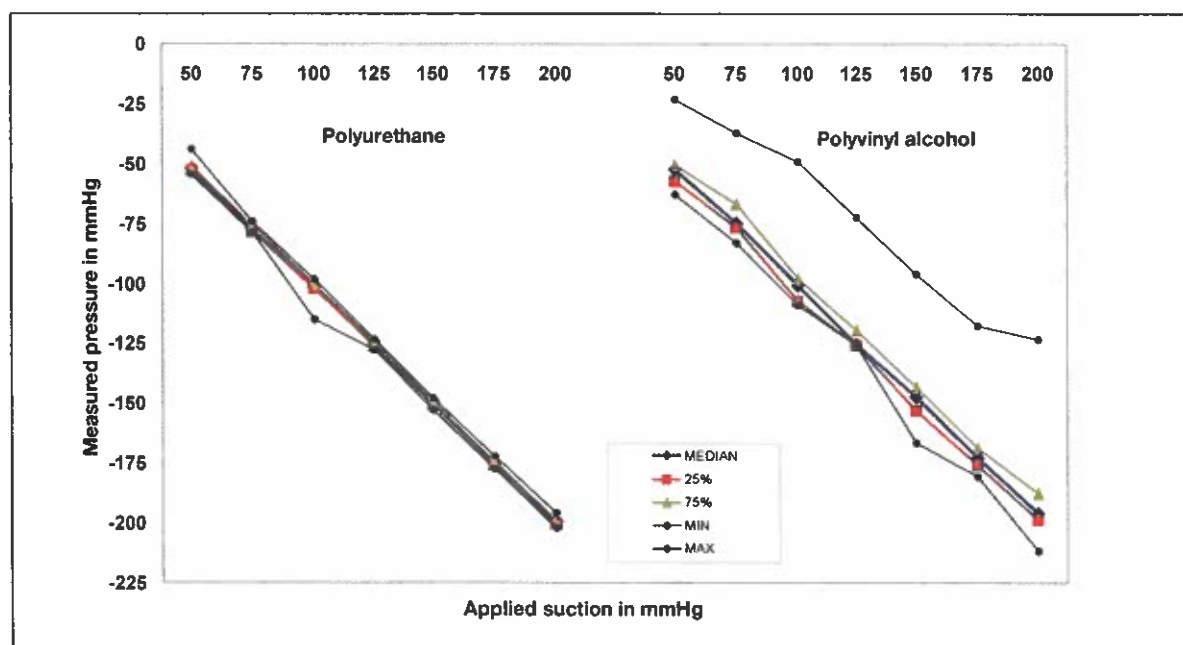


Fig. A7.19 Relationship between applied suction (x-axis) and measured transmitted pressure on the desktop (y-axis) for the two foam materials PU (left) and PVA (right) with downward orientation of the measurement window. Values are presented as median (blue), 25% and 75% quartiles (red/green) and maximum and minimum values (black).

the PU foam, with which the 25% and 75% quartiles vary by only between -0.9 and +1.9 mmHg from the median and with which even the minimum and maximum values normally vary by between -2.5 mmHg (with the exception of one measurement series-outlier) and +3.5 mmHg from the median ($n = 12$). Slightly larger divergence was seen when the PVA foam was used, with pressure values varying between -6.5 and +8.4 mmHg from the median over the entire range of applied suction levels from 50 to 200 mmHg ($n = 16$; one single outlier in the entire series inexplicably showed a reduction in pressure of about 70 mmHg).

Experiment 5

In vitro pressure conditions at the foam/muscle interface

In this series of measurements, the unidirectional measurement window was oriented toward the meat. At all three depths (superficial, 0.5-2 mm and 3-8 mm), there was an increase in tissue pressure proportional to the increase in suction (increment 25 mm from 50 to 200 mmHg; Fig. A7.20). At the surface of the meat, there was an increase in median from -5.9 mmHg

($Q_{25\%}/Q_{75\%}$: -21.6/-2.0; suction: 50 mmHg) to +11.8 mmHg ($Q_{25\%}/Q_{75\%}$: -5.9/-2.0; suction: 200 mmHg); at 0.5-2 mm tissue depth an increase in median from -5.7 mmHg ($Q_{25\%}/Q_{75\%}$: -8.3/-3.8; suction: 50 mmHg) to -0.7 mmHg ($Q_{25\%}/Q_{75\%}$: -3.9/+3.5; suction: 200 mmHg); and at 3-8 mm tissue depth from -5.8 mmHg ($Q_{25\%}/Q_{75\%}$: -13.8/-4.1; suction: 50 mmHg) to -2.2 mmHg ($Q_{25\%}/Q_{75\%}$: -5.9/+0.1) at a suction of 200 mmHg.

Experiment 6

In vivo pressure conditions at the foam/muscle interface

Application of suction pressures between 50 and 200 mmHg at the foam/muscle (*tibialis anterior muscle*) interface at a tissue depth of 2-3 mm resulted in a median increase in pressures from 0.0 mmHg ($Q_{25\%}/Q_{75\%}$: -0.8/+4.6; suction: 50 mmHg) to +5.5 mmHg ($Q_{25\%}/Q_{75\%}$: -1.5/+7.8; suction: 200 mmHg); and to a median of +3.4 mmHg ($Q_{25\%}/Q_{75\%}$: -1.9/+7.4 mmHg) at the conventional applied pressure of 125 mmHg.

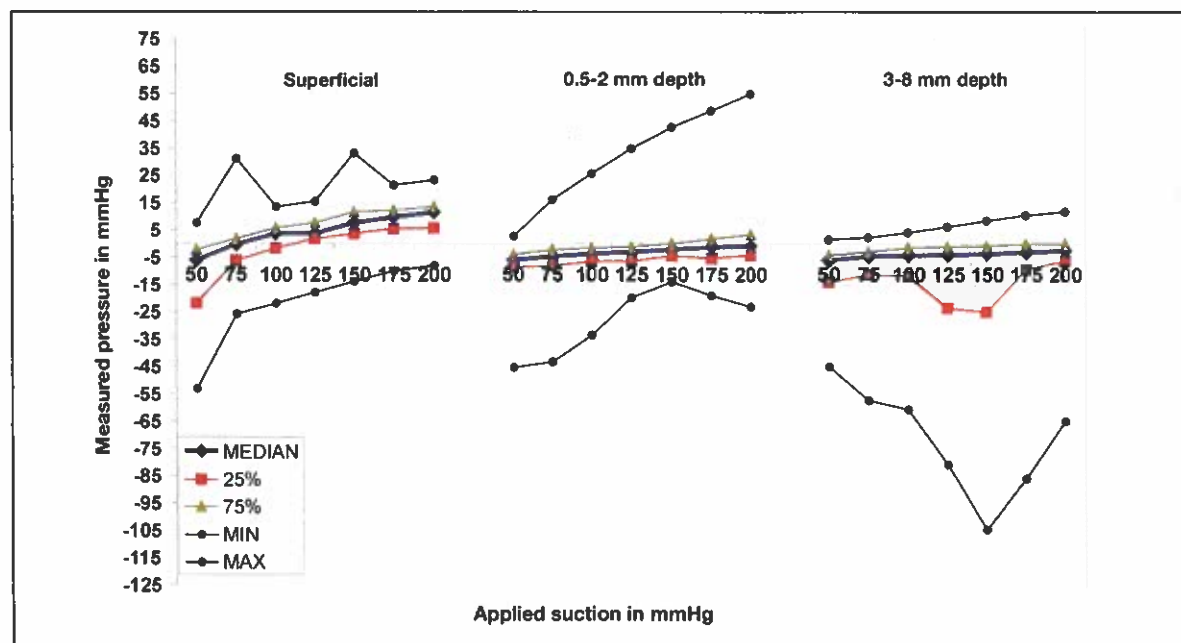


Fig. A7.20 Relationship between applied suction and measured pressure at the muscle tissue surface and at tissue depths up to 8 mm using the PU foam. Values are given as median (blue), 25% and 75% quartiles (red/green) and maximum and minimum values (black).

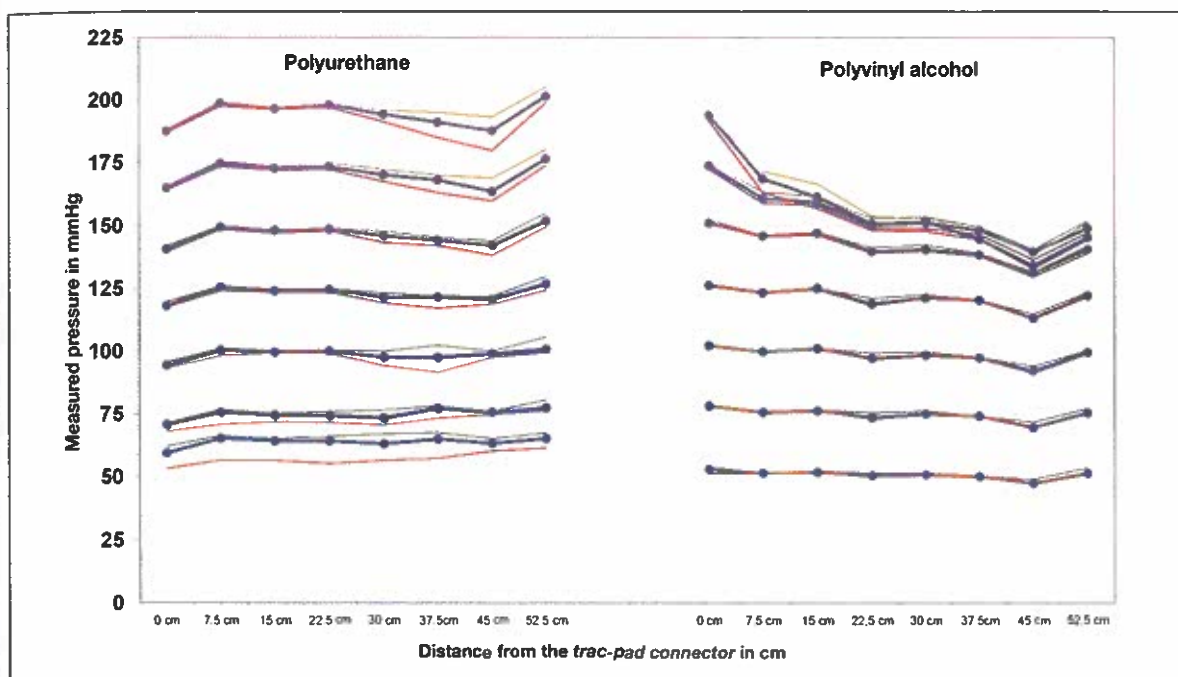


Fig A7.21 Suction in relation to distance from the *trac-pad* connector over a distance of > 50 cm. The blue line shows the median; red, the 25% quartile, and green, the 75% quartile.

Experiment 7

Transmission of the suction effect through the foam

Transmission of the applied suction was observed in both foams over a distance from the *trac-pad* connector exceeding 50 cm. With applied pressures under 150 mmHg, transfer of nearly one-to-one was observed. At higher suction levels and distances over 7 cm, however, there were significant observable differences between the PU and PVA foams (Fig. A7.21). Using the PU foam, there is only slight variation (usually no more than a few mmHg) in measured pressure values over 100 mmHg even at the maximum distance of about 52.5 cm from the *trac-pad* connector. For example, at 125 mmHg values differed by a median 2.2 (Q_{25%}/Q_{75%}: -3.7/-1.1 mmHg) and at 175 mmHg by a median -3.6 mmHg (Q_{25%}/Q_{75%}: -5.3/-2.0 mmHg).

Conversely, with the PVA foam, there was significant reduction in effective suction at only 7.5 cm from the *trac-pad* connector at suction pressures in excess of 150 mmHg.

- At a greater distance, e.g. 52.5 cm, there was a reduction by a median of 9.5 mmHg (Q_{25%}/Q_{75%}: 10.5/7.9 mmHg) at a suction level of 150 mmHg;

- of 24.4 mmHg (Q_{25%}/Q_{75%}: 26.1/21.9 mmHg) at a suction level of 175 mmHg;
- and of 48.9 mmHg (Q_{25%}/Q_{75%}: 52.2/46.9 mmHg) at a suction level of 200 mmHg.

Applying a suction level of 200 mmHg, this represents a reduction in transmitted suction to about 150 mmHg, which corresponds to a reduction in suction force of about 25% (at distances as small as about 20 cm).

Discussion

Objective of the present study was to investigate the pressure conditions that develop at the foam-tissue interface during application of vacuum therapy. Additionally, we tried to ascertain whether the applied suction is transmitted undiminished over larger spatial distances as occurs in the case of foams with larger surface areas and whether there are any significant differences in performance between the two currently available foam materials, polyurethane (PU) and polyvinyl alcohol (PVA).

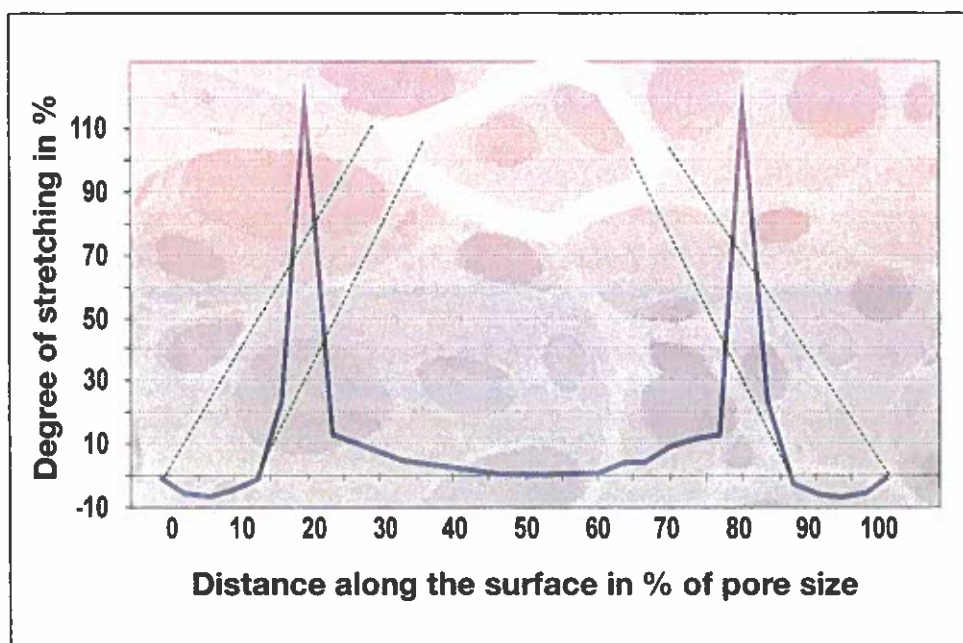


Fig. A7.22 Strain pattern of the individual cells in the wound bed under the pore wall and under the foam pore during vacuum therapy, calculated with a computer model using the method of finite elements. The blue graph reflects the extent of microdeformations in each respective affected cell. The white ring indicates the pore wall, while the interrupted black line represents the projection of the pore wall onto the corresponding deformation value (modified from Saxena et al.)

Our findings show that the applied suction is transmitted nearly undiminished through the foam to the wound surface. For the PU foam, this has been documented for levels of applied suction between 50 and 200 mmHg over distances of nearly 60 cm using a single *trac-pad connector*. When a PVA foam is used, our data reveal a relevant reduction in suction strength at applied suction values in excess of 150 mmHg with increasing distance from the *trac-pad connector*. In addition, we found that positive pressures of over 50 mmHg can develop in the superficial wound layers. The shape of the wound (concave or convex) is a factor that contributes significantly to the extent to which such pressure develops.

What happens at the wound surface?

To date, only one study has appeared in the literature in which researchers measured the pressures developing along the foam-wound (or substrate) interface³. In this study, the authors show that negative pressures do not develop on the cells and that, even with very strong vacuum sources (Redon drainage system) with suction values up to 900 mmHg, positive pressures do not exceed 26 mmHg.

As already discussed in Chapter 6, further information on pressure conditions at the wound surface and adjacent tissues can be only indirectly derived from data published by Wackenfors et al. (2004) and Saxena et al. (2004)³⁴. Wackenfors and her co-workers describe on the basis of animal experiments the existence of hypo- and hyperperfused areas in the tissue. The extent of which depends on the type of tissue (subcutaneous tissue, muscle) and on the strength of the suction applied during vacuum therapy. For example, they observed areas of hypoperfused or ischemic tissue immediately adjacent to the wound in subcutaneous tissue up to 2.5 cm in depth (50 mmHg: 1.8 cm; 100 mmHg: 2.1 cm; 200 mmHg: 2.5 cm). Associated with such areas they observed a hyperperfused region up to 4.5 cm from the wound margins. Outside of such areas there were no observed changes in microcirculation. In principle, similar results were also measured in muscle tissue but the thickness of the individual tissue layers was smaller, with hypoperfusion at an applied suction of 50 mmHg to a depth of 1.0 cm; at 100 mmHg of 1.4 cm; and at 200 mmHg of 1.7 cm. Similarly, the area of hyperperfused tissue exhibited a depth of approximately 2 cm.

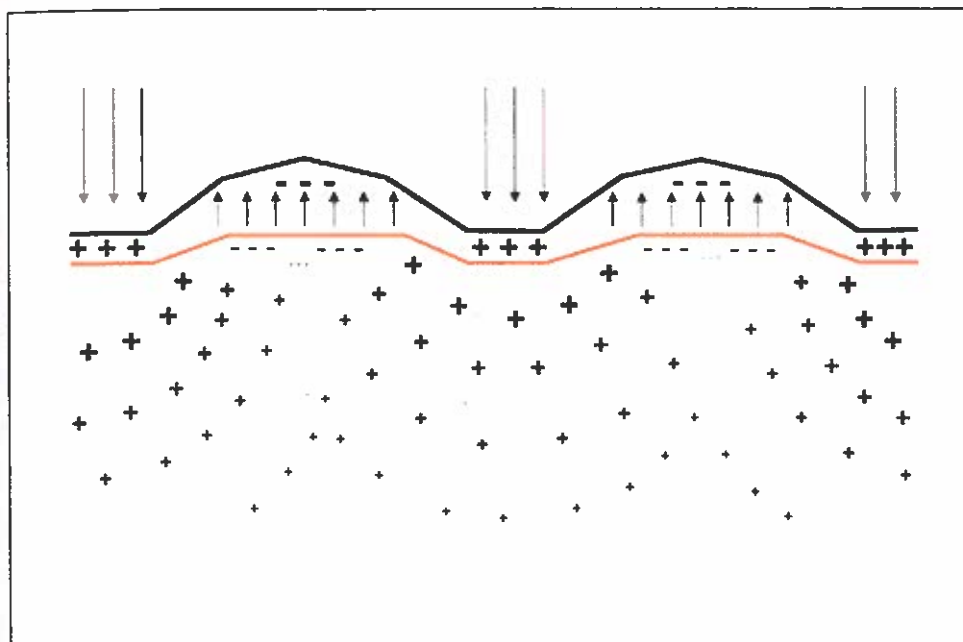


Fig. A7.23 Pressure distribution in tissue under the influence of vacuum therapy in the upper tissue layers of the wound. Black line: lower margin of the foam. Orange line: upper layer of the wound. The long arrow indicates the area in which pressure acts on the tissue. The pore walls are pressed into the wound. Near the surface, these positive pressures extend into the tissue and dissipate. At the points of pore domes, negative pressures act on the wound surface. Because of the pressure applied by the pore walls, cell components are exposed to strain in the negative pressure zone and simultaneously to negative pressure. Under certain conditions, this may, to a limited extent, extend to the upper levels of the tissue. This model unites the results of studies by Saxena et al. and Wackenfors et al.

The research group of Saxena approached the problem discussed here from a completely different standpoint. Using computer simulation, they calculated the degree of cell microdeformation under the influence of the foam pressing into the wound. They calculated the degree of compression (up to -10%) of the cells in the vicinity of the pore wall, extreme strain ($> 100\%$) at the margins of the pore wall and a moderately pronounced cell strain ($5\text{-}20\%$) in the vicinity of the pore dome (see Fig. A7.22).

Before attempting to derive a uniform hypothesis from the four available studies regarding the actual pressure and suction conditions, it would be useful to assess the limitations of the individual studies.

In both our study and that reported by Maier et al., a unidirectional measurement probe was positioned with its measurement window oriented toward the "wound". At a probe size (4F) of approximately 15×2 mm (measurement window approximately 5×2 mm), it is clear that, despite its numerous pores and pore walls, the foam superimposed over the probe presses it into the tissue. The area of the measurement window is occupied by about 50 to 250 pore domes and their corresponding

walls (in the pressure zone, depending on pressure and foam material, the pores are deformed such that pore size is reduced to only $50\text{-}400$ μm , while the pore walls are about $80\text{-}250$ μm or thicker). The measured data therefore reflect, not the measurement value in a single potential suction dome (pore) or under a single pore wall, but rather the pressure values that develop in the immediately subjacent tissue layers. Further limitations secondary to *ex vivo* wound models using meat or fruit, as well as investigations using tabletops and studies in humans using only a single study subjects are not considered here.

While these two studies do not provide any detailed information on the true heterogeneity of the distribution of pressure beneath the impressed foam, such information may be derived from the results of the computer simulation described by Saxena and co-workers. This study, in turn, is limited by the fact that it is restricted to the uppermost cell layer in the wound bed. No data regarding changes occurring at a greater depth are provided. In addition, they do not consider the actual foam architecture in the tissue/foam interface zone under the effects of pressure.

The effects of vacuum therapy at deeper tissue levels can, however, be estimated from data published by Wackenfors and co-workers, whose individual measurements, however, were registered at distances around the wound that are gigantic compared to the size of the pores.

Despite the above described limitations, the data from these two sources complement one another and can serve as a platform for further considerations leading to formulation of a new hypothesis on pressure distribution within the tissue-foam contact layer under the influence of applied vacuum.

First, the "confirmed" data:

1. Both positive and negative pressures develop at the upper surface (tissue/foam interface) of the wound.
2. The pressures that develop here are dependent on the suction level of the vacuum source.
3. The median pressure values that have been registered range between -25 mmHg and +15 mmHg (see Fig. A7.20).
4. Maximum recorded pressures range from -105 mmHg to +55 mmHg (see Fig. A7.20).
5. Positive pressures develop at points of contact between the foam and its solid components (pore wall).
6. Negative pressures develop where the pore "dome" is sufficiently broad so that there is no contact with the tissue and the suction can be transferred to the tissue surface unhindered.
7. The distribution of positive and negative pressure values is dependent on foam architecture (spatial proportion of pore walls and pores). The analysis of electron micrographs of different foams under varying suction conditions has yielded a spatial relationship of wall to pore of 1:1 to 1:4.

The pressure that develops from the pore walls spreads in a circular fashion from the contact zone into the tissue and progressively weakens. As a result, a zone of increased pressure develops in the upper wound levels. It would appear reasonable that, due to this pressure, perfusion in this zone would decrease and this is borne out by actual data reported by Wackenfors et al. (Fig. A7.23).

The following mechanical effects appear to act on the tissue during vacuum therapy:

- Pressure induced compression of small haemorrhages in the wound bed (haemostasis).

- Mechanical deformation of the cells in the area of the contact zone (foam/wound bed) due to "squeeze" and strain effects.
- Pressure induced hypoperfusion zone (dependent on suction strength and tissue) extending about 1-2.5 cm from the wound.
- Cyclical hypo-/hyperperfusion situations with consequences for angiogenesis.
- Hyperperfusion bordering on the hypoperfused tissue area (up to 4.5 cm from the wound margin, followed by tissue with no reaction to the vacuum therapy).

How does vacuum therapy really work?

The reasons given for the generally accepted efficacy of vacuum therapy relate primarily to the induction of granulation tissue and reduction in wound surface area. These effects are noted even in wounds in bradytrophic tissue, over bones and even over prosthetic implants made of metal. This favourable effect is believed to be due to:

- Improvement in the perfusion of the wound margins and adjacent tissue. It has been estimated that an increase in local blood flow of up to 400% can be induced.
- Reduction in interstitial fluid.
- The consequences of mechanical forces acting on the affected cells, which are supposed to stimulate cell proliferation (see Chapter 6).

A direct effect of therapy on improving perfusion at the wound margins has not been confirmed in the available studies (see also Chapter 6). It appears plausible that exactly the opposite may occur. A narrow zone of hypoperfusion forms adjacent to the wound margin and may even become ischemic if the applied pressure is too high. It appears, however, that one of the most important positive effects of vacuum therapy is the reduction in interstitial fluid. This is particularly pronounced in cases of burns to the hand in which a vacuum glove dressing is used. Vacuum therapy applied in such cases, however, is simply a dressing applied in circumferential fashion in the sense of a compression dressing, which naturally promotes a proximal drainage of lymphatic fluid (positive tissue pressures of 15 mmHg have been measured under applied pressures of 200 mmHg).

With a large-area wound on a flat surface the vacuum dressing can also be seen as a "compression dressing". In these cases, vacuum therapy generates a hetero-

geneous pressure distribution with development of a pressure gradient that can then be followed by the interstitial fluid stream. Near the pore walls, superficial positive pressures drive interstitial fluid in the direction of the negative pressure zone (foam), where they can be aspirated upon reaching the wound surface. Once relieved, the superficial zone is again “filled” with fluid from deeper tissue levels and, by ongoing constant pressure from the pore walls, this fluid continues to travel toward the surface.

The above considerations do not integrate the observation of Wackenfors et al. that, distant from the wound and the hypoperfused zone in its immediate vicinity, a hyperperfused area develops. Assuming that these observations also apply in humans, one can postulate that this, too, represents a mechanism for the removal of interstitial fluid. At first, the pressure transmitted to the tissue declines in the direction of this hyperperfused zone. Hence, a second pressure gradient develops, again directed away from the wound. Interstitial fluid is now displaced into deeper tissue levels. The concomitant hyperperfusion facilitates removal of this fluid.

A consequence of these two fluid streams is the reduction in interstitial oedema. Due to this direct effect that reduces tissue pressure, perfusion can increase as a secondary effect of vacuum therapy. This indirect mechanism underlying the increased perfusion was also postulated by Isago et al.^{1,2}

Practical Conclusions

Against this background of theoretical considerations, there are several concrete consequences for practical application of this method, such as the selection of suction strength and suction mode. The currently recommended suction strength of 125 mmHg was based on an animal experiment by Morykwas et al., which, when comparing suction strengths of 25, 125 and 500 mmHg, showed that a suction strength of 125 mmHg was most quickly followed by reduction in wound size⁴. In another study, also based on animal experiments, Isago et al. compared suction strengths of 0, 25, 50, 75 and 125 mmHg in terms of associated wound healing success. They found that there were no significant differences between respective speeds of wound healing achieved at suction strengths of 50, 75 and 125 mmHg. Hence, it appears that suction strengths falling in the range of 50 to 125 mmHg are essentially equivalent in terms of suitability for vacuum

therapy. Based on these findings, it appears that suction pressure should be selected so as to create non-homogeneous pressure conditions in the tissue yet not high as to cause extensive ischemia near the wound surface. The applied suction pressure should not, therefore, be standardized to 125 mmHg. It is apparent that high suction pressures (e.g. 900 mmHg), especially in primarily poorly perfused tissues, are disadvantageous and can produce ischemic areas near the wound margins.

The geometric application of the foam also appears to be important for the actual perfusion of the tissue affected by vacuum therapy. Equivalent suction strengths produce divergent patterns of pressure distribution in deeper tissue layers depending on whether the wound is concave or convex.

It is clearly recommended that, even in the case of large dressings, only one *trac-pad connector* should be used. This also applies for the white PVA foam at suction levels less than 150 mmHg.

Both positive and negative pressures develop at the upper surface (tissue-foam interface) of the wound. The pressures are dependent on the suction level of the vacuum source. Pressure values that have been registered range between -25 mmHg and +15 mmHg. Positive pressures develop at points of contact between the foam and its solid components (pore wall). The summation of this pressure distribution results in compression of the tissue, which can, in turn, lead to hypoperfusion or ischemia of the adjacent tissue areas. Vacuum therapy produces a heterogeneity of pressure distribution in the tissue, which permits development of pressure gradients along which interstitial fluids can be removed from the wound. This mechanism might explain the anti-oedematous function of vacuum therapy, which may also lead to a secondary improvement in tissue perfusion.

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Part A / Chapter 8

Side Effects and Risks of Vacuum Therapy

C. Willy

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To date, only a few individual reports of side effects and complications occurring in association with vacuum therapy have been published. Of particular clinical relevance are the occurrence of *toxic shock syndrome* as a consequence of unnoticed loss of suction ($n = 1$), the development of wound infection caused by anaerobes during vacuum therapy and loss of blood and fluid due to uncontrolled suction ($n = 3$). The most common side effects of vacuum therapy are pain caused by the application of suction, pain at dressing change as well as maceration and pressure injury to the skin areas adjacent to the wound.

The international literature on vacuum therapy has thus far documented the clinical course of well over 10,000 patients. The number of reported complications, observed side effects or existing risks is, however, quite low.

In an attempt to create as complete a picture as possible, we wish not only to highlight the successes of vacuum therapy but also to assess potential risks and problems. At the same time, we will discuss the measures that can be taken to avoid or manage these complications. Finally, we will address the potential risks associated with various modifications that have been instituted for the technical application of vacuum therapy.

Side Effects

Side effects that must be considered in connection with vacuum therapy include:

- Ingrowth of granulation tissue into the foam.
- Pain associated with the effects of suction and dressing changes.
- Maceration and pressure damage to skin areas adjacent to the wound.
- Reduction in perfusion caused by pressure on small-caliber vessels.

Ingrowth of Granulation Tissue into the Foam

This problem can occur when black PU foam is not changed within the recommended time interval of approximately 2-3 days^{1,10}. Clinically, this ingrowth is relatively unproblematic since the foam can be removed without major difficulty. In cases in which dressings are changed significantly later than recommended, small particles of PU foam can remain in the wound and must be completely removed⁶.

Our own experience has shown that tissue ingrowth is most typically seen in well-nourished soft tissue with a high tendency toward granulation tissue formation (e.g. muscle tissue following fasciotomy for compartment syndrome). Conversely, there may be no significant ingrowth of tissue even after four or five days without dressing change in cases of poorly perfused wound beds consisting of indurated tissue (e.g. wound bed after debridement of a sacral pressure sore in patients in poor general health). It seems that the greater the tendency toward granulation tissue formation, the higher the probability that ingrowth of granulation tissue into the pores of the foam will occur. Nevertheless, the question

arises as to whether this ingrowth of granulation tissue into the foam should indeed be considered an "unwanted side effect" of vacuum therapy.

When white PVA foam is used, ingrowth of granulation tissue is not observed within the recommended three to seven days between dressing changes.

Pain due to Application of Suction or Dressing Change

Patients generally tolerate low levels of negative pressure (125 mmHg) without pain. In some cases, however, pain is caused by suction-induced pressure of the foam onto the wound bed. In our own experience, such pain is most often reported by patients treated for leg ulcers. Selection of a lower level of negative pressure (50-100 mmHg) is an initial strategy that is often successful. In many cases, it is possible to slowly increase pressure once pain is relieved. The beneficial effects of vacuum therapy can also be observed at lower pressure levels and a reduction in applied suction in response to pain is not associated with adverse effects on wound healing. More problematic is the high level of suction (900 mmHg) that is used for Redon drains.

Pain is frequently reported when intermittent suction is applied. In these cases, too, pain often resolves with a temporary or permanent reduction in the suction force. Now, the introduction of vacuum instillation therapy provides the option of regular (several times per day), automatically controlled application of local anesthetics that may contribute to pain control during vacuum therapy and dressing changes. If such mechanical support is unavailable, local anesthetics can be applied either in a retrograde direction through the evacuation tube or by direct injection into the foam 30-60 minutes prior to vacuum dressing change. In such cases, the risk of systemic absorption must be carefully assessed. Some authors simply recommend the injection of Ringer's lactate solution as a means of lysing adhesions and facilitating dressing changes¹⁰.

Skin Damage Around the Wound

Skin maceration has been reported in up to 20% of wounds². Sensitive skin in the vicinity of the wound may also exhibit erosive skin lesions following the removal of an adhesive drape (see Fig. A8.1). Many measures are available to improve this situation. Skin adjacent to the wound margin should be protected with skin-friendly dressings (silicone mesh, hydrocolloid dressings). Likewise, a liquid skin protectant can be sprayed on the affected skin.



Fig. AB.1 Epithelial defect at the wound margin after two days of vacuum therapy in an 84-year-old female with a sacral pressure sore.

Causes for maceration of previously healthy skin may include a piece of foam that extends beyond the wound edges to healthy skin. Especially in heavily exuding wounds, the retention of excessive moisture often makes skin maceration unavoidable². In such cases, the dressing must be cut to the exact wound dimensions. In the case of a foam “bridge” linking two adjacent wounds that are treated with a single suction unit, direct contact between the skin and foam cannot be prevented. In such cases, the healthy skin subjacent to the foam “bridge” should be protected with a liquid skin protectant or a skin-friendly dressing (see also Part D for advice on skin protection).

In the case of small wounds (< 4 cm), the *trac-pad* that is attached to the sealed wound may cause pressure damage secondary to suction. In most cases, a temporary pressure mark may occur, but no permanent damage will ensue. Though, individual cases of pressure necrosis have been reported³. If the diameter of the wound is smaller than that of the *trac-pad connector*, the margin of healthy skin should be protected first. Once, the wound has been successfully sealed, a second piece of foam with the same diameter as the *trac-pad* should be placed over the wound and fixed with a second layer of adhesive drape. In this way, the second piece of foam rather than the *trac-pad* comes into contact with the skin. All relevant techniques are discussed in more detail in Part D.

Reduced Perfusion

To date, no clinical report has addressed the question of perfusion disturbances secondary to vacuum therapy.

Wackenfors et al., however, used laser Doppler flowmetry in an experimental study and found a reduction in perfusion in areas of “healthy” tissue immediately adjacent to the wound¹³. These data must certainly raise the concern that a reduction in perfusion may occur in at least some portions of adjacent tissue.

In our own experience, a reduction in peripheral perfusion was observed only once following application of the foam. Thirty minutes after debridement and successful sealing of a wound in a 35-year-old male patient who sustained a complex trauma to the lateral aspect of the foot in a forklift truck accident, a bluish discolouration of the fourth and fifth toes was observed. Removal of the vacuum dressing resulted in an immediate apparent normalisation of perfusion. This reduction in perfusion, however, was probably caused by suction-induced pressure on small exposed macroscopic vessels rather than by a reduction in nutritive perfusion at the microcirculation level.

Documented Complications

Toxic Shock Syndrome

Toxic shock syndrome is one of three serious complications that have been reported in the literature on vacuum therapy⁷. An analysis of the documented incident (1999; 48-year-old male with a wound to the abdominal wall; MRSA positive; seven-days of vacuum therapy, possibly no foam change) suggests that the toxic shock in this patient was due to the systemic effects of bacterial toxins produced by *Staphylococcus aureus*. These toxins were absorbed as a result of an accumulation of secretions in a PVA foam that had probably been left in place for seven days.

The patient survived. The available documentation in the literature does not permit any conclusions regarding the initial degree of wound contamination or the extent of primary debridement. It is not clear whether the foam had been changed during this period, but it appears likely that there had been no dressing change. Because of the inadequate documentation, one can only speculate on the exact mechanism behind the development of this complication. It appears necessary at this point to emphasize the importance of radical surgical wound debridement and the necessity of short intervals between dressing changes in patients with contaminated wounds.

Uncontrolled blood and fluid loss

A description has already been given of the risk of arterial haemorrhage that may occur when a vacuum dressing is directly placed over exposed vessels (Part A - Chapter 3: Indications and Contraindications). White et al. described a case of bleeding secondary to arterial erosion that required the transfusion of six units of blood (approximately two liters) before haemostasis could be achieved¹⁴. The authors emphasized the importance of careful monitoring of patient whenever the foam is placed adjacent to an exposed artery. Another research group described a case of massive fluid loss secondary to vacuum therapy in two patients, in both cases leading to hypovolemic shock³. The severe complications that have been described in the literature can be prevented by using commercially available therapy units with integrated visual and audible alarms alerting providers or patients when the attached canister is full.

Wound infections caused by anaerobes

In another reported case (2001; 76-year-old male with an inguinal wound; MRSA positive; suction force and vacuum source are not reported), an alteration of the wound flora resulted in the development of anaerobic sepsis during the course of a four-day vacuum therapy treatment. *Bacteroides spp.* and coliform bacteria were found to be the causative organisms⁴.

The patient survived. Based on the available documentation in the literature, it is impossible to determine the initial degree of wound contamination of the wound and the extent of primary surgical debridement.

It is possible that negative pressure was applied to a contaminated wound in a closed system that allowed no or little drainage of exudate. Assuming that vacuum therapy further reduced perfusion in an elderly patient with already poorly perfused tissue (see Chapter 7 and the findings of Wackenfors et al.¹³), the prevailing anaerobic conditions may have favoured the growth of certain (pathogenic) microorganisms. An assessment of the sequence of events that led to this complication requires knowledge of the following:

- What level of negative pressure was applied? Did the authors use a modern unit and a negative pressure level as low as 75 mmHg? Did they apply a negative pressure level of 125 mmHg, which is the most commonly recommended pressure setting? Did they use a therapy unit together with a Redon drain in

order to apply a negative pressure level as high as 900 mmHg? According to current knowledge, a pressure level of 900 mmHg is associated with a considerable reduction in nutritive perfusion and would thus play a key role in the case discussed here.

- Which mode of suction was selected? While continuous suction tends to be associated with a reduction in wound bed perfusion, intermittent suction leads to an increase in perfusion^{11,13}.

An example from our own experience will serve to illustrate these considerations (Fig. A8.2-4): an 84-year-old bed-ridden female patient presented to our department with a sacral pressure sore that had persisted for about six months. In this case, the application of continuous suction at only 125 mmHg resulted in development of progressing necrosis in the wound bed. When a lower suction pressure (75 mmHg) was selected and the settings were changed from continuous to intermittent suction, the wound bed improved.

The Pros and Cons of Alternative Vacuum Sources

After having discussed the complications that have been described in the literature, we should now take a closer look at the different vacuum therapy suction sources currently available for routine clinical use.

At present, vacuum therapy is not performed exclusively using VAC therapy units (vacuum generators recommended by the manufacturer of vacuum therapy foam systems: VAC^{ATS}, VAC^{Freedom}, VAC^{INSTILL}). Other systems in use are the collecting bottle of a Redon drainage system, wall-mounted suction units (at least in an inpatient setting) and other commercially available systems.

Once the wound has been sealed, it is in principle possible to use suction sources, therapy units and systems other than those supplied by KCI. The other available units, however, have significant technical disadvantages. For example, none of the alternative systems provide the safety of visual and audible alarms to indicate a leak or blockage or to alert patients or providers when large amounts of blood or fluid are removed from the wound. By contrast, vacuum therapy units supplied by KCI (VAC^{ATS} and VAC^{Freedom}) are connected to a canister with a maximum volume of only 500 ml or 300 ml and are fitted with an audiovisual alarm to indicate when a canister is full.



Fig. A8.2 Day 0. Sacral pressure ulcer following radical surgical debridement (the cranial edge of the wound is on the left side of the picture).



Fig. A8.3 Day 2 after starting vacuum therapy (125 mmHg, continuous suction, PU foam, no instillation). The picture shows necrosis involving ligamentous paravertebral structures at the cranial edge of the wound (at 8 o'clock in the picture). Superficial necroses can also be seen in central regions of the wound.



Fig. A8.4 Day 7 after starting vacuum therapy (75 mmHg, intermittent suction, PU foam, no instillation). The picture shows the presence of bradytrophia at the cranial edge of the wound (at 8 o'clock) and the resolution of necrosis in the left and central portions of the wound (at 5 and 6 o'clock) with the development of granulation tissue.

Redon Drainage System

Redon drainage systems cannot ensure a continuous removal of wound fluid. These high-vacuum systems start operating at a pressure level of 800-900 mmHg. Depending on the amount of fluid collected, however, the pressure then drops to almost 0 mmHg (see Fig. A8.5). As a consequence, a negative pressure of about 75-125 mmHg, which is considered in the literature to be the optimum level of suction^{8,12,13}, can be maintained for a limited period of time only.

Redon wound drainage systems are unable to maintain negative pressure in the presence of even very small leaks, which cannot always be prevented at unfavourable sites. In these cases, suction bottles must be changed repeatedly. Our own experience has shown that neither conventional Redon systems nor modified suction containers fitted with an integrated manual pump are useful. Vacuum maintenance is essential for the outcome of treatment. It goes without saying, however, that responsibility for meeting this requirement cannot be borne by patients or nursing staff. Another disadvantage of Redon drainage systems is that they have no audible or visual alarm to indicate a full suction container. Wound fluid can thus flow into the foam or stay in the wound and create a dangerous situation for the patient.

Wall Mounted Suction

When wall-mounted suction is used, it is usually not possible to select the exact pressure level desired. The built-in manometer generally allows only a coarse adjustment of suction. Unlike a Redon drainage system, a wall-mounted suction unit provides the option of continuous suction that can compensate for small air leaks and maintain the vacuum. Since, however, larger leaks cause an uncontrolled stream of air to pass through the wound, the affected area can become desiccated, leading to tissue necrosis. Conversely, an uncontrolled aspiration of blood from a wound can lead to life-threatening complications.

Further disadvantages of wall-mounted suction include the interruption of suction during transport of the patient within the hospital, a significant restriction of patient mobility and limited usefulness in the home care setting.

In addition, wall-mounted suction does not offer the clinical advantage of an automatically controlled instillation therapy.

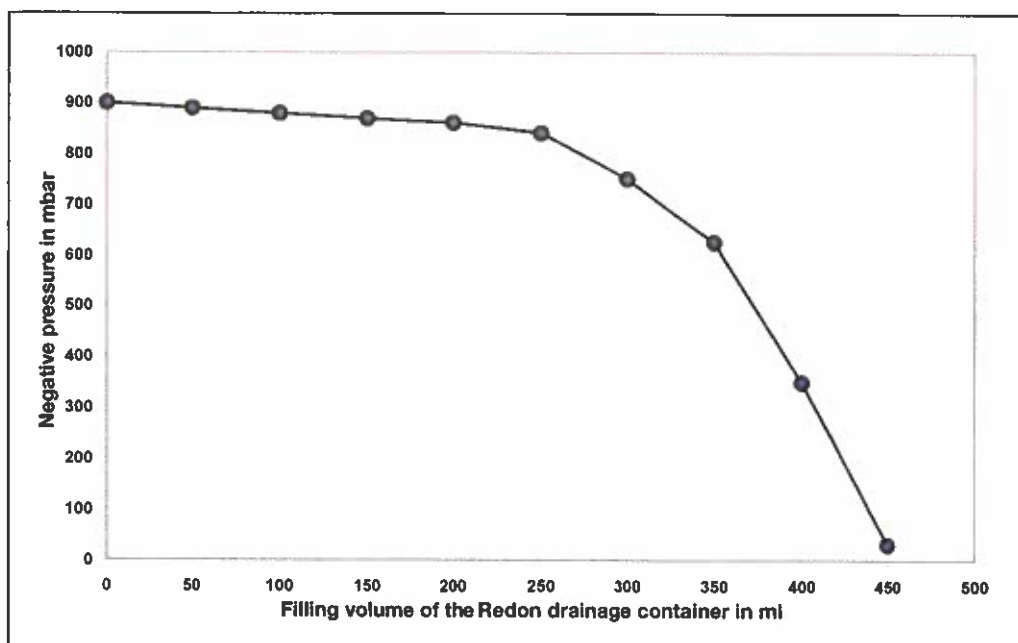


Fig. A8.5 Suction force of a Redon drainage system in relation to volume of fluid collected in a Redon container (from: Mahadger, C.; Siegert, R.; Jäger, H.; and Weidauer, H.: Druck-Volumen-Analysen von Wundsaugdrainageflaschen und Saugvermögen von Drainageschläuchen. *Langenbecks Arch Chir*, 379: 285-290, 1994.)

Electronic Suction Systems

Similar restrictions apply to currently available electronic vacuum sources. These systems have the capacity to maintain suction and can thus compensate for small air leaks and maintain the vacuum. Because of the size of the secretion collection reservoir integrated into most of these suction systems, there may be an uncontrolled loss of blood. Despite the compactness of these systems, it is not always possible to use them with batteries. This restricts patient mobility, can lead to an undesired loss of suction during the transfer of patients in the hospital, and is uncomfortable for patients to use at home.

Modern vacuum therapy units use an electronically controlled feedback system that ensures the maintenance of the selected pressure level even in the presence of small air leaks and thus guarantees the effectiveness of vacuum therapy. Feedback control is based on data provided by four small-calibre measurement tubes built into the suction tube. This function is not provided by alternative suction sources, which lack the necessary connections. Audiovisual alarms alert the staff to large air leaks (loss of seal), blockage of the tubing and full canisters. Using these therapy units, the above complications could

probably have been either avoided or recognised promptly. Automatically controlled instillation vacuum therapy is possible only with the VAC^{INSTILL} system. The differences in the currently available suction systems are summarized in Table A8.1.

Inadequate Duration of Vacuum Therapy

As a result of the successful application of vacuum therapy, the use of this wound management technique has increased explosively and the spectrum of its indications for use has been continuously expanded. Unfortunately, vacuum therapy was applied inappropriately in a number of cases. Either the duration of treatment was inadequate or other measures such as plastic surgical procedures were unnecessarily delayed.

A key requirement for the successful use of vacuum therapy is the initial surgical debridement of the wound. This shows that vacuum therapy is only one step in the wound management algorithm in the majority of cases. Vacuum therapy does not automatically result in spontaneous re-epithelialisation and subsequent wound closure. In many cases, debridement, vacuum therapy and a period of wound bed preparation are different phases

Tabelle A8.1 Performance characteristics of the most commonly used vacuum sources

Vacuum source	REDON drainage principle	REDON drainage + manual pump	Wall-mounted suction unit	Electronic pumps	VAC ^{ATS} ®, VAC ^{INSTILL} ®, VAC ^{FREEDOM} ®
Suction force freely selectable	-	-	(+)	+	+
Constant suction force	-	-	+	+	+
Compensation for small air leaks	-	to a limited extent	+	+	+
Instillation, automatically	-	-	-	-	optional
Battery operation possible	not applicable	not applicable	-	to some extent	+
Full mobility	+	+	-	to a limited extent	+
Alarm to indicate loss of suction	-	-	-	-	+
Alarm to indicate a leak	-	-	-	-	+
Alarm to indicate full canister	-	-	-	-	+
Alarm to indicate blockage	-	-	-	-	+

that precede definitive wound closure (mesh-graft, secondary closure, plastic surgery, etc.).

The literature as well as our own experience have shown that there were cases in which a change in therapy was indicated but was made, if at all, only after a delay⁵. For this reason, we consider it important to emphasise once again that a change in the wound management technique should be considered if the aims of vacuum therapy (formation of new granulation tissue, wound cleansing, bacterial clearance) appear unachievable after two or three dressing changes.

The above described incidents and complications are almost completely avoidable if the fundamental guidelines of vacuum therapy are observed and commercially available vacuum sources are used that are tailored to the special requirements of vacuum therapy. It is particularly important to ensure that

- radical surgical wound debridement is performed,
- the duration of therapy is in accordance with the properties of the foam material and the contamination and perfusion of the wound,
- the level of suction can be freely selected,
- intermittent suction can be used when appropriate, and
- vacuum sources are used that provide the safety of visual and audible alarms.

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Part B

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Part B / Chapter 1

Applications of Vacuum Therapy in Acute Traumatology

L. Labler

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The vacuum therapy concept, also known under the synonyms "topical negative pressure" (TNP), "subatmospheric pressure" (SAD), "vacuum sealing technique" (VST) and "sealed surface wound suction" (SSS), has been applied in treatment of a variety of surgical conditions, including chronic wounds, infected wounds, burn injuries and plastic surgery. To date, reports in the surgical literature consist mainly of case reports and the same is true for traumatology. The present review focuses on both the application and limitations of this therapy system in the acute treatment of open and closed mechanical tissue injuries.

Areas of Application

Contaminated Wounds and Wounds with Tissue Defects

Heavily contaminated wounds require a stepwise procedure followed by a delayed primary closure or plastic surgery. In cases of heavily contaminated wounds or wounds with tissue defects, the so-called "R0-resection" of damaged and potentially infected soft tissue is often not feasible and prolonged wound management must be performed. Initially, the wound is dilated as much as possible to allow complete exploration of all wound cavities. The first debridement should be performed stepwise. Besides resection of necrotic or heavily contaminated soft tissue, debridement includes mechanical wound brushing and saline-solution lavage in order to reduce the concentration of inoculated pathogens in the contaminated wound as far as possible. If needed, *jet lavage* may be used. However, the extent of the tissue damage often can be fully assessed only after 24-48 hours.

Consequently the next debridement (the *second look* operation) should be carried out by the same surgeon who performed the first treatment. These surgical interventions should be performed in the operating room rather than at the patient's bedside. This enhances the efficacy of a correctly performed secondary debridement in minimizing the risk of infection. Appropriate antibiotic

therapy depends on sensitivity testing; it is an accessory measure only and does not serve as a substitute for careful surgical debridement. Vacuum therapy has an advantage over conventional methods for temporary soft tissue closure²¹ in facilitating improved granulation, increased local perfusion and enhanced bacterial clearance. Attention has to be paid to the wound cavity: in order to prevent possible retention of wound secretions, it must be completely filled with foam cut to the cavity's dimensions (Figs. B1.1 and B1.2). Tamponade of the wound cavity should be avoided. Secure haemostasis of larger vessels by means of ligature or coagulation must precede application of the vacuum therapy in order to prevent secondary haemorrhage (Fig. B1.2). If required, a plastic surgeon should be consulted at the time of the *second look* operation in order to plan an early soft tissue closure.

Penetrating Injuries

Apart from the surgical repair of injuries to the body cavities, vascular or neural structures or of fractures caused by penetrating trauma (stab, gunshot), soft tissue injuries should be treated according to the above-described principle. Tractotomy, in which the penetrating defect caused by a stabbing injury or entry of a projectile is opened along its course and debrided, with inspection of surrounding soft tissues for associated damage (cavitation), should be

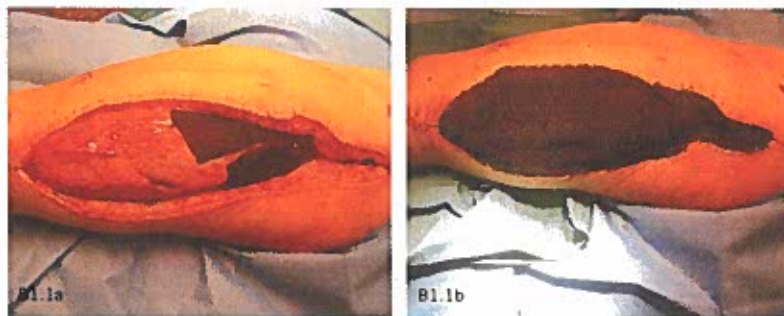


Fig. B1.1a-b A+B: Subcutaneous wound pouch formation after compartment cleavage on left thigh. Filling of wound pouches with foam in multiple layers to prevent formation of cavities.



Fig. B1.2 Significant secondary bleeding after insufficient haemostasis with formation of a large haematoma after compartment cleavage on left thigh and coverage with vacuum therapy.

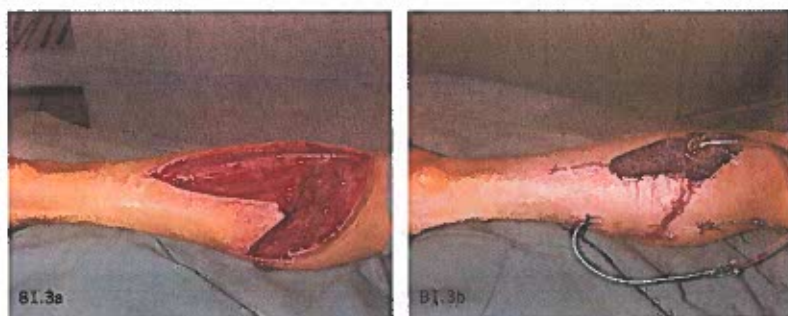


Fig. B1.3a-b A: Situation after gunshot injury through fibular muscle and therapy by means of tractoromy and compartment cleavage. B: Wound conditioning with vacuum therapy.



Fig. B1.4a-c A: Morel-Lavallée injury in the scope of a pelvic ring injury and fracture of left thigh after transfer from abroad. B: *Second look* operation with haematoma removal of the infected décollement of the pelvic region. C: Dead space reduction by vacuum therapy.

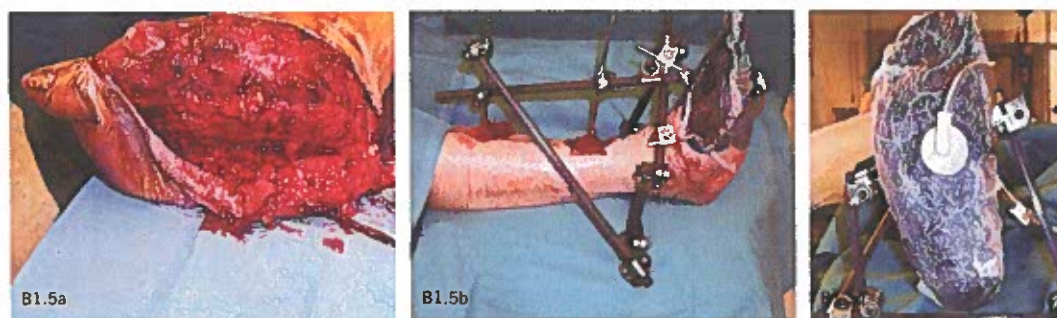


Fig. B1.5a-c A: Complete degloving of the right sole of foot with open fractures of mid- and forefoot. B+C: Stepwise debridement and temporary fixation of fractures by Kirschner wires. Removal of the skin and its re-fixation as full thickness graft by vacuum therapy. In addition, a fixateur externe was attached for immobilisation and soft tissue protection.

performed³. These wounds are not primarily closed; definitive closure by a direct suture or plastic coverage is reserved to *second look* operations. Once sufficient haemostasis has been achieved, vacuum therapy (Fig. B1.3) may be initiated in such situations as well as for early temporary soft tissue closure²³.

Decollement Injury

The extent of decollement very often is underestimated, especially with closed injuries. The haematomas of a closed decollement are removed and the wound cavity debrided. The dead space of the decollement cavity is closed by adapting sutures and a large drainage inserted. After

surgical debridement, an open decollement is preferably treated with tamponade without excessive pressure on the tissue; during the *second look* operation it can be definitively closed. Caution is necessary with the Morel-Lavallée syndrome, in which wounds may contain a bacterial colony and which accompanies pelvic fractures¹³. When the wound cavity cannot be closed in the course of a *second look* operation due to additional underlying soft tissue injuries, vacuum therapy may be applied to diminish the dead space and to condition the wound bed. Wound cavities must be filled completely with the foam (Fig B1.4). Vacuum therapy may be applied also in case of degloving injury^{14,17}. Fat is completely re-

moved from the abrasion and the latter is replanted as skin transplant, if necessary as a mesh-graft, on the injured body part and fixed by vacuum therapy (Fig. B1.5). If required, depending on the body part, an additional immobilisation with a fixateur externe may be performed. The last named fixation method is preferred to the external plaster bandage as it does not compromise the surrounding soft tissue. The pins of the fixateur, however, often compromise the vacuum seal. As an alternative, we have started completely packing the injured region, including the fixateur (see also Part D – “Practical Advice”).

Compartment Syndrome

Open wounds secondary to fasciotomy for treatment of compartment syndrome resulting from contusion or extremity fracture may be covered, provided haemostasis is secured, with vacuum therapy (Fig. B1.6) as an alternative to other temporary alloplastic coverage such as Epigard® (see also Part B – Chapter 2).

Infected Postoperative Wounds

Because they may serve as the nidus of a deep infection that spreads subfascially, wound infections that appear postoperatively must undergo surgical exploration. Adequate surgical debridement with bacteriological cultures and sensitivities for planning antibiotic therapy remains the cornerstone of therapy. In the case of implanted hardware, careful consideration must be paid to whether the implant can remain in the wound. In such cases, vacuum instillation therapy according to the method of Fleischmann can be used (see also Part A – Chapter 5 “Vacuum Instillation Therapy”). As soft tissue swelling and the defect itself often prevent closure, vacuum therapy may be an option for temporary coverage^{7,8,22}. *Second look* operations should follow the initial surgical exploration and, if necessary, plastic coverage should be planned.

Open Fractures

In the case of open fractures with serious soft tissue trauma and accompanying vascular injuries, a temporary stabilisation process (fixateur externe or interne) must be chosen following completion of stepwise debridement. Then, required vascular reconstruction is performed^{11,12}. The muscle compartments, if they were not already opened by the trauma, should be surgically split to limit the effects of possible ischemia/reperfusion damage. The soft

tissue defect due to both the trauma and the debridement may be covered by vacuum therapy closure. However, the indication of the vacuum therapy must be critically weighed during the *damage control* period since secondary bleeding may occur in patients with exposed fractures and marrow cavities and because of possible coagulopathy, at least in non-compressible wound cavities. In such cases, vacuum therapy should only be applied within the scope of later *second look* operations and with stable coagulation data after initial tamponade, if required, and coverage with Epigard® (Fig. B1.7)^{49,19}. Our own experience has shown that, in comparison to Epigard®, the application of vacuum therapy for soft tissue conditioning of third-degree open fractures results in a reduced rate of infection and pseudarthrosis¹⁶.

Amputation Injuries

In cases of incomplete or complete amputations secondary to trauma in which reimplantation is out of question, a definitive repair of the amputation stump is often not feasible because of the local and general situation of the patient. Thus, soft tissue debridement in the stage of *damage control* comes to the fore. An amputation stump resulting from a guillotine-like marginal zone amputation remains open and a temporary soft tissue coverage by means of vacuum therapy may be feasible. Utmost caution is required to assure that the foam not be in direct contact with the marrow cavity, which might lead to profuse bleeding. The definitive level of amputation will be established in the course of the planned *second look* operations and assessment of remaining soft tissue damage (Fig. B1.8).

Open Pelvic Injuries

Severe pelvic trauma is often associated with visceral injuries as well as gluteal decollement (Morel-Lavallée syndrome, see above) and other open injuries, mostly inguinal or perineal²¹⁵. Colostomy, rectal washout as well as aggressive debridement of the soft tissue injury are important cornerstones of therapy. Vacuum therapy offers a suitable alternative for treatment of such complex wounds (Fig. B1.9). It has also been successfully applied after infection of the pelvic floor or at anastomotic insufficiency.

Open abdomen

Treatment of open abdomen is part of the *damage control* concept and integrated into the medical care

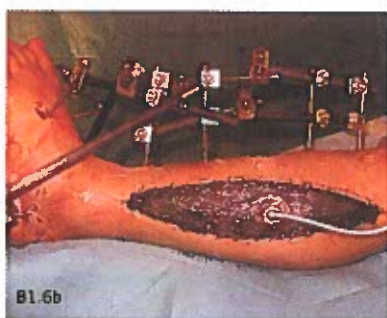


Fig. B1.6a-b A: Open left lower leg fracture (Gustilo 3A) with opened flexor compartment secondary to trauma and a closed lateral compartment syndrome. Stepwise debridement and fixation with fixateur externe overlapping the joint. B: After complete lateral and medial compartment cleavage follows vacuum therapy.

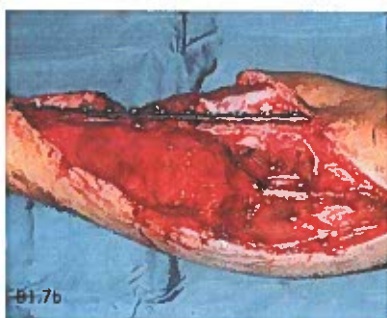


Fig. B1.7a-d A: Open lower leg fracture with vascular injury (Gustilo 3C). B: After stepwise debridement and compartment cleavage, temporary osteosynthesis with locking compression plate (LCP, Synthes®, 4436 Oberdorf, Switzerland) and vascular reconstruction with greater saphenous vein interposition graft from the opposite side. C: Primary soft tissue coverage with tamponade and Epigard® because of bleeding tendency from the fracture region. D: Temporary soft tissue coverage in the course of vacuum therapy performed after every second look operation.



Fig. B1.8a-d A+B: Farming accident with subtotal crush amputation of right upper arm and avulsion amputation of proximal left forearm. C: After extensive debridement, exarticulation of the right shoulder joint and amputation of left upper arm. The temporary soft tissue closure together with reduction of the dead space is performed by vacuum therapy. D: The result after healing.

algorithms for cases of severe abdominal infection, after early total-care intervention and for treatment of abdominal compartment syndrome (ACS). Vacuum therapy is an established technique for a temporary abdominal wall closure (Fig. B1.10) ^{1,5,20}. The use of specially made *abdominal dressing* is particularly advantageous in open abdomen situations with gaping wound edges. Suction prevents retraction of the fascial edges. Also pre-

vented or reduced in frequency are grotesque incisional hernias and resulting difficult abdominal wall reconstructions^{18,24}. In cases of severe abdominal infections, our experience has shown that the above technique may be combined with positioning of an additional piece of PU foam deep within the abdominal cavity at the depth of the source of infection (see also Part B - Chapter 17).

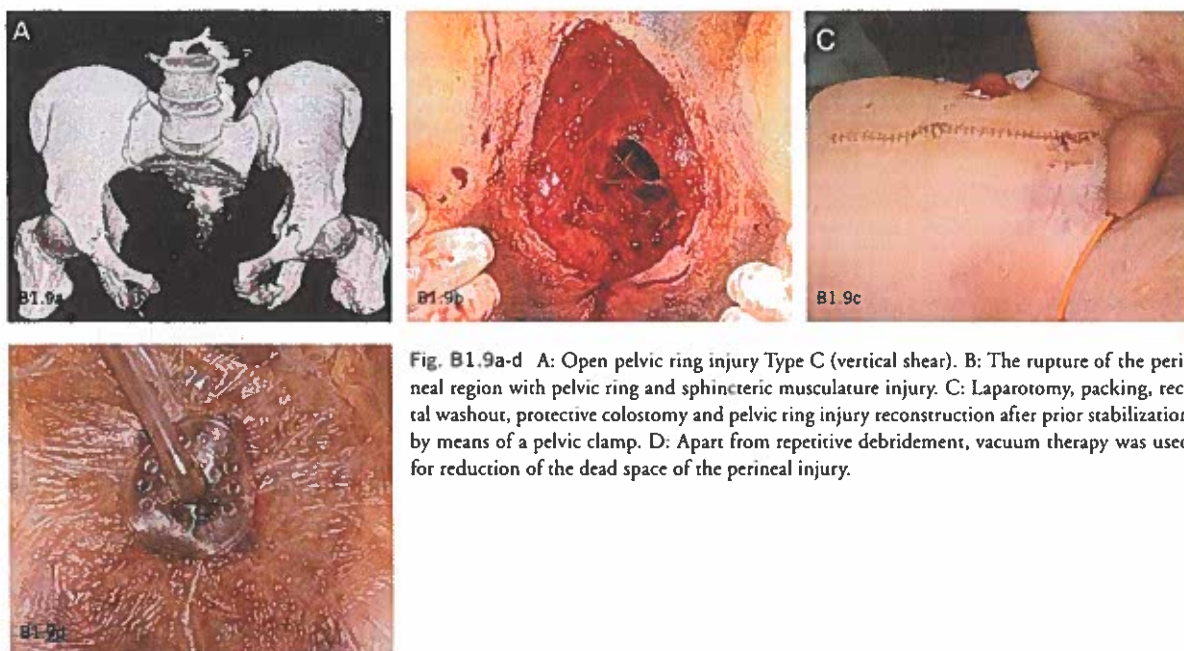


Fig. B1.9a-d A: Open pelvic ring injury Type C (vertical shear). B: The rupture of the perineal region with pelvic ring and sphincteric musculature injury. C: Laparotomy, packing, rectal washout, protective colostomy and pelvic ring injury reconstruction after prior stabilization by means of a pelvic clamp. D: Apart from repetitive debridement, vacuum therapy was used for reduction of the dead space of the perineal injury.

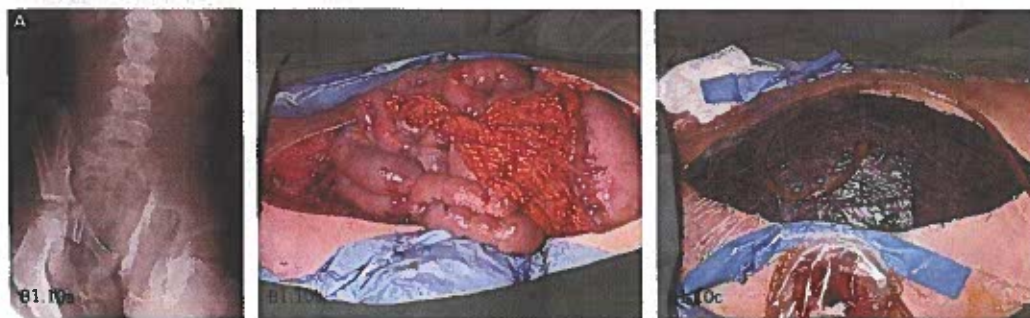


Fig. B1.10a-c A: Severe truck roll-over trauma of the pelvic region with closed traumatic hemipelvectomy left. B: *Damage control* with laparotomy and packing for haemostasis, colostomy and temporary reconstruction of the pelvis with pelvic clamp and cerclage of the symphysis. C: Management of open abdomen with several *second look* operations and temporary closure by means of *abdominal dressing*.

Vacuum therapy has become firmly established in traumatology and enjoys broad application. This method, however, does not replace adequate surgical treatment of soft tissue injuries and should, moreover, be regarded as a temporary measure prior to definitive treatment of the defect and for wound conditioning. Besides its useful mechanism of action on the cellular level, the mechanic drainage principle and reduction of dead spaces in the wound defects, provided that the vacuum therapy is correctly performed, are important factors for reduction of bacterial colonization and treatment of infection in open wounds. For safety, caution is advised when using the method in acute trauma situations where bleeding might occur due either to the localization of the wound or to an existing systemic coagulation defect.

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Part B / Chapter 2

Vacuum Therapy for the Closure of Dermatofasciotomy Wounds – A Review

C. Willy

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Vacuum therapy is an alternative to standard methods of managing dermatofasciotomy wounds (e.g. dermatotraction with prepositioned intracutaneous sutures, vessel loops, special skin expansion systems, or mesh-grafts). Only six *peer-reviewed* articles have been published in the literature on this subject. Of these, two are case series (level 4 evidence), three are case reports (level 5 evidence) and one, a case control study (historical control, level 3b evidence). Vacuum therapy offers several advantages when used for this indication. It allows surgeons to turn large open wounds into clean, healthy and closed wounds. Wound secretion is continuously drained from the wound and collected in a canister. The wound is sealed and thus protected from exogenous sources of contamination. Vacuum therapy reduces the frequency of dressing changes and minimises soiling of the patient's bed, bed linen, towels and clothing, even in the case of heavily exuding wounds. The application of tension to the wound edges effectively counters the retractive forces on the wound, which is a common problem in wound healing. Low pressure on muscle tissue has an anti-oedema effect. A low level of intermittent negative pressure should be applied in order to ensure optimum perfusion of muscle tissue that is damaged by ischaemia.

Introduction

Compartment syndrome of the upper and lower limbs is a common complication after severe trauma, vascular ischaemia, crush syndrome and electrothermal injuries. Treatment consists of expedient fasciotomy in order to relieve the pressure on muscles, vessels and nerves.

In the past, fasciotomy wounds were usually covered with synthetic skin substitutes in the acute phase and definitively closed with split-thickness skin grafts a few days later. In some cases, the size of the wound was reduced by sutures at the wound edges before a skin graft was used (Fig. B2.1-2)^{2,6,12}.

There is general agreement that this wound management technique has the disadvantage that transplanted skin is often insensate, easily injured and particularly vulnerable to the effects of mechanical friction^{5,6,12,13}. In addition, many patients are dissatisfied with the cosmetic outcome.

For these reasons, there is a clear tendency both in practice and in the literature to close fasciotomy wounds without skin grafting. A wide variety of methods have been established for this purpose. What all of them have in common is that low-grade tension is used 2-5 days after fasciotomy to approximate the wound edges so that wound closure is usually achieved after 5-14 days¹⁰. In clinical practice, fasciotomy wounds are closed with prepositioned intracutaneous sutures, with vessel loops that are attached to the wound margins with skin staples and then tightened progressively, or with special skin approximation systems (see Fig. B2.3)^{1-7,9-14,16,20}.

Gradual closure is possible if a fasciotomy wound is neither contaminated nor infected, if necrotic tissue is

removed, and if no further extension of inadequately perfused tissue is expected. Not all fasciotomy wounds, however, meet these requirements. For example, *second look* surgery and, where needed, *jet lavage* are indispensable in the first days of treatment for patients with severe soft-tissue trauma and primary contamination. Early plastic surgery and definitive coverage are indicated for the management of large skin and soft-tissue defects.

In these cases, a number of methods are available for covering the defect temporarily in the decontamination and debridement phase until definitive wound closure is possible. Moist dressings or synthetic skin substitutes (Epigard®) that are cut to the size and shape of the wound have several disadvantages. Large amounts of fluid exuding from such a wound, which usually covers an extensive area, keep the dressing constantly wet. The wound edges tend to retract and become indurated. This makes it even more difficult to close the wound later. A lack of tension on the wound edges and a lack of pressure on muscle tissue encourage the development of marked oedema and an increase in muscle volume (ischaemia/reperfusion injury). This further complicates the later closure of the wound.

Using vacuum therapy, surgeons can prevent these adverse effects almost completely. Since *second look* operations in the early phase of treatment are always performed under surgical conditions, vacuum therapy can easily be used for wound management⁸. For this reason, the present chapter will provide an overview of the experience that has been gained from using vacuum therapy for the closure of fasciotomy wounds.



Fig. B2.1 Temporary wound closure with Epigard®.



Fig. B2.2 Definitive wound closure with a mesh-graft.

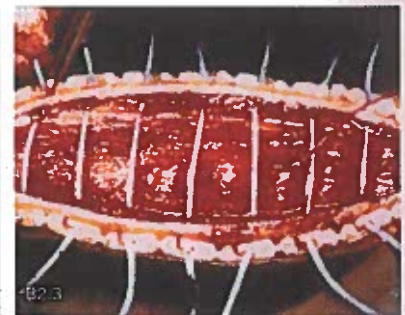


Fig. B2.3 Closure of a dermatofasciotomy wound using an external tissue extender (ETE) consisting of silicone strings and friction stoppers.



Fig. B2.4 A dermatofasciotomy wound is covered with two pieces of polyvinyl alcohol (PVA) foam placed next to each other.



Fig. B2.5 The foam is sealed and placed under negative pressure.



Fig. B2.6 The wound is closed 11 days after the institution of vacuum therapy.

Literature Review

The quantity and “quality” of what is reported in the literature on the use of vacuum therapy for the closure of dermatofasciotomy wounds is typical of the entire literature on vacuum therapy. Fasciotomy wounds were one of the first areas of clinical application of vacuum therapy, and patients have been treated with this form of wound management as far back as the early nineties. Nevertheless, there are only six *peer-reviewed* articles that focus on this indication for vacuum therapy.

- Case series (1996, level 4 evidence; $n = 25$)⁸; method: polyvinyl alcohol (PVA) foam, negative pressure level: -900 mmHg
- Case series (non *peer-reviewed*, 1997, level 4 evidence; $n = 25$)¹⁵, negative pressure level: -900 mmHg
- Case report (double published in 2002, level 5 evidence)¹⁹; method: polyurethane (PU) foam, negative pressure level: -125 mmHg
- Case report (2005, level 5 evidence)¹¹; method: polyurethane (PU) foam, negative pressure level: -125 mmHg
- Case series (2005, level 4 evidence; $n = 14$)¹⁷, method: polyurethane (PU) foam, negative pressure level: -125 mmHg., wound closed after an average of 8 days
- Controlled case study (2006, level 3b evidence ($n = 34$ *vs* 34 patients, consecutively antecedent historical control)²¹, method: polyurethane (PU) foam, negative pressure level: -125 mmHg., wound closed after an average of 6.7 (vacuum therapy group) *vs* 16.1 days (saline-soaked wet-to-dry dressings)

These articles agree that vacuum therapy is a suitable method for the temporary closure of dermatofasciotomy wounds. They also show that vacuum therapy gradually

reduces the size of the wound and makes it thus possible in many cases to close the wound by secondary suture (Fig. B2.4-6)⁸.

In the authors' opinion, the small number of publications on this subject (and especially the lack of comparative studies) is due to the fact that the use of vacuum therapy for this indication has been well established since the introduction of this form of treatment. Since it has never been doubted that patients with fasciotomy wounds benefit from vacuum therapy, this method was simply applied and not subjected to further studies. It is an interesting phenomenon of our time that theory lags behind clinical practice and that clinicians see no need to change this state of affairs.

Discussion

The results that have thus far been reported in the literature highlight the advantages that vacuum therapy offers for the closure of fasciotomy wounds:

- Vacuum therapy allows surgeons to close large, long and open wounds and obtain clean and healthy ones. Exposed bone can be covered safely and hygienically. Wound fluid is continuously drained from a wound and collected in a canister. At the same time, the wound is sealed and thus protected from exogenous contamination.
- Vacuum therapy reduces the frequency of dressing changes and prevents contamination of the patient's bed, bed linen and clothing even in the case of heavily exuding wounds.
- The application of tension to the wound edges reduces wound size and thus helps prevent wound edges from retracting, which is a common problem in wound healing.

- A low level of pressure on muscle tissue has an anti-oedema effect. Interstitial fluid is removed from the tissue or even prevented from accumulating. It appears that subatmospheric treatment for compartment syndrome of the leg after fasciotomy helps to speed wound closure.
- Additionally, the vacuum therapy technique can be combined with the bootlace suture technique (which achieves wound closure by progressive suture tightening) facilitating delayed primary wound closure.

None of the above-mentioned alternative methods can offer these advantages.

Despite the paucity of data in the literature, it is safe to assume that the clinical practice described by the authors is well established. The authors' own experience is that, from 1993 to approximately the year 2001, the treatment of fresh and uncontaminated fasciotomy wounds consisted of wound preparation with synthetic skin substitute and loosely placed sutures. Commencing on the third day of treatment, these sutures were progressively tightened with controlled tension in order to approximate the wound edges (dermatotraction). In rare cases, intramuscular pressure was measured simultaneously during the procedure. By contrast, only vacuum therapy was used for the management of contaminated fasciotomy wounds most commonly associated with open grade III or IV lower leg fractures.

Today, however, negative pressure wound therapy is used for virtually all fasciotomy wounds due to the possibility of safe and hygienic wound closure, the reduced frequency of dressing changes and higher patient comfort. The wound edges are gradually approximated and single interrupted sutures are used to reduce the wound size until the wound is finally closed with a secondary suture. This method can be applied to almost all wounds that are not associated with a skin defect.

Attention should also be drawn to the level of negative pressure and the type of foam that are commonly used. These two aspects have already been discussed in more detail in Part A, Chapter 6 and 7.

Dermatofasciotomy wounds are usually acute long wounds in young patients and therefore the following considerations apply in particular to this indication for vacuum therapy.

It is quite feasible to apply suction to a large area using black PU foam together with only one *trac-pad connector*. By contrast, there are a few aspects to be considered when white PVA foam is used:

First of all, it appears that high suction forces applied to PVA foam cannot be transmitted over long distances. As already described in Chapter 7 of Part A, suction forces are reduced at a distance of more than 5 cm even when a negative pressure of 200 mmHg is applied. The underlying cause is not known exactly, but the collapse of pores could play a role in this process. If the decrease in suction force that is observed at a negative pressure level as low as 150-200 mmHg is extrapolated to the strong negative pressure level of 900 mmHg that is commonly used for Redon drainage systems, it can be assumed that the suction force is markedly reduced a few centimeters from the source of suction. In response to this problem, drainage tubing was embedded in the white foam. Thus it was possible to place several pieces of foam next to one another and at the same time to prevent a decrease in the suction force.

Today, PVA foam is also available without drainages, since the *trac-pad connector* can ensure an almost 1:1 transmission of the suction force in PVA foam at low pressures even over large distances. The studies presented in Chapter 7 of Part A have shown that it is possible to transmit almost unchanged levels of negative pressures of 125 mmHg over distances of 50 cm. Generally, when a *trac-pad connector* is used with polyvinyl alcohol foam, the recommended level of negative pressure is therefore 100-125 mmHg. However, the following points, discussed in detail in Part A, Chapter 6, should be considered in the case of a dermatofasciotomy wound as well:

- Fasciotomy wounds usually do not require the formation of large amounts of granulation tissue. It would therefore not be necessary to apply intermittent suction for this indication (unless a piece of foam would have to be placed directly over exposed bone in the case of a wound with loss of muscle tissue).
- Continuous suction, however, leads to hypoperfusion in the tissue close to the foam dressing. Hypoperfusion increases with the level of negative pressure. Subcutaneous tissue is more severely affected than muscle tissue¹⁸.

Against this background, the following conclusions can be drawn from the above discussion.

- After decompressive dermatofasciotomy for compartment syndrome, low level continuous suction should be used. Particularly, in case of severe ischemia, negative pressure wound therapy using a pressure value of 50-100 mmHg is adequate. The low level of negative pressure appears to be sufficient to apply tension to the wound edges and to produce an anti-edema effect.

- Both the polyvinyl alcohol and the polyurethane foam can be used for covering the dermatofasciotomy wound.

It goes without saying that leaks near an internal fixateur, patient pain, and other factors play a key role in the selection of the negative pressure level.

Vacuum therapy is a suitable form of initial treatment for acute dermatofasciotomy wounds. It is unparalleled in its ability to apply tension to the wound edges and low pressure to muscle tissue, to cover and close wounds safely and hygienically, to provide patient comfort, and to constantly remove exudate from the wound site. A low level of continuous negative pressure (50-75 mmHg) should be applied in order to ensure optimal perfusion of muscle tissue that has been damaged by ischaemia.

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Part B / Chapter 3

Periprosthetic Infections of the Hip and Knee Joint

J. Kelm, K. Anagnostakos and E. Schmitt

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Vacuum therapy is a useful option in the management of early or delayed infections following implantation of an endoprosthesis. To date, however, only four *peer-reviewed* articles have addressed this subject, two case series (evidence level 4) and two case reports (evidence level 5). The advantages of vacuum therapy for this indication are:

- Large, open wounds can be converted to hygienic, perfectly closed wounds
 - Wound secretion is continuously collected in a canister
 - Contamination from the environment is prevented because the wound is perfectly sealed.
- The patient benefits from the fact that - even in case of a heavily draining wound - the dressing requires change only every two to three days, minimizing soiling of the patient's bed and clothing.

Introduction

Despite extensive prophylactic measures, the infection rate in total hip arthroplasty remains between 0.4% and 2.3%^{1,2}. This means that, with 170,000 primary implantations and 7,500 exchange operations carried out in Germany every year, we are faced with about 1000-2500 infected hip endoprostheses.

In principle, we distinguish between early and delayed infection. While early infections occur within the first postoperative weeks and normally originate from primary wound infections or haematomas, delayed infections impress with chronic, persisting pain in connection with a loosening of the prosthesis material within the first years after implantation. Haematogenous generalization, a special variety of infection of the prosthesis that starts from a primary infection focus elsewhere in the body, may occur at any time after implantation, and often goes hand in hand with sepsis.

In treating periprosthetic infections we distinguish between maintenance and exchange of the prosthesis, which can be carried out in either one or two stages. We prefer the method in which the prosthesis is maintained, especially in case of early infections. Here, we make use of surgical debridement, the exchange of all exchangeable components of the prosthesis, the introduction of antibiotic chains, and, finally, irrigation-suction drainage. There is no doubt that the treatment of periprosthetic infections can be further optimized in septic surgery. The recurring or persisting secretion (Fig. B3.1) that occurs despite revision, together with increasing nursing requirements and discomfort to the patient, still remain a problem, especially when trying to maintain the prosthesis.

Although the advantages of vacuum therapy in terms of enhanced granulation, secure drainage of the secretion, and reduction in bacterial contamination support maintenance of the prostheses by treating periprosthetic infections, use of this treatment has not yet become widespread in orthopaedics. To date, only four studies^{13,14,16,17} have investigated application of vacuum therapy in infections after total hip and knee arthroplasty. For example, Fox et al.¹³ report on the application of vacuum therapy in three infected knee-joint prostheses. They managed to maintain one endoprosthesis although partially exposed. In all three cases, wound healing with permanent eradication of infection was achieved using vacuum therapy. The authors conclude that vacuum

therapy enhances epithelialization in small wounds, while helping condition the wound for reception of a muscle or skin transplant, thus obviating the need for extensive and unsatisfactory surgical measures.

Own Experiences

Vacuum therapy is integrated into the treatment concept of maintaining the prosthesis as well as in the concept of exchange of the prosthesis in two stages. To date, 13 patients with different indications and infectious situations, with identified pathogenic organisms, were treated by using vacuum therapy. All cases were preceded with at least one or more unsuccessful attempts at eradicating the infection. Our therapeutic concept consists of:

1. Meticulous surgical debridement and inlay of polyvinyl alcohol (PVA) foams with a tube leading out percutaneously; wound is closed layer by layer.
2. Vacuum therapy with continuous negative pressure of initially 200 mm Hg.
3. Adjuvant intravenous antibiosis according to microbial sensitivities for about four weeks followed by oral antibiotics for another two weeks.

Surgical Treatment

Surgical eradication starts with contrasting the infected cavity with methylene blue. This permits direct, intraoperative assessment of the extent of infection; the material constituting the prosthesis is normally also involved in the infection (Fig. B3.2). Then, the tissue layers are identified to appropriate depth, followed by radical surgical debridement carried out in the same way. All exchangeable components of the prosthesis are removed (inlay, head of the prosthesis), and the infectious cavity is treated with debridement and lavage (Fig. B3.3). Then, the infectious cavity is subjected to tamponade using an abdominal towel soaked in antiseptic solution. After an adequate period, the abdominal towel is removed and the surgical site is jet-lavaged with another 15 liters of solution. After that, the removed components of the prosthesis are replaced by new parts. The polyvinyl alcohol foam, cut to size, is placed ventral and dorsal to the prosthesis, or, in case of the Girdlestone status, into the resection cavity, their tubes leading out percutaneously through all tissue layers (Fig. B3.4). Hermetically



Fig. B3.1 Early infection after primary total hip arthroplasty with persisting draining cavity in the middle and distal thirds of the wound.



Fig. B3.2 Demonstration of the extent of infection by contrasting with methylene blue.



Fig. B3.3 Infectious cavity after debridement and lavage with removed exchangeable components of the prosthesis (inlay, head of the prosthesis).



Fig. B3.4 Periprosthetically placed polyvinyl alcohol foams cut to the appropriate shape with tube leading out percutaneously *in situ*.

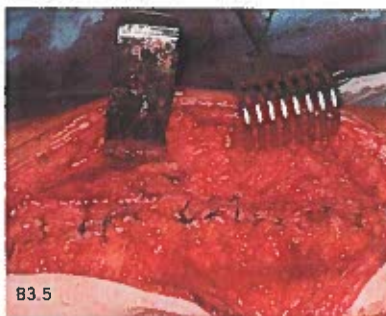


Fig. B3.5 Reconstructed and tension-free adaptation of soft-tissue layer after meticulous preparation.



Fig. B3.6 Tubes leading out percutaneously, connected to Y-adaptor and vacuum therapy unit.

sealed wound closure is performed by meticulous tension-free reconstruction and adaptation of the tissue layers (Fig. B3.5). A vacuum therapy unit is connected to the tubes leading out percutaneously (Fig. B3.6) and initially set at a continuous negative pressure of 200 mmHg.

At 48-72 hours after surgery, we normally observe the transition of haemorrhagic to serous secretion. At this point, the continuous negative pressure is reduced to 150 mmHg (the intensity of the negative pressure complies with the manufacturer's recommendations). Quantity of secretion normally decreases at about ten days after implantation of the foams. In addition, a decline in CRP can be observed, indicating that the foams can be removed. The foams are removed by opening the wound layer by layer. Thorough *jet lavage* is repeated. In cases with corresponding culture and sensitivity findings, exposed prosthetic material was enveloped in Sulmycin® sponges. The wound was then re-closed under tension-free conditions with exact reconstruction of the tissue layers, and the skin was adapted with metal clips.

Results

Primary eradication of infection was achieved in 12 of 13 cases. Due to the vacuum therapy, the number of dressing changes could be reduced from twice a day before the vacuum therapy "era" to once every other day for the first week and once every three days in the second week of vacuum therapy. Over an average *follow-up* of 15 months (range 3-58 months) there was only one new periprosthetic infection caused by another agent. In one case, a mixed infection of *Staphylococcus epidermidis*, *MRSA*, *Enterobacter* and *Candida albicans* was not eradicated by using the vacuum therapy. This infection was eradicated by removing the prosthesis and implanting an antibiotic-loaded PMMA spacer. Furthermore, a polymorbid female patient (cirrhosis of the liver, thrombocytopenia) suffered from haemorrhage on the eighth postoperative day. Due to the early removal of the foams, however, there was no negative influence of vacuum therapy on the further course of the disease.

Discussion

When the surface of a prosthesis is contaminated by a bacterial population, the surrounding tissue is also involved in a periprosthetic infection, triggering a local immune reaction. The most frequent problem is the persisting secretion, which may lead to permanent wound healing disturbances. Pathophysiologically responsible for wound healing disturbances are interstitial oedemas, disturbed microcirculation, and bacterial contamination. This normally requires removal or exchange of the endoprosthesis. Vacuum therapy is responsible for an increased granulation rate, an amelioration of local perfusion and enhanced bacterial clearance⁴. If the interstitial wound oedema has been reduced by means of the vacuum, compressed arterioles can re-open. This results in improved local tissue oxygenation and an optimized removal of inhibitors and toxins⁴.

Furthermore, some studies indicate that incipient vascular regeneration in the wound area^{4,6} enhances local perfusion and increases the local concentration of antibiotics. Thus, the wound is provided with enhanced cellular and humoral immunocompetence, resulting in a significant reduction of bacterial load⁴. Vacuum therapy has been established in many surgical fields as an effective treatment option in cases of wound infection. Fleischmann⁷ was able to demonstrate that even exposed implants could be maintained using vacuum therapy. Other authors observed an overgrowth of granulation tissue around the implants^{8,9}. This seems to be very important especially in cases of infection after implantation of knee-joint prostheses, which are covered by only a very thin layer of soft tissue because the implants are located quite close to the surface¹³.

The usual vacuum therapy makes use of foam inlays and wound closures using transparent adhesive tapes. In the method described here, however, the foam is placed periprosthetically into the resection cavity, the tubes are led out percutaneously and the wound is then hermetically sealed and closed in the conventional way. Effective eradication of infection requires radical surgical debridement^{4,9} as well as mechanical and antiseptic cleansing of the exposed parts of the prosthesis in order to reduce the quantitative bacterial count. Furthermore, an exact anatomic representation of the tissue layers is required in order to achieve a tension-free wound closure after having placed the foams. This enhances the tissue blood flow as well as the infection eradication, and meets the

biomechanical requirements of a well-functioning hip-joint. The advantages of vacuum therapy include a facilitation of, and reduction in, dressing changes⁵ in connection with increased comfort for the patient^{4,10,11}, and the possibility of cost minimization¹². However, the deep positioning of the periprosthetically placed foam makes continuous inspection of the foam impossible. This disadvantage has to be compensated by a close-meshed monitoring of the infection (body temperature, CRP, and white blood cell count) as well as critical analysis of the secretion.

Vacuum therapy in connection with a radical surgical treatment is a very promising treatment option in cases of infected knee- or hip-joint prostheses. Although the current literature does not provide us with many reports, it seems that the effects of vacuum therapy may contribute to maintaining the implant *in situ*, thus avoiding the exchange of the prosthesis. The number of dressing changes is reduced, and soaked bandages due to heavily secreting wounds are avoided. This significantly increases patients' comfort, while reducing nursing demands. This type of wound treatment could be combined with temporary ambulatory therapy phases. The modern vacuum instillation therapy may further facilitate the treatment of infected endoprostheses (see Part A, Chapter 5).

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Part B / Chapter 4

Vacuum Assisted Closure in the Treatment of Osteomyelitis

M. Diefenbeck, T. Mueckley and G. O. Hofmann

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The advantage of vacuum therapy in the treatment of osteomyelitis is that wound secretion, usually contaminated by bacteria, is constantly drained from the wound by negative pressure. At the same time extravascular fluid is reduced. In addition, it is possible to instill antiseptics and antibiotics into the surgical site via the drains (instillation therapy).

Although vacuum therapy is frequently used in the treatment of acute and chronic osteomyelitis in clinical practice, there are only three *peer-reviewed* publications in the literature dealing with this topic - one case series (EbM-level: 4) and two case reports (EbM-level: 5) published in 1998, 2005 and 2006, respectively.

Introduction

Posttraumatic osteomyelitis is an infection of a bone by micro-organisms occurring after trauma. When it follows fracture, open reduction and internal fixation it can be a bacterial implant-related infection. Often all compartments of the bone, i. e. periosteum, cortex, spongiosa and bone marrow, as well as surrounding soft tissue, are involved.

Acute posttraumatic osteomyelitis, often termed "deep surgical site infection", appears within the first weeks after internal fixation or trauma. The time interval for development of chronic infection is not exactly defined¹. In the literature durations between four and six weeks are found^{2,3}. Infections of the bone that become symptomatic after this period are considered chronic osteomyelitis.

Important for the diagnosis of acute osteomyelitis is the combination of the patient's history, clinical examination and laboratory results. On examination of the wound, redness, swelling, warmth and secretion are suspicious. Laboratory findings usually include a high or rising level of C-reactive protein (CRP). In addition, febrile temperatures ($> 38.5^{\circ}\text{C}$ for more than three to four days postoperatively), pain at the surgical site and fatigue can be elicited.

In contrast to acute osteomyelitis, the diagnosis of chronic osteomyelitis does not depend as much on clinical examination and laboratory results. Clinical examination can range from normal, healthy skin and soft tissue to draining sinuses and large skin ulcerations. Laboratory findings may include a high white blood cell count (WBC) and high CRP levels, but these are not essential. Further diagnostics, including radiography (with contrast of fistulae), computed tomography (CT) scans and magnetic resonance imaging (MRI) can provide information about the localisation of the inflammation. Finally, osteomyelitis is proven by the growth of bacteria in tissue samples taken from the fracture or implant site on microbiological examination. Those tissue specimens are taken during the first surgical revision of the infectious site. They provide the rationale for the systemic antibiotic therapy.

Therapy of Acute and Chronic Osteomyelitis

Surgical debridement and necrectomy represent the fundamental step in the treatment of osteomyelitis. All

necrotic and infected tissue must be removed, leaving only viable, well-perfused tissue⁴. Sequesters must be extracted. This is the only option for depriving bacteria of their nutrition supply while at the same time enabling the immune system to reach the site of infection through intact and well-perfused tissue. Resulting soft tissue and bone defects require reconstruction (mesh-graft, local and free flaps, spongiosa-plastics or callus distraction) in sequential surgeries⁵.

Surgical treatment may be supported by lavage of the surgical site with antiseptics (povidone-iodine or polyhexamethylene-biguanide, e. g. Lavasept®) in combination with systemic and local antibiotics. Recommended are intravenous or oral antibiotics in accordance with the resistance of the bacteria demonstrated by microbiological examination of tissue samples. For the success of this adjuvant therapy, the complete removal of sequesters and necrosis is a prime requirement.

Acute Posttraumatic Osteomyelitis

In acute postoperative osteomyelitis (duration from internal fixation to signs of infection less than six weeks) the internal fixation device may not be removed during the first surgical revisions.

The surgical site has to be reopened, the suture material completely removed and debridement performed. During this step a tissue sample for microbiological examination should be taken. Next, the wound is rinsed with isotonic solution or, alternatively, with antiseptics, e.g. Lavasept®. In some cases *jet-lavage* with an isotonic solution may be used. At the end of the surgical revision local antibiotics (in accordance with the resistance of the bacteria) can be implanted in the surgical site. There are degradable (gentamicin-collagen-sheets) and non-degradable (gentamicin-PMMA-beads) drug delivery systems. In the case of gentamicin-resistant bacteria as cause of a surgical site infection, vancomycin-PMMA-beads or vancomycin-collagen-sheets exist⁶. Some authors favor a single revision concept and close the surgical site by a suture after installation of drains⁵. We recommend a sequential revision concept with follow-up debridements until the tissue samples are free from bacteria. Only in case of a microbiologically sterile sample wound closure is performed⁵. Between two revisions the wound is temporarily covered with a vacuum therapy dressing.

Chronic Osteomyelitis

In chronic osteomyelitis (duration from internal fixation to signs of infection over six weeks) a more radical approach is often necessary to achieve quiescence of the infection. Implants or internal stabilisation devices have to be removed during the first revision and an extensive bone and soft tissue debridement must be done. The extent of the bone debridement can vary from a sequestrectomy, resection of one-third of the bone's circumference to complete resection of a bone segment⁴. Stability is maintained by external fixation⁷ or by an Ilizarov's fixateur⁸.

Often, debridement of soft tissue is extensive, so that the surgical site has to be closed by a free flap. With sequential therapy the wound can be covered temporarily using vacuum therapy as in acute osteomyelitis.

Vacuum Therapy in Osteomyelitis

Vacuum therapy is used in the above mentioned treatment concept as a temporary wound closure or "wound dressing" between two revisions.

The advantage of vacuum therapy is that the wound is continuously drained and the fluid, which is often contaminated by bacteria, is removed. Extravascular fluid is also reduced⁹.

At the same time it is possible to instil antiseptic or antibiotic solutions at the surgical site¹⁰. The implanted foams promote granulation and reduce the size of the wound¹¹. It has to be stressed that the main therapy in osteomyelitis is the surgical debridement and removal of sequestrs.

Vacuum therapy dressings on top of sequestrs or necrosis left in situ endangers the success of the treatment and may lead to spread of the infection.

In contrast to the frequent use of vacuum therapy in the treatment of osteomyelitis only little literature exists. There are only three *peer-reviewed* publications concerning its use in infected bones.

- One case series (1998; EbM-Level 4, case reports on acute infection after open reduction and internal fixation, open fractures and chronic osteomyelitis of the femur), technique: PVA foam, constant vacuum at 125 mmHg and instillation therapy¹⁰
- One case report (2005, EbM-level 5, n = 1; case report of chronic osteomyelitis of the tibia), no information about foam material or vacuum pressure¹³.
- One case report (2006, EbM-level 5, n = 1; case report, the protocol includes aggressive excisional debridement of infected or necrotic bone, open bone grafting with cancellous autograft, vacuum-assisted wound closure by secondary intent, and eradication of chronic infection with concomitant parenteral antibiotics¹⁶.

Although vacuum therapy is frequently used in the treatment of osteomyelitis today, the scientific knowledge of the method is still very limited. More experimental and clinical data are needed to understand the mechanisms behind this method. Of special interest is the situation of a "shift" in the bacterial spectrum that happens during vacuum therapy, as suggested by Moues and Chester^{14,15}. Additionally, there are many open questions dealing with the vacuum instillation therapy, especially whether the use of an antiseptic solution is more effective in the eradication of infection than using vacuum therapy without instillation and regarding the usefulness of local antibiotic solutions.

The fundamental step in the treatment of osteomyelitis is the radical surgical debridement and necrectomy of infected tissue. Usually, sequential surgeries are necessary to achieve quiescence of the infection. Within this treatment protocol, vacuum therapy is used between two revisions as a temporary wound dressing. The advantage of vacuum therapy is that contaminated fluid is constantly removed into a closed system. Granulation is accelerated and the size of the wound reduced. A promising modification of the technique seems to be the so-called "vacuum instillation therapy", in which antiseptic or antibiotic solutions are used to irrigate the surgical site via the drains and foams (Part A, Chapter 5).

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Part B / Chapter 5

Vacuum Therapy for Wound Healing Problems after (Posterior) Spinal Surgery

C. Willy, G. Bergenthal and U. Ziegler

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Five *peer-reviewed* publications (evidence levels 4 and 5) report on the use of vacuum therapy for the treatment of a total of 40 patients with spinal wounds. Posterior instrumentation was exposed in the majority of cases. The dural sac was additionally exposed in seven patients. All wounds healed well without requiring major surgery. The four working groups unanimously concluded that vacuum therapy successfully stimulated the formation of granulation tissue even in wounds with exposed hardware and allowed complete wound and hardware coverage to be achieved. Despite the presence of deep spinal infection, none of the patients required hardware removal.

Introduction

Wound infections occur in approximately 4% of patients undergoing spinal surgery from a posterior approach. This figure was based on a study involving 850 spinal procedures⁶. Depending on the indication, however, as many as 15% of the patients may develop an infection. As a consequence of this complication, metal hardware inserted during surgery may be found at the base of the wound in the presence of deep infection. After laminectomy, the spinal dura mater may be exposed in the wound bed.

Treatment has thus far consisted of irrigation, debridement, wound drainage, antibiotic treatment and delayed closure of the wound. A few patients, however, require plastic surgery involving the use of myocutaneous or fasciocutaneous flaps for wound coverage^{4,6}.

Against this background, five working groups described their experience with the use of vacuum therapy in the treatment of spinal infections at the site of surgery after a posterior approach.

Table B5.1 Publications on the use of vacuum therapy for wound healing problems after spinal surgery

Year	Author/Journal	Evidence level	Number of Patients / Indication	Vacuum Therapy	Course
2001	Yuan-Innes et al ¹ <i>Spine</i>	5 (Case report)	n = 2 Infection after posterior spinal surgery; exposed spinal hardware; Causative organisms: <i>Staphylococcus</i> , <i>Pseudomonas aeruginosa</i> (case 1); <i>Staphylococcus epidermidis</i> and <i>Diphtheroides</i> (case 2)	No details	Duration: 6 and 10 weeks respectively; Results: 1x split-thickness skin graft, 1x spontaneous closure
2002	De la Torre et al ² <i>Ostomy Wound Management</i>	5 (Case report)	n = 1 Pressure ulcer at the T-10 level with exposed hardware	No details	Duration: 2 weeks for complete coverage of the hardware, 3 months for complete coverage of the defect
2004	Antony et al ³ <i>J Nat Med Assoc</i>	4 (Case series)	n = 16 Infection after posterior spinal surgery; Causative organisms: <i>Staphylococcus</i> , <i>Enterococcus</i> , <i>Candida albicans</i> , <i>Pseudomonas aeruginosa</i>	Polyurethane foam; negative pressure level: 125-150 mmHg Mode of suction: no details average duration: 27.6 days (2-178 days)	Duration: Ø 8 weeks Results: secondary suture (n = 8), spontaneous closure (n = 8)
2005	Mehbod et al ⁴ <i>J Spinal Disord Tech</i>	4 (Case series)	n = 20 Infection after posterior spinal surgery; exposed instrumentation, including seven patients who had decompression with exposed dura	No details Ø 2.2 procedures	Duration: Ø 7 days (5-14 days) Results: no removal of instrumentation
2006	Becker et al ⁵ <i>Zentralbl Chir</i>	5 (Case report)	n = 1 Infection after posterior spinal surgery; exposed spinal hardware; Causative organisms: <i>Staphylococcus epidermidis</i> , <i>Peptococcaceae</i>	Polyurethane foam; negative pressure level: 100-125 mmHg Mode of suction: continuous	Duration: 6 weeks for almost complete coverage of the hardware, 3 months for closure of the wound, no removal of the hardware

Literature Review

Table B5.1 provides an overview of the data reported in the publications on the use of vacuum therapy in spinal surgery patients¹⁻⁴. It offers information on when and where the relevant papers were published, what level of evidence is represented according to the standards of Evidence-based Medicine, how many patients were studied, when vacuum therapy was indicated, which therapy settings were used, and what outcome was achieved.

The use of vacuum therapy in the treatment of spinal wounds has been described in the literature since 2001. A total of 40 patients were studied. In the majority of cases, vacuum therapy was used for patients with exposed posterior instrumentation. In seven cases, the dural sac was exposed. All wounds healed well and did not require major surgery. Wounds that required surgical closure were closed by secondary suture or skin grafting.

Discussion

In the literature, five publications (two retrospective case series and three case reports, evidence levels 4 and 5) report on the use of vacuum therapy to treat patients with wound healing problems and infections after posterior spinal surgery. There were no complications and all wounds were closed without major surgery.

When it is impossible to close the usually deep wounds using simple measures (secondary suture), extensive plastic surgery involving the use of myocutaneous or fasciocutaneous flaps would be necessary. These surgical procedures are not infrequently associated with significant morbidity. They are typically associated with longer surgical durations, increased blood loss and heightened risk of infection, as well as with wound healing problems, seroma formation and donor site morbidity. When vacuum therapy is used, these complications do not occur.

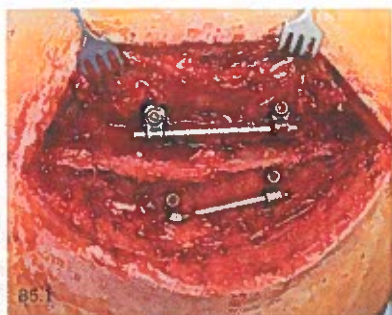


Fig. B5.1 Wound infection after posterior and anterior surgery at the T-6 level in the presence of spondylodiscitis (seventh postoperative day) after primary wound debridement and two days of vacuum therapy.



Fig. B5.2 A piece of polyurethane foam was placed onto the wound. A hole was cut in the adhesive drape, which was applied ventrally in order to protect the skin.



Fig. B5.3 A strip of foam was placed over the skin in the left lateral direction in order to prevent pressure damage and discomfort from the relatively stiff *tmc-pad* connector. Excess adhesive drape was used to protect the skin.



Fig. B5.4 Detailed view of the wound after two further days of vacuum therapy. The picture shows marked granulation tissue around the lower pedicle screw (on the right side of the picture).

Vacuum therapy helps turn complex wounds (exposed hardware, exposed dural sac) into "simpler" superficial wounds. Accordingly, the literature reports that complete wound closure required split-thickness skin grafting in only one case and secondary suture in one further case.

The four working groups unanimously reported that vacuum therapy induced formation of granulation tissue even in wounds with exposed metalwork until complete coverage was achieved. Despite the presence of deep

spinal infection, none of the cases required hardware removal. What is lacking in some reports is detailed information on whether foam is placed directly onto an exposed dural sac. In addition, the literature does not provide data on the level of negative pressure that should be used for this indication. The authors have thus far used continuous suction at a negative pressure level of 125 mmHg. The direct application of foam to an intact dural sac showed no adverse effects.

Vacuum therapy can be successfully used in the treatment of spinal surgery patients with postoperative infections extending as far as the dural sac. Vacuum therapy made it possible to avoid major surgery in all cases described thus far. Comparative studies that investigate the results of conventional methods *versus* vacuum therapy and represent a high level of evidence are not available. Continuous suction at a negative pressure of 100-125 mmHg has thus far been used in the treatment of patients with wound healing problems after spinal surgery. It should be borne in mind, however, that lower levels of negative pressure are associated with lower compressive effects (e.g. on the dural sac) and do not adversely affect the formation of granulation tissue.

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Part B / Chapter 6

Exposed Tendon, Bone and Hardware

C. Willy and G. Bergenthal

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When vacuum therapy was still in its infancy, researchers were surprised to find that this treatment modality offered great potential for stimulating granulation tissue formation. Six articles with a focus on this unexpected effect have thus far been published in *peer-reviewed* journals and have described a total of 107 cases where exposed tendon, bone and hardware were successfully covered with granulation tissue using vacuum therapy. Different modes of suction and pressure levels were used in these studies. Experimental investigations suggest, however, that intermittent suction should be applied to encourage the formation of granulation tissue.

Introduction

Exposed tendon, bone and hardware represent a major therapeutic challenge in the surgical treatment of wounds of the extremities. The coverage of these wounds with split-thickness skin grafts is associated with poor functional results and therefore not recommended in the majority of cases. Wound closure and acceptable functional results can, however, usually be achieved with plastic and reconstructive surgical procedures. Nevertheless, there are situations in which the problem of exposed structures cannot be managed using plastic reconstructive surgery. These include impaired blood flow in the extremity, marked lymphoedema, extension of the injury to adjacent soft tissue or donor sites (especially in extensive burns) and the possibility of contamination. In addition, donor site complications can also result in tendon exposure.

The temporary coverage of these types of defects was an early application of vacuum therapy. Surprisingly, the application of topical negative pressure was found to encourage the formation of granulation tissue over bradytrophic tissue and even over exposed metalwork more rapidly than any other dressing technique. There were some cases in which granulation tissue growth was so marked that it was eventually possible to cover the skin defect with mesh-graft without requiring flap surgery as had previously been planned.

Against this background, the present chapter will provide an overview of the experience that has been gained from using vacuum therapy for the stimulation of granulation tissue formation over exposed bradytrophic tissue, bone and metalwork.

Literature Review

Six articles published in *peer-reviewed* journals between 1997 and 2006 focus on this indication for vacuum therapy:

- One case series (2001; level 4 evidence; n = 75, including 10 patients with exposed plates for osteosynthesis; course of treatment: wound closure in 71 of the 75 patients; 12 secondary sutures, 58 mesh-grafts, 5 musculocutaneous or fasciocutaneous flaps), polyurethane foam, continuous suction at a negative pressure level of 125 mmHg¹.
- One case report (2002; level 5 evidence, n = 1; course of treatment: use of vacuum therapy for 12 days for the coverage of an exposed Achilles tendon after burn injury, then use of mesh-graft), no information about the level of negative pressure³.
- One case report (1999; level 5 evidence; n = 2; course of treatment: complete epithelialisation after 2 weeks), polyurethane foam, negative pressure level of 125 mmHg, no information about mode of suction².
- One case series (1997; level 4 evidence; n = 16; exposed bone with a mean surface area of 8 cm² (range: 6-10 cm²), including six exposed plates for osteosynthesis with a mean surface area of 2.8 cm² (range: 1-4 cm²); course of treatment: wound closure in 14 of 16 patients; mean time to healing: 16 days (range: 7-28 days); polyvinyl alcohol foam, no information about negative pressure level, continuous suction, vacuum source: Redon drainage container or vacuum therapy units other than a VAC^{ATS} system⁴.
- One case report (2005; level 5 evidence; n = 3), polyurethane foam, continuous suction at a negative pressure level of 50-125 mmHg⁶.
- One case series (2006; level 4 evidence; n = 10 patients, exposed orthopaedic implants) polyurethane foam, continuous suction at a negative pressure level of 125 mmHg course of treatment: wound closure in 9 of 10 patients; mean time to definitive closure procedure: 9 days (range: 14 days); vacuum source: VAC^{ATS} system⁷.

Another interesting case report (level 5 evidence) is presented in Part C by R. E. Horch and his research group: *Case 4 "Limb salvage in a case of arterial obstructive disease and exposed tibial and fibular bone using vacuum therapy and split-thickness skin grafting"*.

Discussion

In the reviewed articles, the beneficial effects of vacuum therapy on the coverage of exposed bone and even metalwork were completely unexpected by the authors. In addition, the articles show that vacuum therapy can successfully encourage granulation tissue growth even in elderly patients.

Wound coverage was usually achieved after two to six weeks. The protocols that were used differed widely. Both types of foam were used. The level of negative

pressure varied between 125 mmHg and approximately 900 mmHg. In all articles that provided detailed information about the mode of suction, negative pressure was applied continuously.

Working at the Wake Forest University School of Medicine, DeFranzo applied continuous suction at a negative pressure level of 125 mmHg in order to promote granulation tissue formation. Argenta appeared as a co-author of this article, which was published in 2001. It is interesting to note that he and Morykwas, who together popularized vacuum therapy in the United States, reported in one of their earliest studies in 1997 that the intermittent mode was associated with a 60% stronger stimulation of granulation tissue formation in animal experiments than the continuous mode⁴. Thus, it appears contradictory that, despite these clear results, members of the same research group selected continuous therapy for an indication that requires particularly rapid and

effective granulation tissue formation. DeFranzo did not discuss this contradiction.

Still unanswered is the question of how effective intermittent suction is for this indication. Clinical studies comparing the two modes of suction in comparable human patient populations are not yet available. An assessment of intermittent therapy must therefore rely on the study that Morykwas and Argenta published in 1997 and on theoretical arguments. A number of studies can be found in the literature that focus on blood flow under the different types of suction^{8,9}. There is widespread agreement that the use of continuous suction appears to decrease blood flow whereas intermittent suction appears to increase blood flow, which may be due to reactive hyperemia. This is one theoretical explanation of why intermittent suction could be of particular benefit to induce new granulation tissue in wound situations with exposed tendon, bone and hardware.

When plastic surgery procedures cannot be used for the coverage of exposed bone, tendon or metalwork, vacuum therapy is the treatment of choice for these wounds. The mechanisms underlying this surprising potential for stimulating granulation tissue formation are not yet known. Experimental evidence suggests that intermittent suction at a pressure level of 50 to 125 mmHg should be used for this indication.

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Part B / Chapter 7

Vacuum Therapy in the Treatment of Acute Burns – An Overview

L.-P. Kamolz and C. Willy

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The purpose of this overview is to demonstrate the importance of vacuum therapy in the treatment of burn wounds. To date, vacuum therapy has been applied in the treatment of burns and scalds to the hand. Some research centers intraindividually compared vacuum therapy with silver sulfadiazine treatment (SSD) in bilateral burns.

Clinical results of the available studies (11 *peer-reviewed* studies plus an assignment based on animal experiments) showed that vacuum therapy in treatment of burn injuries has strong anti-edematous effects, optimizes wound healing, reduces the need for secondary surgery and facilitates care. In contrast to those treated with vacuum therapy, conventionally treated patients (SSD) showed a significant decrease in perfusion as measured by fluorescence-videography. Further investigations are required to evaluate the efficacy of vacuum therapy in burns at other localisations.

Introduction

Burn trauma is one of the most complex types of injury¹. The trauma causes numerous physiological, metabolic and immunological reactions and changes^{1,5}. The last decades have seen a significant improvement in the outcome of burn trauma. This improvement is due to early debridement (necrosectomy) and wound closure^{6,7}. If these measures are taken very early the patient's chances of survival increase, the hospital stay will be shortened and costs are reduced^{6,8,9}. Fast wound closure facilitates early mobilization and rehabilitation, with better long-term functional results.

When tissue is exposed to heat, there are several zones of tissue damage. The burn's depth is not determined by temperature alone but also to a great extent by the time the tissue is exposed to heat. Within the coagulation zone cell demise is irreversible. Next to the coagulation zone is the zone of stasis, followed by the zone of hyperemia. Initially, most cells in the zone of stasis remain viable. However, in case vascular occlusion or thrombosis occur in this zone secondary to edema, perfusion will decrease, and hypoxia and ischemia occur, promoting cell destruction. Thus, the area of tissue irreversibly damaged by the burn may further expand^{16,17}. This post-traumatic expansion of the damaged tissue area, called postburn, usually begins within the first three hours after the trauma and lasts about 48 hours.

Numerous techniques for reducing postburn have been evaluated¹. These techniques focus on reducing edema because of the extreme importance of preserving microcirculation. Animal experiments have shown that fresh second degree burns can be successfully treated with vacuum therapy. Postburn also was reduced¹⁹. During vacuum therapy the entire wound surface is exposed to a defined and controlled negative pressure, which has an anti-edematous effect due to a gentle compression of the wound base. This effect encourages blood flow significantly¹⁸. Based on these findings, vacuum therapy was applied in human hand burn wounds in various studies.

Laser-Fluorescence Videography Studies

Clinical studies^{18,20-23} investigated the efficacy of vacuum therapy applied in bilateral second degree hand burns and focused on its role in reducing postburn. The wounds on both hands were examined daily and progress documented (see for general overview Table B7.1). If sur-

gery became necessary, therapy was discontinued and the patient underwent surgery.

Dressing

In most instances, the contralateral hand was treated with silver sulfadiazine (SSD). The hand that was burned or scalded more severely was chosen for vacuum therapy. A continuous suction of 125 mmHg was chosen for all studies. Prior to application of vacuum therapy, the wounds were covered with a lanolin-impregnated gauze, placed in an intrinsic-plus position in the polyurethane hand-dressing foam and then sealed.

Methods of Examination

Regardless of the cause of the trauma, it is very important for planning treatment to assess the exact severity of the burn by determining the wound depth and expansion¹. Traditionally, this has been done by repeated clinical examinations¹⁰⁻¹². This is, however, a more or less subjective method. Although various methods to standardise the clinical examination have been proposed, none of them has yet gained general acceptance.

Vascular supply and perfusion indicate the extent of tissue damage¹³. One method of determining microcirculation is dynamic laser-fluorescence videography, also known as ICG videoangiography (IC-View, Pulsion, Germany). It not only facilitates an objective, qualitative and quantitative assessment of blood flow (measuring of the average pixel intensity by a special software) but also can be used to assess changes in blood flow that may occur as a result of burns (postburn)^{14,15}. This technique has been applied to determine fluorescence intensity and its uptake time (time between injection and maximum fluorescence). Apart from this technology based examination, clinical assessment and digital photo documentation were part of all studies (Fig. B7.1-2).

Results

A total of 22 patients with bilateral hand burns have been included in these studies published to date. The concurring results of the three teams (Munich, Lütgendortmund and Vienna) showed a reduction of connective tissue edema in clinical use^{18,20-23} (Table B7.1). Videoangiography documented stability of the microcirculation during vacuum therapy whereas the microcirculation in the contralateral hand treated with SSD decreased significantly during the second and third *post-trauma* days (Fig. B7.3).

Table B7.1 Maximum mean pixel intensity (MPI)

	Vacuum therapy	SSD	Difference between groups
Baseline	52.7 ± 12.0%	55.7 ± 8.8%	n.s.
Day 1	50.4 ± 12.4%	44.0 ± 6.3% ($p = 0.004$)	n.s.
Day 2	51.3 ± 10.8%	42.7 ± 6.7% ($p = 0.001$)	$p = 0.001$
Day 3	51.6 ± 15.1%	44.8 ± 6.6% ($p = 0.008$)	$p = 0.006$

As a result of these favourable effects, hands treated with vacuum therapy required fewer operations (split thickness grafting). Compared to other therapies, the use of vacuum therapy was more often associated with uncomplicated wound healing^{22,23,24}. Due to the compression produced by the foam and its stiffness the patient did not need to elevate the affected limb, nor was splint fixation necessary, both of which limit the patient's mobility²².

The hands treated with vacuum therapy did not show a decrease in perfusion as documented by videoangiography ($n = 7$, second degree [partial thickness] burns of both hands, treated within six hours after injury). Perfusion figures were as follows.

The time from application to maximum mean pixel intensity (MPI) was 1.7 ± 2.2 sec faster at baseline in the SSD group, but slower on the following days (day 1: 3.4 ± 8.2 sec, day 2: 3.8 ± 6.1 sec, day 3: 5.2 ± 6.9 sec; $p = 0.013$). During therapy, a reduction in edema up to 500 ml was observed. Schrank et al. 2004 achieved similar results (data is qualitative, not quantitative)^{20,21}.

This clinical data is also supported by animal experiments. In a randomized experimental animal study (species: pig), Banwell et al. (2000) observed that contact burns ($n = 32$; second degree) showed a significantly ($p < 0.0001$) higher blood flow (doppler flow measurement at times 0, 24, 48 and 72 hours after application of vacuum therapy for 48 hours and 72 hours; suction: 125 mmHg; mode not indicated) compared to the foam dressing without suction (FWS) alone and conventional silver sulfadiazine dressing (SSD). The number of tangential excisions required to repair the tissue was significantly lower (6.3 ± 0.7 versus SSD: 13.0 ± 0.7 ; fws 14.9 ± 0.7) after vacuum therapy (72 hours after trauma)²⁵.

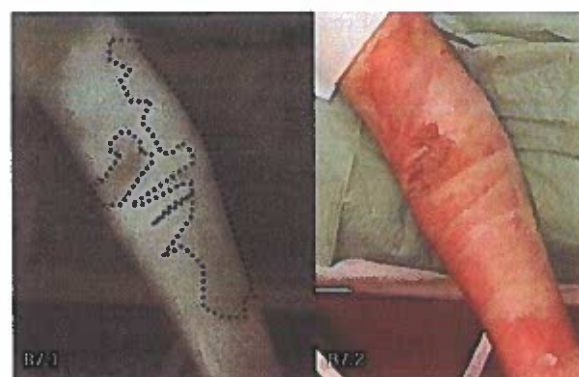


Fig. B7.1 and 2 2a-degree and 2b-degree scald of the right forearm. Left, ICG videoangiography: deep green areas represent 2a-degree scald, while paler green areas represent 2b-degree scald. Right, digital photo documentation of the clinical finding.



Fig. B7.3 Bilateral hand burn. The patient's left hand was treated with vacuum therapy. Left column: Day 0, right column: Day 3. First row: digital photo documentation. Rows 2-4 show sequences of ICG videoangiography. Row 5: inverse color scheme of ICG videoangiography. Whereas on Day 0 both hands take up an nearly equal amount of color within the same time, the results of Day 3 show that the hand treated with vacuum therapy took up the color more earlier and faster.

Table B7.2 Literature with higher Evidence-based Medicine level (*peer-reviewed* and non-*peer-reviewed* articles): Use of vacuum therapy in burn wounds

Year	Author / Journal	Level of evidence	Severity/Time of trauma	Localization/ Number	Method	Effect
2003	Schrank et al. ²⁰ <i>Eur Surg</i>	3b	2 nd a-b < 6 h	n = 6 ; compared to conventional treatment of contralateral hand	Vacuum therapy with PU hand dressing kit , continuous 125 mmHg for 48 h	Reduction and prevention of connective tissue edema, reduced bacterial colonization. Advantage in handling: fixed position of the hand, no elevation, no splint fixation.
2003	Schuhmann et al. ¹⁸ <i>Eur Surg</i>	3b	2 nd a-b < 6 h	n = 2 ; n = 2 ; compared to conventional treatment of contralateral hand	Vacuum therapy, PU hand dressing, continuous 125 mmHg for 48 h	Significantly decreased tissue swelling compared to the contralateral hand (removal of necrosis and split skin), uncomplicated wound healing. Advantage in handling: fixed hand position, no elevation, no splint fixation.
2003	Kamolz et al. ²³ <i>Eur Surg</i>	1b	2 nd a-b < 6 h	n = 5 ; compared to conventional treatment of contralateral hand (silver sulfadiazine cream)	Vacuum therapy, PU hand dressing, continuous 125 mmHg for 48 h, control IC-View perfuso- graphy	Reduction and prevention of connective tissue edema, hyperperfusion in the hand treated with vacuum therapy. Advantage in handling: fixed hand position, no splint fixation.
2004	Schrank et al. ²¹ <i>Zentrbl Chir</i>	1b	2 nd a-b < 6 h	n = 11 ; compared to conventional treatment of contralateral hand	Vacuum therapy, PU hand dressing, continuous 125 mmHg for 48 h, control IC-View perfusography	Reduction and prevention of connective tissue edema, uncomplicated wound healing, escharotomy was avoided in some cases. Advantage in handling: fixed hand position, no elevation, no splint fixation, cost-effective, savings of time and personnel.
2004	Haslik et al. ²⁴ <i>Zentrbl Chir</i>	1b	2 nd a-b < 6 h	n = 8 ; compared to conventional treatment of the contralate- ral hand (silver sulfadiazine cream)	vacuum therapy PU hand dressing, continuous 125 mmHg for 48 h, control IC-View perfusography	Reducing and preventing of connective tissue edema, hyperperfusion in the hand treated with vacuum therapy. Advantage in handling: fixed position of the hand, no splint fixation.
2004	Kamolz et al. ²² <i>Burns</i>	1b	2 nd a-b < 6 h	n = 7 ; compared to conventional treatment of the contralate- ral hand (silver sulfadiazine cream)	Vacuum therapy, PU hand dressing, continuous 125 mmHg for 48 h, control IC-View perfusography	Reduction and prevention of connective tissue edema, hyperperfusion in the hand treated with vacuum ther-apy, significant decrease of perfusion in the conventionally treated group. Advantage in handling: fixed hand position, no splint fixation.

Discussion

The present review of experience with vacuum therapy in the treatment of burns encompasses 11 *peer-reviewed* papers by nine different teams. Unlike other studies comprising the literature on vacuum therapy, these are not randomized controlled studies (RCT) but, instead, four of these 11 studies compare results of the two treatments intraindividually (plus two non-*peer-reviewed* studies)²¹⁻²⁴. In these studies, the more severely burned hand was treated with vacuum therapy, while the contralateral hand was treated with conventional silver sulfadiazine cream. Hence, these experiments are not original RCTs (level of evidence 1b). Nevertheless, when objective and quantitative data are presented, concerning the difference between the two hands²¹⁻²⁴, a level of evidence of 1b should be assumed, otherwise the level of a case-control study (3b) should be applied^{18,20}.

Without exception, hand burns were treated with polyurethane foam (hand dressing) and a continuous suction at 125 mmHg. Compared to the conventional therapy with silver sulfadiazine cream, vacuum therapy had a strong anti-edematous effect. In some cases, again compared to the contralateral hand, it was possible to reduce the number of operations. Due to these results the American FDA approved the application of vacuum therapy for the treatment of superficial and deep dermal scalds/burns in December 2002.

The results described in Chapter 7 (Part A) show that the foam hand dressing exerts a positive pressure of 6-15 mmHg on the tissue. The pressure intensity is directly dependent on the selection of suction between 50 mmHg and 200 mmHg. This pressure is the reason for the direct anti-edematous effect of vacuum therapy, which indirectly results in enhanced tissue perfusion. A favourable side effect is that the tissue is compressed, obviating the need for constant elevation of the patient's hand. Because the foam is stiff under the suction, splint fixation is not necessarily required. Despite the positive effects of vacuum therapy applied at 125 mmHg it should be noted that tissue pressures of 8-10 mmHg with a suction of 125 mmHg may cause tissue ischemia in a few cases. Thus, the pressure should be chosen carefully in order that, on the one hand, the anti-edematous effect can be established but, on the other, that nutritive perfusion is not reduced, even in critically perfused tissue. One must also consider whether continuous suction is really better than intermittent suction, since continuous

suction always involves hyperfusion whereas, when intermittent suction is applied, the oozing of interstitial liquid caused by the pressure (anti-edematous effect) could be combined with hyperemic effects. Further experiments in this field would be desirable.

Results from human studies show that therapy should begin within six hours if possible and should be applied continuously for at least 48 hours to reduce the formation of edema and thus reduce postburn^{15,22,25,26}.

Based on the experience with superficial and deep dermal hand burns and scalds, vacuum therapy is cost effective, reduces treatment time and the requirements on personnel involved in the process, and favourably influences the clinical process. It is possible that the effect which compresses the tissue can also be successfully used for burns on the torso, if appropriate dressings and dressing techniques can be adapted.

In fact, further groups demonstrated a benefit using the vacuum therapy system in thermal injuries²⁶⁻³¹. In case reports or reviews they present their experiences using topical negative pressure application to secure the fixation of skin substitutes, such as tissue-engineered skin substitute²⁸, Integra® and split-skin graft^{27,29,32} as well as to treat burns on the torso³¹. Even in the treatment of pediatric patients vacuum therapy seems to be successful for fixation of Integra® (continuous mode and 150 mmHg) and split-skin graft (continuous mode and 125 mmHg)^{27,30}. In this connection one modification of vacuum therapy (125 mmHg, continuous, dressing change every 48 hrs) in torso burns is remarkable. Thus, Terrazas et al³¹ (2006, case report, n=1) describe that they prepared the burn wound for vacuum dressing by using a film of lidocaine 2% gel followed by a dime-thickness layer of silver sulfamylon and then a soft-silicone dressing (to avoid painful removal of vacuum foam).

For further information dealing with the vacuum treatment of burn wounds see Part B Chapter 8 (Vacuum Assisted Closure and the Treatment of Burn Injury) and 9 (Vacuum Therapy Technique in Alloplastic and Autologous Tissue Transfer in Burn Patients).

The use of the polyurethane vacuum hand dressings has proven useful in the management of burn wounds. The studies intraindividually compared conventionally treated hands to those treated with vacuum therapy, showing that vacuum therapy reduces edema, optimizes wound healing and reduces the need for further surgery. A continuous suction strength of 125 mmHg has been chosen in all studies published to date. Based on the available experimental results and theoretical consideration, this suction must be analyzed critically. It might be possible that lower suction strengths and intermittent pressure could produce even better results.

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Part B / Chapter 8

Vacuum Assisted Closure and the Treatment of Burn Injury

W. T. Stoeckel and J. A. Molnar

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In the authors' institution vacuum therapy is used as the primary coverage dressing for excised burns treated with skin grafts and for those that have required placement of bioartificial skin substitutes, including Integra®. In contrast to Chapter 7 (main topic: investigation of soft tissue perfusion by means of videoangiography) and Chapter 9 (main topic: alloplastic and autologous tissue transfer), the following chapter deals with the results of current research on vacuum treatment of thermal injury.

Introduction

Over the past several years, vacuum assisted closure (VAC, KCI, Inc., San Antonio, TX, USA) therapy has become a first-line treatment option for the promotion of wound healing in a variety of wound types. Vacuum therapy has been successfully used to treat and salvage chronic pressure wounds as well as problematic wounds due to dehiscence and infection, contaminated traumatic wounds, and exposed abdominal and thoracic cavity wounds.

The use of vacuum therapy for the treatment of both chemical and thermal burn injuries has also been documented. The physiologic mechanisms of action by which sub-atmospheric pressure results in acceleration of wound healing continue to be elucidated in current studies. Research has demonstrated vacuum therapy to be effective in both improving the wound environment and facilitating healing by multiple molecular, vascular, and cellular processes¹.

Tissue Edema and Vascular Density

Tissue edema is a normal physiological response to injury but can have deleterious effects on wound healing. If tissue edema progresses unchecked, fluid pressure within the interstitial space can become greater than local capillary pressure. The resultant collapse of local microvasculature leads to a failure of perfusion, which inhibits healing potential and compromises tissue viability. Removal of localized edema by sub-atmospheric pressure therapy can enhance blood flow by improving this pressure gradient between the interstitial space and capillary system. Studies have demonstrated a four-fold increase in blood flow using topical negative pressure therapy at -125 mm Hg in a porcine wound model² (*using the intermittend mode - comment by the editor*). Increased dermal blood flow in burn wounds has also been demonstrated with the use of topical sub-atmospheric pressure³.

Vascular density is simply the ratio of the number of vessels per volume of perfused tissue. Areas of the body with higher vascular density tend to heal better and faster due to an increased ability to provide the tissue with needed nutrients, fight local infectious processes with scavenger cells, and modulate the flux of inflammatory mediators and cytokines. The importance of vascular density is evidenced clinically when observing that wounds of the face heal more rapidly than those of the extremities. This is largely due to the superior

capillary density of facial tissue.

It is clear that interstitial edema negatively affects the vascular density of a wound bed. An increase in fluid volume in a given region secondary to an inflammatory response coupled with a constant vascular supply, by definition, results in a decrease in vascular density (Fig. B8.1). In other words, when edema develops, a given number of capillaries become responsible for supplying nutrition to a greater volume of tissue. This negatively impacts the affected area's healing potential. Removal of this excess fluid would return the vascular density to its original ideal physiologic state. This is one of the mechanisms by which use of vacuum therapy dressing may promote burn wound healing.

Inflammatory Control

In addition to promoting removal of excess fluid with restoration of a healthy interstitial fluid gradient, sub-atmospheric pressure therapy may also serve to remove pro-inflammatory mediators from the wound bed. Although beneficial at the time of acute injury for initial cellular debridement and phagocytic activity, inflammatory response cells can negatively impact long term healing if they are not cleared from the wound bed. Many cytokines, chemokines, proteolytic enzymes and acute phase proteins found in wound fluid and serum are actually inhibitory to wound healing. Collagenolytic enzymes including matrix metalloproteinases (MMPs) are effective for clearing the extracellular matrix space needed for the creation of new vasculature during the angiogenic phase of healing. But neutrophils and other sources of inflammatory mediators are designed to undergo apoptosis and the proteolytic enzymes are intended for quick clearance. Residual activity becomes detrimental to the normal anabolic nature of wound healing. These enzymes, which are found in high concentrations in chronic, non-healing wounds, have been shown to be effectively removed from wounds with the use of sub-atmospheric pressure⁴.

Infection Control

Burn wounds, by their nature, are especially prone to infection. The loss of skin integrity, which is the body's greatest natural defense against infectious invasion, is compromised in all burn injuries. Controlling the

local environment of burn wounds by both preventing further contamination and eliminating existing pathogens is critical to effective healing. Vacuum therapy accomplishes these goals in several ways. First, as an occlusive dressing, it prevents external bacterial contamination. Second, the increased blood flow to the wound elicited by topical negative pressure, the removal of cellular debris and reduction in edema serve to decrease the potential for infection. Animal studies have demonstrated log factor decreases in wound bacterial concentrations over time with topical negative pressure². This technique allows the wound to be optimally clean with a bacterial count below 10^3 bacteria per gram of tissue. Recently developed foams coated with silver are now available which may further control the growth of bacteria in the wound and be indicated for the treatment of burns.

Cellular Response

Compression of the vacuum therapy foam results in deformation of the underlying tissue cells surrounding the wound. On a microscopic level, small blebs of tissue are pulled into the pore spaces within the sponge. There is a direct effect on cellular mitotic activity mediated by mechanical stress at the foam-tissue interface. Cellular deformation creates changes in molecular pathway stimulation, mitosis regulation, ion transport, second messenger release, protein synthesis control, and fibroblast activity³. Several studies have demonstrated cellular promotion of angiogenesis^{6,7,8}. Specific gene groups important for tissue growth and cell proliferation have been shown to be upregulated. The altered activity of gene products, including MAP kinases, IL-6, CDK4, immediate early protein, and IL-enhancer binding protein lead to increased fibroblast activity and collagen turnover. Tissue growth factors including TGFB-1 and VEGF expression have likewise been shown to be enhanced⁹. Each of these processes has been implicated in the improvement of wound healing seen with topical negative pressure therapy^{10,11,12}. For further details, see Part A, Chapter 6 "Experimental Basis I - Review of the Literature".

Clinical Indications in Burn Care

Skin Grafting

The success or "take" of a skin graft depends upon its ability to survive several phases of healing and maturation.

Initially, the graft must adhere to recipient tissue via the anchoring properties of a thin fibrin network that stabilizes the graft as definitive revascularization occurs. For the first two to three days, the graft undergoes "plasmatic imbibition" in which recipient bed transudate is absorbed by capillary action into the grafted dermal blood vessels. Success in this time period ensures graft vessel patency, adequate graft nourishment, and prevention of desiccation. It is critical for assuring graft survival during this time to prevent shearing forces, infection, or accumulation of fluid between the graft and wound bed. If the graft avoids mechanical disruption, true neovascularization develops over the next three to four days. This occurs by the establishment of new vascular connections between the graft and the recipient wound bed. Furthermore, new capillary in-growth provides a definitive blood supply and assures graft survival.

The importance of preventing graft dislocation, especially during revascularization, has been well known and historically addressed with compression dressings and tie-over bolsters. Ideally, constant and uniform tension and pressure over a skin graft provides the best environment to optimize successful take. Unfortunately, the irregular surfaces of many burn wounds appropriate for skin grafting make bolster and pressure dressings difficult to apply and unreliable. Hand burns, for example, are particularly difficult to treat with bolstering as even distribution of pressure over all areas of the graft often is impossible. Motion of the patient of any sort can also result in sheer forces that compromise the graft take. Vacuum therapy dressing resolves the issue of applying uniform pressure and assures positive contact by providing continuous, uniform, subatmospheric pressure to a graft even with irregular overlying surfaces. This safeguard against shearing and dislocation allows the revascularization process to proceed undisturbed^{13,14,15}. Multiple studies have demonstrated excellent graft take when the vacuum therapy is used in conjunction with skin grafting^{13,14,15,16}. For further details, see Part B, Chapter 9 "Vacuum Therapy Technique in Alloplastic and Auto-logous Tissue Transfer in Burn Patients".

Use of vacuum therapy dressing with skin grafts also has the advantage of automatically splinting mobile areas such as the hands, feet, axilla and perineum. When the vacuum is applied to the foam, the sealed system conforms perfectly to the underlying wound bed and becomes stiff. The stiffness is a result of transmural pressure.

ure on the sponge, usually at approximately one-sixth of an atmosphere. When multiplied by the area of the foam, these pressure forces become quite large. Movement of the involved area becomes difficult and this allows for effective splinting. This is another mechanism by which the dressing helps to minimize graft loss in mobile areas.

In addition to the avoidance of shearing forces and prevention of intervening fluid accumulation, protection against bacterial contamination is critical to graft survival. Use of vacuum therapy to secure skin grafts also addresses these issues. As mentioned earlier, the vacuum therapy dressing itself is an occlusive dressing, which primarily protects against bacterial contamination. Moreover, the continuous removal of wound fluid minimizes seroma and hematoma formation and thereby secondarily eliminates a potential substrate for bacterial growth. Again, the elimination of interposed fluid collections ensures optimal contact between graft and recipient surfaces and allows both the dermal and vascular connections to develop uninterrupted.

Integra®

Bioartificial skin substitutes including Integra® (Integra Life Sciences, Plainsboro, NJ, USA) have been described as a temporary alternative to classic autograft or soft tissue coverage in difficult wound beds. Integra is a bilayer collagen template that can be applied to wounds with exposed bone, joint, or tendon. These defects formerly required coverage with vascularized flaps to ensure effective healing due to the compromised nature of their blood supply and propensity for bacterial contamination. Integra® effectively covers these wounds and functions as an epidermal substitute until the dermal matrix becomes adequately vascularized. Once this is accomplished, the outer silicone layer can be removed and traditional skin grafting can be applied to the neodermis with excellent results. Colonization of the Integra® usually takes 14-20 days during which time the matrix is at risk for failure. As with skin grafting, the success and viability of Integra is directly related to prevention of hematoma and seroma formation, elimination of shear forces and protection against infection. Vacuum therapy has been shown to enhance engraftment with Integra® by accelerating vascularization and improving the take rate¹⁷. The creation of multiple small perforations in the silicone sheet allows the overlying vacuum therapy foam to remove fluid, improve approximation to underlying tissue, and more rapidly facilitate colonization of the ma-

trix. Functional cellular and vascular colonization usually occurs in seven days compared to the previously reported two to four weeks. A skin graft can then be applied to the vascularized matrix and secured with a vacuum therapy device. Success with this technique has been excellent.

The use of Integra® has application in burn management for both the acute treatment of full thickness burns as well as the reconstructive treatment of wounds that have developed burn-scar contracture. Full thickness burns can involve tissue depths that require excision of non-viable tissue with the resultant exposure of tendons, cartilage, and occasionally bone. The use of Integra® is suited for preparing these wounds for future grafting procedures. Similarly, burn scar contractures often require deep tissue excision during operative scar release. The use of Integra® has been gaining in popularity as an adjuvant therapy in these wounds¹⁸. Clinical impressions at our institution suggest that hypertrophic scarring and contracture is inhibited in skin grafts overlying Integra® treated wounds, making it particularly useful in the treatment of burn scar contracture.

Acute Burn Coverage

A particularly difficult aspect in the treatment of burn injury is assessing and controlling the progression of the burn wound. Often, burns assessed to be partial thickness at the time of injury are observed to progress with time to involve deeper tissue layers even to the point of becoming full thickness lesions. Clearly, controlling or preventing the phenomenon of burn wound progression is beneficial in minimizing morbidity. Several factors known to be involved include avoiding malnutrition and sepsis, prevention of mechanical and chemical trauma, and removing surface debris. More important may be the optimization of fluid resuscitation and maintenance of systemic and local vascular perfusion.

As described above, the application of sub-atmospheric pressure treatment to chronic and acute wounds has been shown to improve vascularization, decrease edema, improve vascular flow, minimize bacterial counts and speed vascularization of regenerative constructs^{19,20}. The same factors appear to be involved in the treatment of burn injuries. Morykwas et al. demonstrated in a burn wound model that sub-atmospheric pressure treatment minimized tissue damage and appeared to slow the phenomenon of burn wound progression¹³.

Increased edema of a wound including that second-

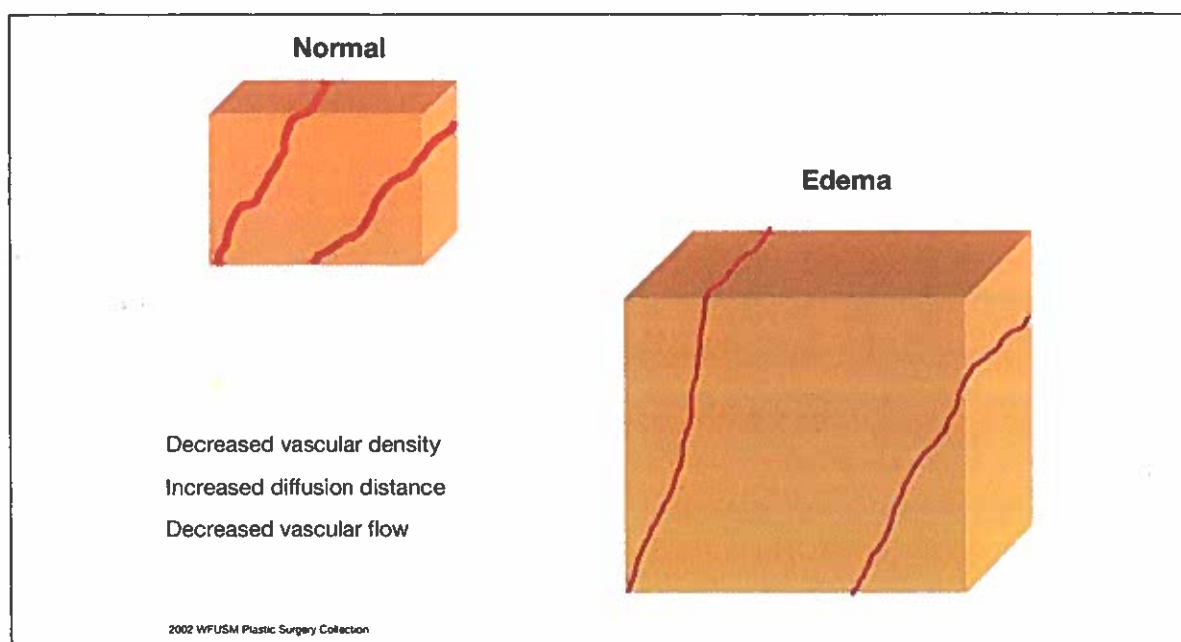


Fig. B8.1 Vascular density changes with burn injury and subsequent edema progression. As interstitial fluid volume increases with edema, the existing vasculature supplies an increasing volume of tissue. Diffusion distances are increased and the relative vascular flow is compromised.

ary to burn injury indicates decreased vascular density, increased diffusion distances, and, ultimately, decreased blood flow (Fig. B8.1). Clearly, minimizing edema should aid tissue perfusion and help optimize cellular metabolism in the wound, thus decreasing the risk of burn wound progression. In addition, decreased edema may indicate decreased stasis of interstitial fluid. Improved flux of interstitial fluid may promote removal of harmful inflammatory mediators and byproducts of cellular metabolism, thus disrupting the cycle of tissue damage. Clinical application of subatmospheric pressure to acute burn wounds has been demonstrated to minimize edema in burned hands²¹. The resultant acceleration of healing is clearly another advantage of vacuum therapy (Fig. B8.3-8).

Epithelialization of the burn wound is a definitive endpoint in the management of this injury. Even the process of skin grafting is nothing more than placing a layer of epithelial cells on the excised wound. The exact mechanism by which sub-atmospheric pressure speeds epithelialization is unknown. Perhaps, it is a combination of multiple factors including decreased edema, increased blood flow, removal of harmful inflammatory mediators and promotion of an optimal wound environment with minimal debris and optimal moisture.

Rhabdomyolysis with Electrical Injury and Deep Thermal Burns

Rhabdomyolysis is a skeletal muscle injury that leads to the release of intracellular contents into the interstitial space of injured tissue. The release of these contents, which include myoglobin, potassium, phosphate, and creatine kinase, may cause further fluid shifts due to altered osmotic gradients, with possible subsequent development of a compartment syndrome. Released myoglobin eventually reaches the systemic circulation and can lead to acute renal failure in some patients. Rhabdomyolysis has a variety of etiologic factors including crush injury, electrical injury, and even deep thermal burns.

The proposed mechanisms thought to cause the acute renal failure seen with rhabdomyolysis are interrelated. Renal vasoconstriction secondary to fluid shifts and volume depletion decreases glomerular filtration and can lead to ischemic tubule damage. Myoglobin precipitation within the distal tubules can lead to cast formation with resultant obstructive damage and myoglobin uptake has been shown to result in direct cytotoxic effects within the proximal tubule system.

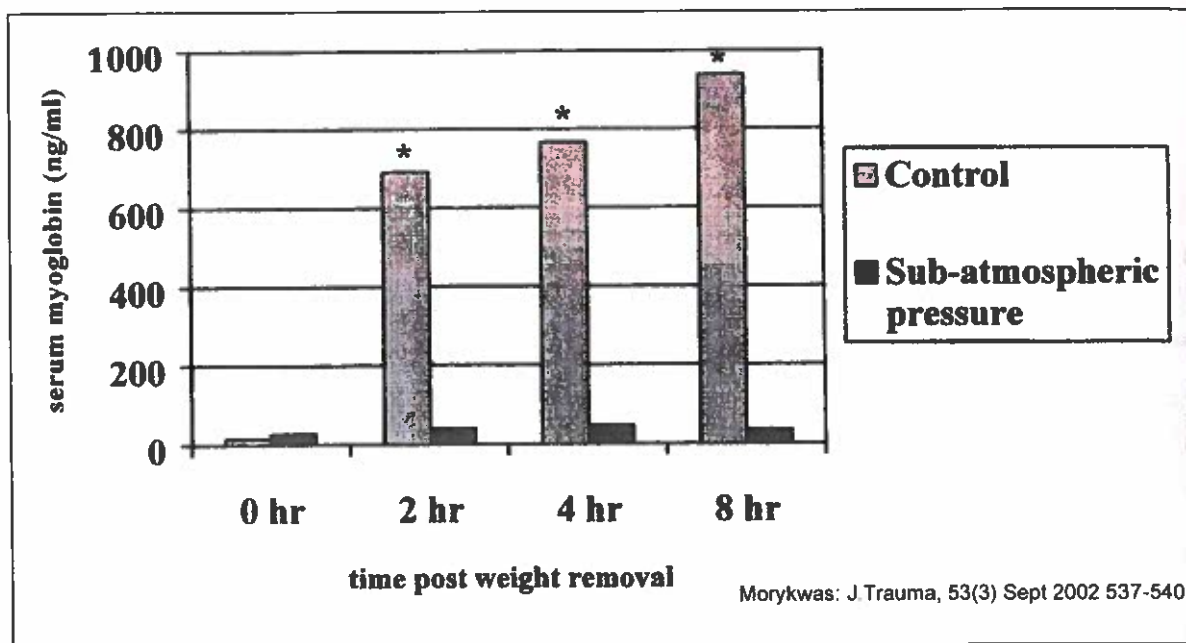


Fig. B8.2 Mean serum myoglobin levels after removal of a 15-kg weight from the posterior compartment of the rabbit hind limb. Serum myoglobin levels are statistically significantly higher (* $p < 0.01$) for the untreated, control animals at two, four and eight hours after weight removal. From: Morykwas: *J Trauma*, Volume 53(3), September 2002, 537-540.

Traditional treatments for developing rhabdomyolysis include volume restoration and attempts to remove myoglobin from the systemic circulation. Urine alkalinisation with bicarbonate and treatment with mannitol diuresis help to remove the heme product and minimize cast formation in the distal tubules. A more effective mechanism to prevent renal injury has been seen with the vacuum therapy as it has been shown to remove myoglobin at the site of injury, thus limiting the amount of myoglobin that ever reaches the renal system. Morykwas et al. describe a 10-fold decrease in serum myoglobin levels seen with crush injury in an animal model by using the vacuum therapy at the injury site²² as illustrated in Figure B8.2. Patients with significant electrical injury or deep thermal burns requiring fasciotomies for developing compartment syndrome are at risk for the development of rhabdomyolysis and subsequent renal failure. Application of the vacuum therapy may be effective in reducing the risk of renal injury by reducing serum myoglobin levels.

Technical Remarks

Interposition of Non-Adherent Dressings

The use of vacuum therapy for the fixation of skin grafts is well described (see Fig. B8.9-12). However, placement of the foam dressing directly onto a skin graft or skin substitute will invariably lead to a dilemma when the dressing is to be removed. The grafted tissue becomes adherent to the dressing as blebs of tissue are pulled into the micropores of the foam. Removal of the foam results in disruption of the graft from the wound bed. To prevent this unwelcome complication, a non-adherent dressing should be placed over the grafted tissue prior to sponge coverage. A layer of Adaptic® non-adhering dressing (Johnson and Johnson, New Brunswick, NJ, USA) or silicone-coated Mepitel® (Molnlycke Health Care, Göteborg, Sweden) can be placed freely or fixed with staples over the graft for this use. Alternatively, one may use the white, polyvinyl alcohol foam which is inherently less adherent to tissues than the black polyurethane foam.

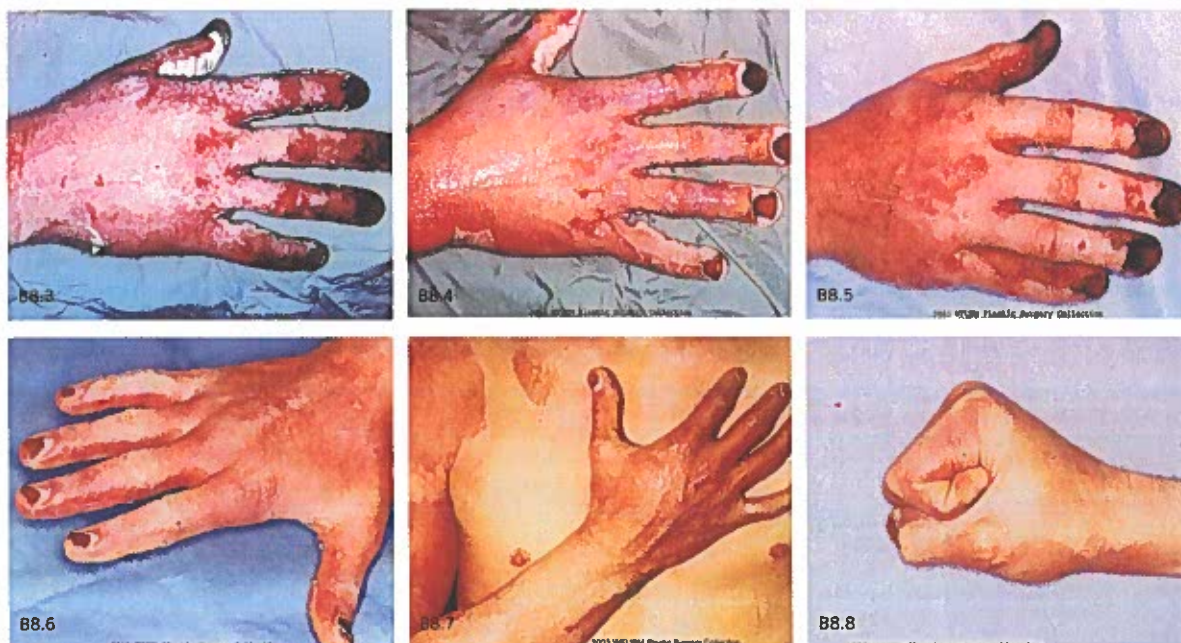


Fig. B8.3-8 Acute burn injury treated with vacuum therapy. Deep burns of the hand were treated with serial vacuum therapy changes with good results of both form and function. In this case, the need for grafting was eliminated by the excellent response to the negative pressure therapy.

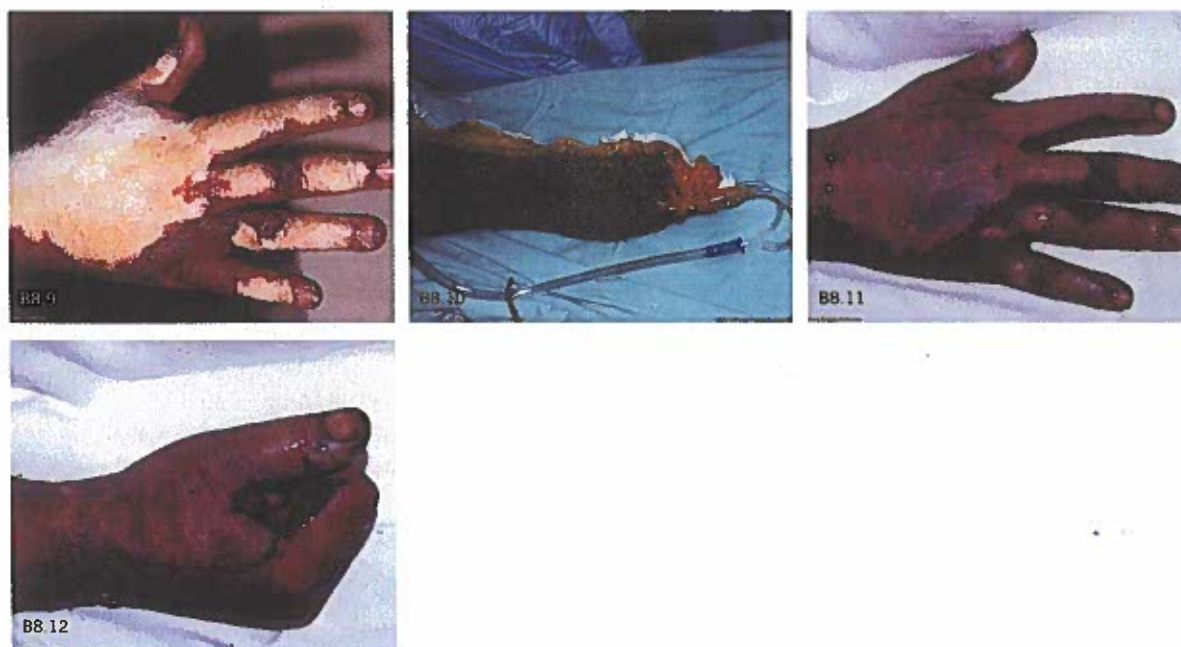


Fig. B8.9-12 Full thickness hand burn treated with excision and split thickness sheet grafting. Vacuum therapy was used to improve graft take by limiting shear forces, removing wound fluid, and providing bacterial protection. The vacuum therapy dressing was removed on post-operative day four.

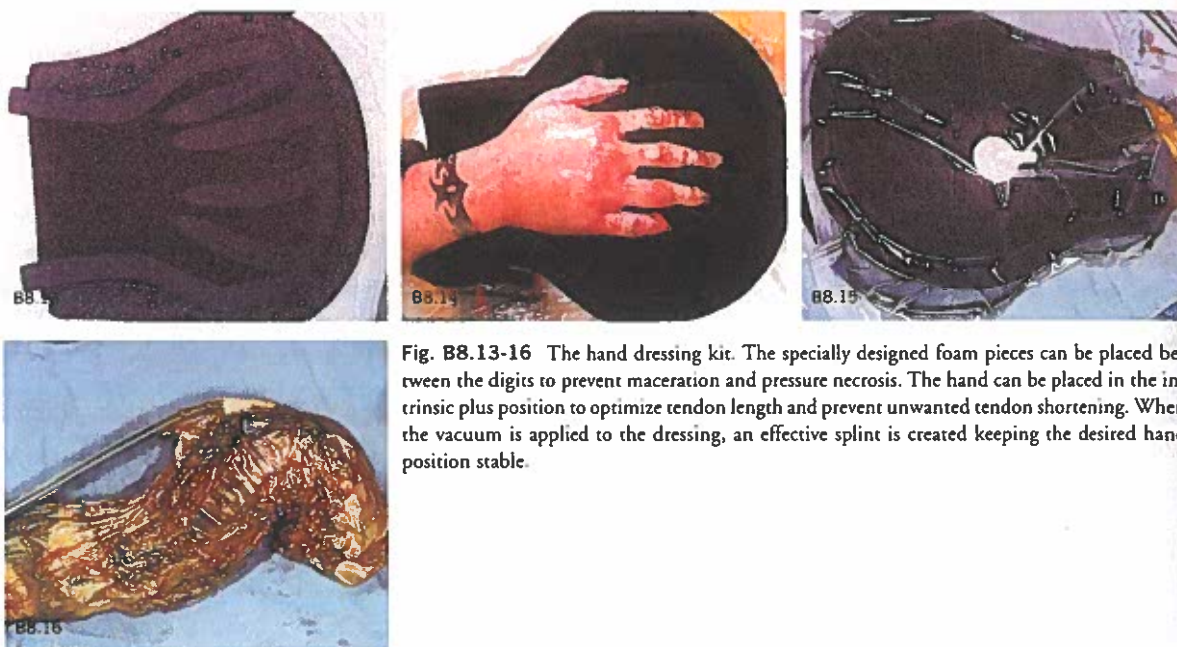


Fig. B8.13-16 The hand dressing kit. The specially designed foam pieces can be placed between the digits to prevent maceration and pressure necrosis. The hand can be placed in the intrinsic plus position to optimize tendon length and prevent unwanted tendon shortening. When the vacuum is applied to the dressing, an effective splint is created keeping the desired hand position stable.

Hand Dressing Kit

As previously mentioned, hand burns are often difficult to treat with bolstered skin grafts due to their irregular surface and difficulty in obtaining uniform pressure across the wound. Traditional vacuum therapy sponges are similarly difficult to use for graft fixation as obtaining an airtight seal with the adhesive drape is precarious. A specially developed foam is available for the use in hand wounds (Fig. B8.13-16) that minimizes the difficulty in obtaining the seal needed for topical negative pressure therapy. This hand-dressing kit not only assists in graft fixation, but can also serve, in part, as a splinting device. The hand can be positioned appropriately before the suction pressure is applied, usually in the intrinsic plus position. Once the negative pressure is applied, the foam molds to the hand surface and freezes its position. An effective splint is maintained as long as the negative pressure is provided. Care must be taken when transporting patients or in cases when the negative pressure is lost. The hand needs to be repositioned in the desired orientation prior to application of the negative pressure to avoid the development of tendon shortening, contracture, or skin maceration due to overlapping digits or damage to the extensor surface tissues due to hyperflexion at the interphalangeal joints. We attempt to routinely place the hand in the intrinsic plus position taking care to place foam between the digits and to avoid fle-

xion at the interphalangeal joints. This position not only avoids tissue damage but also maximizes stretch on the joint ligamentous structures to maximize functional outcome postoperatively.

Y-Connectors

Often, burn injuries involve multiple limbs or skin areas. A connecting adapter is available for the vacuum therapy dressing system. This allows the consolidation of separate foam and tubing systems while only requiring the use of a single vacuum pump device. Each of the connected foams is subject to the same negative pressure created by the pump since the connection is provided in a parallel fashion. Concerns about sub-optimal negative pressure being applied to any of the individual wound sites can be allayed.

When dealing with multiple site injuries treated simultaneously with separate vacuum therapy foams, it is often beneficial to consolidate the sub-systems with a Y-connector. Doing so can reduce treatment costs by eliminating the need for multiple vacuum pumps. More importantly, patient mobility can be significantly enhanced. Ambulating with a single vacuum therapy system is possible, but mobility limitations associated with being fixed to more than one pump unit can be quite burdensome. The only concern when using a Y-connected system arises when maintaining the seal on any of the

individual wound locations is thought to be questionable or of concern. If any of the individual seals is lost, then the seal is lost for all the components of the system. This can make troubleshooting seal problems challenging. Areas prone to difficult seal include the perineum, perianal skin, hair bearing skin, and wounds with deep skin folds. It is often more judicious to use multiple vacuum pumps in such situations to avoid the risk of losing the vacuum seal in more than one wound area and to simplify troubleshooting seal issues should they arise.

Length of Vacuum Therapy

Skin grafts treated with vacuum therapy at our facility have shown excellent take rates and success after subatmospheric pressure therapy durations of four days. Clinical judgment often plays a role in deciding the exact time of vacuum therapy foam removal based on the nature of the wound bed and clinical suspicion of possible complications. As a rule, skin grafts can be safely treated with vacuum therapy for three to five days with good results. Earlier removal can increase the risk of graft shearing and jeopardizes the revascularization process. Treatment for more than five days can result in unwanted adherence of the foam to the grafted material despite interposed non-adherent dressings.

Vacuum therapy dressing on wounds treated with Integra® is routinely removed after six to nine days. This time period allows for adequate colonization of the dermal layer onto the wound bed after which the silicone

layer can be removed and covered with a split thickness skin graft. Leaving the vacuum therapy foam in place for longer time periods increases the risk of adjacent skin maceration and impregnation of the foam into the soft tissue.

Intermittent *versus* Continuous Suction

The vacuum therapy system can be used in both continuous and intermittent pressure modes. Morykwas showed that, compared with continuous negative pressure application, the intermittent application of subatmospheric pressure actually results in a repetitive release of second messengers with a greater resultant stimulation of granulation tissue formation in wounds³³. This is thought to be secondary to greater protein and matrix molecule synthesis as a result of an increased cellular response to cell shape deformation as described above. However, in some patients, there appears to be greater discomfort related to the on-and-off nature of the intermittent mode of therapy. Often, the initial application of the negative pressure provides a momentary sense of discomfort that quickly subsides when a pressure equilibrium is established. From this standpoint, the continuous mode of therapy is often more patient friendly. Also, in cases of skin grafting and bioartificial skin substitute coverage, the intermittent mode of therapy increases the risk of graft shearing when the vacuum pressure is not applied to the foam. At our institution, we use the continuous mode of therapy for all such patients.

Current research shows promise for the use of subatmospheric pressure therapy in the acute treatment of burn injuries as both a means of accelerating epithelialization and of minimizing burn wound progression. Particularly in electrical injury and deep thermal burns, application of the vacuum therapy may be effective in reducing the risk of renal failure by reducing serum myoglobin levels in case of rhabdomyolysis.

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Part B / Chapter 9

Vacuum Therapy Technique in Alloplastic and Autologous Tissue Transfer in Burn Patients

H. Schwarze, A. Schönborn and B. Hartmann

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This review evaluates the significance of vacuum therapy and its application to alloplastic and autologous tissue transfer. A survey of available studies published in *peer-reviewed* journals revealed that vacuum therapy, with its excellent graft immobilization, plays an important role in the fixation of both split-thickness skin grafts (31 studies) and Integra® (five literature reports). In fact, findings show that fixation is possible even on irregular surfaces and that patients do not require additional dressings for immobilization. However, only three of the total 36 publications are characterized by an increased level of evidence (1b, two studies; 3b, one study; Oxford Center Classification).

Introduction

In plastic reconstructive surgery, wound closure follows the "concept of escalation" starting with secondary wound healing and skin grafting up to reconstruction with free flaps and microvascular anastomoses. Surgical planning takes into account defect size, depth, and localization. Furthermore, successful defect closure should be performed as soon as possible with the goal of permanent closure and best possible functional and aesthetic results¹.

A skin graft is defined as a segment of epidermis and dermis completely elevated and separated from its underlying structures (donor site) and transferred to another anatomical area of the human body (recipient site). A split-thickness skin graft consists of full epidermal and partial dermal layers. Depending on the thickness, split-thickness skin grafts are classified into thin (0.2 mm), medium (0.4 mm), and thick (0.6 mm) grafts. Thin split-thickness skin grafts were first introduced by L. Ollier, a French surgeon², whose technique was subsequently modified by the German surgeon C. Thiersch (1822-1895), resulting in the so-called Ollier-Thiersch technique. With this technique, certain layers of the basal membrane are incorporated into the graft inducing rapid reepithelialization (10 days) of the donor site. Donor sites of 0.4 mm split thickness skin grafts (Blair-Brown technique) reepithelialize from hair roots and sebaceous glands within a period of 14 days. Reepithelialization of thick split-thickness skin grafts is induced by epithelial hair bulbs and sweat glands and takes 10-14 days. Full thickness skin grafts described by Wolfe-Krause range from 0.8 to 1.5 mm and comprise the entire skin. Donor sites that cannot reepithelialize by themselves are primarily closed by adaptation of wound edges.

During the first five days after grafting, skin grafts at the recipient site are exclusively nourished and supported either by diffusion (plasmatic imbibition) or by coincidental anastomoses between graft and recipient vessels (inosculation). The skin-supporting arterial vascular system is located between dermal and subcutaneous fat tissue. Vessels of this arterial system run into the subcutaneous fat tissue, as well as into hair follicles and sweat glands, and towards the epidermis. Vessels running towards the epidermis form another vascular network, the so-called subpapillary plexus. This plexus is located at the cross-section of the papillary and rete ridges, where capillary loops originate from connective tissue papillae. In contrast, the venous vascular system forms a less

distinct network, and it is located in the midst of the rete ridges³. Therefore, the vascular pattern of each graft is determined by its thickness.

Successful skin grafting depends on the capacity to form vascular anastomoses between the graft and the recipient wound bed. Because full-thickness skin grafts have a fully intact vascular structure including the entire horizontal vascular network previously described, these grafts have more difficulty than do thin split-thickness skin grafts in overcoming the early period (two to five days) of grafting until sufficient vascular formation is achieved. This is due in part to the larger amount of biological material, which, in the early period, has to be nourished by simple diffusion⁴. However, thick split-thickness skin grafts also generally have more difficulty reintegrating because, mechanically, they are more resilient, resensitize better, and show a lower degree of secondary contracture.

During the period of revascularization, the entire skin graft requires direct and permanent contact with the recipient wound bed in order not to jeopardize the process of recapillarization. In order to avoid graft shifting by shear forces and the collection of blood and wound fluid that might lead to graft failure, it is common to secure skin grafts by so-called tie-over bolster dressings. This becomes especially important when dealing with uneven surfaces, with severe wound exudation, and with areas of exposure to constant movement. Other options for securing skin grafts include the use of fibrin glue, silicone rubber dressings, and self-adherent films^{5,6,7,8}. Regular bolster dressings require a certain amount of experience and adequate skill, and have several disadvantages: the dressings' pressure is not evenly applied to the entire wound bed and hematomas and seromas cannot be detected.

Fixation of Skin Grafts by Means of Vacuum Therapy

It seemed logical to attempt to secure skin grafts at difficult recipient sites using the vacuum therapy, which entails placement of a foam on top of the graft^{9,10}. In this way the entire graft is fully attached to the recipient wound bed independent of any surface irregularities. In addition, the vacuum therapy system minimizes the risk of graft shifting and the development of hematomas or seromas, reduces the risk of infection by decreasing bacterial loads, and improves blood circulation by stimu-

lating blood flow within the recipient wound bed^{11,12}. Because the sponge's soft texture allows easy adaptation to any movement, additional immobilization by plaster casts is not necessary. Thus, physiotherapy can be started very early, and the disadvantages of complete immobilization can be avoided⁹. Outpatient treatment is feasible using the so-called VAC^{Freedom} system, a very small pocket unit.

Technique of Graft Fixation

Vacuum sealing of split-thickness skin-grafted recipient sites is performed in the following manner. Prior to transfer the harvested skin graft is either scarified (full-thickness skin graft) or prepared as meshed graft 1:1.5 (split-thickness skin graft). This allows good drainage of wound exudation. After graft placement and stapling, a non-adherent gauze (Jelonet®) exactly corresponding to the graft size is placed on top of the skin graft. Then, the gauze is covered with the foam and finally sealed with a self-adhesive drape overlapping the defect. To avoid maceration of the surrounding skin it is important that the foam size correspond exactly to the wound bed. In our department we prefer black polyurethane foams (pore size 400-2000 µm) instead of white polyvinyl alcohol foams (pore size 0.7-1.5 mm). Compared to white foams, the black foam initiates denser formation of granulation tissue. However, in meshed skin grafts, this could result in a more "pebbled" appearance. To minimize this effect the foam should be removed or changed after five days. If necessary, the foam itself can be stapled with clips. In case of larger wound beds with skin grafts, full defect coverage can be achieved by placing several foams side by side. In our opinion a pressure of 75-100 mmHg seems to be sufficient. It is important that the vacuum is not interrupted at any

time during the first five days after sponge placement and initiation of negative pressure treatment with the vacuum therapy system. In our department, we regularly use the vacuum therapy system when dealing with skin grafts on difficult recipient sites. Furthermore, this technique can be applied to any acute or chronic wound as well as to any burn wound. Its reliability has been proven especially in areas where skin grafts are exposed to shear forces, such as the trunk, axilla, upper and lower extremities (Figs. B 9.1-3).

In cases of deeper burn wounds that require surgical treatment down to the adipose tissue immediate grafting is often not possible. In these cases formation of a thin, well-vascularized tissue layer can be initiated by first applying vacuum therapy. The thin tissue layer then represents a good wound bed for grafting.

Efficient vacuum therapy has also been reported for treatment of superficial and deep dermal burn wounds of hands. In such cases, the application of the polyurethane hand dressing kit has been successful. It has been possible to significantly reduce burn progression and the number of surgical interventions by negative pressure therapy¹³. A more detailed description of this technique is presented in Part B, Chapter 7.

Numerous studies have confirmed these observations. To date, 31 reports appearing in *peer-reviewed* journals have addressed the topic of skin-graft fixation: in general, these reports have supported the advantages of vacuum therapy. However, it should be noted that, in 29 of these 31 reports, the level of evidence is 4 or 5 (case series or case reports). In two studies (level of evidence 1b [n = 22 *versus* 22, intra-individual comparison], and level of evidence 3b [n = 34 *versus* 27, case-control study]) it has been demonstrated that patients treated with vacuum therapy less often required secondary split-thick-

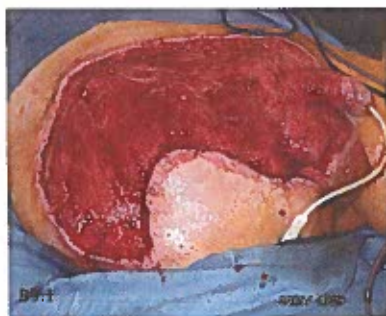


Fig. B9.1 48-year old patient after crush trauma: soft tissue defect at the lower abdomen including genitals after debridement.

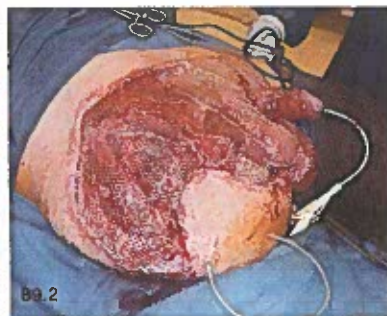


Fig. B9.2 Split thickness skin graft (Mesh 1:1.5, scarified sheets at the penis) of defect.



Fig. B9.3 V.A.C. fixation of split thickness skin graft at difficult anatomical area.

ness skin grafting¹⁴, while, in half of the patients, the incorporated graft showed a superior quality¹⁵. For additional recent information see Part B, Chapter 27.

Vacuum Therapy and the Dermis Equivalent Integra®

Integra® dermal regeneration template is a bilayer membrane system consisting of a synthetic top layer that represents the epidermal part of the skin and a deeper layer, representing the dermis. This system permits reconstitution of a skin equivalent with physiological properties that control fluid loss and act as a barrier against superinfection ("epidermis"), while at the same time offering resistance and elasticity ("dermis"). The top layer consists of a polysiloxane polymer film 0.1 mm in thickness, which controls fluid and gas exchange from the dermis, similar to normal epidermis. The layer is applied in liquid form on the extracellular matrix in order to obtain firm bonding between the two components, thus constituting a veritable "artificial skin". The dermal layer is 2 mm thick and consists of a combination of bovine collagen 1 and glycosaminoglycan (chondroitin-6-sulfate) cross-links with glutaraldehyde. A pore size of 50-150 µm promotes cellular in-growth, followed by gradual biodegradation of the template by recipient fibroblasts^{16,17}. Fourteen to 21 days after Integra® application the neo-dermis can be covered with a thin split thickness skin graft.

The use of Integra® in the treatment of deep burn wounds was first reported by Burke and Yannas¹⁸. It offers a better dermal regeneration with a significantly reduced development of scar tissue^{17,19}. With its slogan, "epidermis is life, dermis is quality of life," Integra® has been successfully used worldwide in more than 10,000 patients. It received FDA approval in 1996 and EU approval in 1998. The published clinical data about Integra® supports excellent long-term results. Integra® is applied in many primary and secondary burn surgery cases, and in the field of reconstructive surgery²⁰⁻²⁵.

Integra® Fixation by Vacuum Therapy

The successful use of Integra® requires a certain learning curve. The key to its success is solid fixation on clean, non-infected recipient sites. Similar to skin grafts, bolster dressings can aid in the fixation of Integra®. However, when dealing with defects of extremities the use of plaster casts is recommended. Vacuum therapy guarantees a solid and secure contact between Integra®

and the recipient wound bed. The constant drainage of wound fluid minimizes the risk of infection and leads to perfect adaptation of the inserted foam, including areas with uneven surfaces such as the axilla. The development of seromas and hematomas beneath Integra® is avoided by constant pressure and this clearly improves the graft's take rate.

Preoperatively bacterial cultures from the recipient site are recommended to detect potential pathogens, especially hemolytic bacteria. If necessary, a topical antiseptic treatment, e.g. Lavasept® or Octenisept®, can be started. The surgical debridement of the wound bed with rigorous hemostasis is followed by precise insertion of Integra® into the defect (maximum overlap tolerance: 2-3 mm). In the field of acute burn surgery, Integra® has been used successfully after excision of necrotic tissue down to adipose tissue or muscle fascia. The dermis equivalent can be applied to both adipose tissue and to pre-conditioned wounds²⁶. Fixation is achieved by stapling, after which the site is covered with non-adherent dressing material (Jelonet®). A black PU foam with small pore size, corresponding in size to the Integra® template, is placed on top of the dressing and covered with a self-adhesive drape. In cases of larger defects, several foams can be positioned side by side to cover the whole wound bed. Finally, the drainage tube is placed with its *trac-pad connector* on top of the film. Integra® fixation is performed by applying continuous negative pressure of 125 mmHg. The first dressing change should be carried out after five to seven days, verifying that no infection has occurred. To avoid graft shifting or any graft damage through shear forces it is recommended to carefully loosen the foam from its wound bed. The new foam can again remain for another five to seven days. After full incorporation of Integra® final coverage and closure can be obtained with a thin split-thickness skin graft (0.2 mm) between the fourteenth and twentieth days after surgery. At this stage graft fixation will be so strong that recourse to conventional dressings is sufficient (Fig. B 9.4-7).

In our department patients are regularly treated with this new technique. A retrospective analysis revealed a significant reduction of healing period from 20 days without the vacuum therapy system (control group) to 14 days with the vacuum therapy system. Similar observations have been reported by others²⁷. To date, this clinical observation has only been explained hypothetically.

While seromas, hematomas and mechanical detachment can lead to treatment failure with Integra®, wound infection carries the highest risk of negative treatment outcome. In these cases the vacuum therapy system with its constant drainage leads to reduction of bacterial load, clearly contributing to treatment success.

The good results in our own field are supported by similar observations of other groups. However, there are only a few reports on clinical data and experience in the

literature. A review of the literature returns only five *peer-reviewed* articles²⁷⁻³¹: three case reports (evidence level 5), one case series (evidence level 4), and one RCT²⁷ (evidence level 1b; n = 6 in each case). The last-mentioned study also shows that vacuum therapy reduces the time between Integra® fixation and split-thickness skin grafting from 24 ± 3 days (regular therapy) to 10 ± 1 days ($p < 0.002$). Similarly, the take rate has increased from $78 \pm 8\%$ to $98 \pm 2\%$ ($p = 0.003$).



Fig. B9.4 Third-degree burn trauma through electric shock with electric burn mark at lower extremity.



Fig. B9.5 Wound excision and wound coverage with dermis equivalent Integra®. Stable fixation of Integra®-sheets by vacuum therapy.



Fig. B9.6 First change of dressings on 5th day after surgery. The Integra®-sheet sticks to the wound ground of the recipient site.



Fig. B9.7 Three months after final wound closure with split-thickness skin graft: Integra® grafting has induced the formation of neodermis which leads to complete defect healing within the skin layer.

Successful autologous and alloplastic tissue transfer and tissue replacement depends primarily on a constant, regular contact between graft and the entire recipient wound. Conventional dressing techniques for securing of skin grafts and for dermis equivalents like Integra® can be replaced by vacuum therapy. This is especially true for uneven surfaces and for areas exposed to constant movement carrying the increased risk of graft shifting. Vacuum therapy can counteract graft failure through reduction of shear forces, drainage of hematomas and seromas, reduction of bacterial loads as well as full and even graft adaptation to the entire wound bed. The combination treatment of the dermis equivalent Integra® together with vacuum therapy significantly reduces the overall period of healing. Sufficient fixation of split-thickness skin grafts can be achieved by applying a constant negative pressure of 75-100 mmHg, while fixation of Integra® is best achieved by applying a constant negative pressure of 125 mmHg.

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Part B / Chapter 10

The Enormous Effects of the “Tiny” Foams – Vacuum Therapy in Plastic and Reconstructive Paediatric Surgery

C. Schiestl

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The indication for using vacuum therapy in children differs in several key aspects from its application in adults. In children, the major emphasis is on fixating the artificial dermis and skin grafts, as well as treating severe soft tissue trauma. In this regard, vacuum therapy, as a fixation system, has enabled problem-free operations to be conducted even on very young children. This, in turn, means that the heightened risk of malignant transformation of a large-surface nevus can now be taken into account even in the early postnatal and infancy stages. Also in contrast to the situation in adults, postoperative wound infections are a rare indication. This is attributable to the fact that children are considerably less susceptible to infection as a complication of a fresh wound. These particular characteristics of children in the postnatal and infancy stages have yet to be considered in the international literature on vacuum therapy.

Introduction

We started utilizing vacuum therapy at the University Children's Hospital of Zurich, Switzerland in 2001. At that time, we, as paediatric surgeons, were confronted with an unusual case. It was a matter of a posttraumatic defect of the abdominal wall that spanned the entire breadth of the abdomen, together with an intestinal fistula. The adipose young boy was 11 years old and weighed 110 kg. As is so often the case, the clue – the key link. – came from nursing personnel. With the aid of vacuum therapy and only a single operation, the intestinal fistula had healed within two weeks' time and the abdominal wall was intact. We sensed that something was in the air.

In a second case, we were confronted with a monstrous hamartoma in the area of the right leg of an 11-month-old infant (case study 6). After complete surgical excision, a nearly circular defect developed down to the muscle fascia in the lower leg region. To cover the area, we used artificial dermis (Integra®) to build up a two-layer skin structure. After only 24 hours, we found that the bandage was permanently moist owing to an intense lymphatic flow from the wound. The result was an infection and rejection of the Integra®. With the aid of vacuum therapy, the artificial dermis, after renewed application, was able to heal without problem.

Within the space of only a few days, vacuum therapy had helped us out of very precarious situations with two children. Over the past three years, we have employed vacuum therapy in 92 cases of plastic-reconstructive surgery on children. As a consequence, it is clear that the indications for using vacuum therapy in paediatrics differ significantly from those in adults. In the children we treated, fixation of the artificial dermis and skin transplants as well as the treatment of severe soft tissue trauma were of prime importance.

Indications

Chronic Wounds

Although vacuum therapy has achieved broad acceptance in the treatment of chronic wounds in adult surgery, it remains rather rare in paediatrics. Chronic wounds are not very common in children, with the prominent exception of children suffering with spina bifida, where a common problem is poorly healing wounds in the area

of the debilitated lower extremities. In our total of 92 applications, vacuum therapy was employed in 14 cases of chronic wounds, ten of which were related to spina bifida. In four instances, vacuum therapy was used on newborns, who, because of their poor general condition, demonstrated retarded wound healing (Fig. B10.1-4).

Acute Wound Infections

Treatment of acute wound infections represents an indication for vacuum therapy in only about 7% of cases, making it a rare indication in comparison to its use in adult medicine. This is attributable to the fact that children are considerably less susceptible to infection as a complication of a fresh wound.

Soft Tissue Defects

The availability of vacuum therapy has put us in the position of being able to pretreat a large soft tissue defect over a longer period of time so that coverage with a two-layer artificial dermis can be promoted without an increased risk of infection. This means that vacuum therapy can be employed in all three phases of tissue reconstruction. During the first phase, the wound is cleansed for 1-2 weeks and prepared for the artificial dermis. Subsequently, the Integra® is implanted and securely affixed under utilization of the vacuum therapy system. Finally, after approximately two to three weeks, once the body's own neodermis has developed from the artificial dermis, an extremely thin epidermal graft is made and it, in turn, is also affixed with the aid of the vacuum therapy system.

Within the scope of treating soft tissue defects, we employed vacuum therapy on 22 children. *"How did we actually do it in the old days without vacuum therapy?"* During the past three years, this question has been heard many times at our clinic, mostly in connection with large-surface traumatic soft-tissue defects. The answer is that, before vacuum therapy, we had less time to close the wounds. However, the procedures for covering an extensive soft tissue defect have become more sophisticated and time-consuming in recent years as a result of the innovative products associated with tissue engineering. Needless to say, though, outcomes have improved. Especially in paediatric applications, vacuum therapy has afforded us the opportunity to employ new procedures that, without this treatment system, would have been very difficult to achieve.

Case Study 1

Fig. B10.1 Chronic wound after wound dehiscence in the ankle region, three weeks after extension of the Achilles tendon of a 7-year-old girl with spina bifida.



Fig. B10.2-3 After vacuum therapy for 10 days (125 mmHg/continuous mode), the wound over the Achilles' tendon has closed except for a small area that was usurped by the tendon itself.



Fig. B10.4 After six weeks, stable wound conditions around the Achilles' tendon. On the tenth day after starting use of vacuum therapy, the skin over the tendon was mobilized and shifted to cover the remaining defect.

Case Study 2

Fig. B10.5 Chronic wound after wound dehiscence in a premature baby in poor general condition, subsequent to a laparotomy performed due to necrotizing enterocolitis.

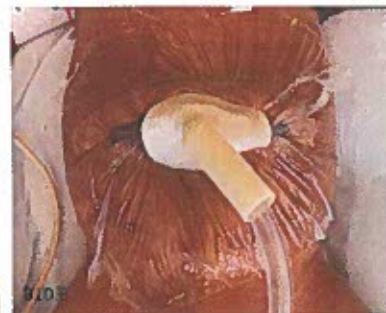


Fig. B10.6 Vacuum therapy was employed for seven days (125 mmHg/continuous).



Fig. B10.7 After seven days of vacuum therapy, the wound is sufficiently prepared for the secondary closure.

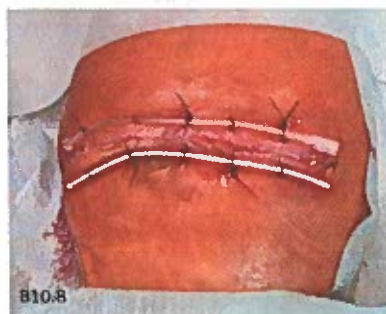


Fig. B10.8 Problem-free secondary closure of the wound following seven days of vacuum therapy. Complication-free course of further healing.

Case Study 3



Fig. B10.9-10 Severe lawnmower injury in the area of the left forefoot in a 5-year-old boy, with amputation of toes II through IV.

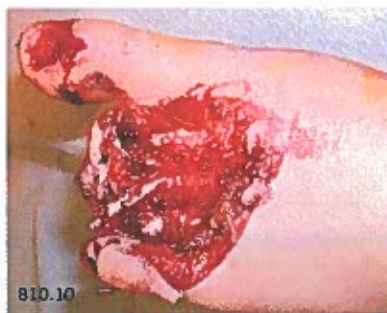


Fig. B10.11 Condition of the wound following debridement and marginal coverage of the defect using skin from the amputated toes.



Fig. B10.12 After five days of vacuum therapy, a significant filling of the defect has taken place in the area of the forefoot.



Fig. B10.13 After 14 days of vacuum therapy, the defect is ready for the epidermal graft.



Fig. B10.14 The same boy three months after the epidermal graft. The wound conditions are stable and the boy can walk normally without shoe inserts.

Fixation of Artificial Dermis and Skin Grafts

The younger they are, the greater children's innate urge to move around. One of the most difficult endeavours in the field of paediatric plastic and reconstructive surgery is to prevent that urge for a certain amount of time, in order, for example, to allow an extensive skin graft or artificial dermis to heal. In terms of large congenital nevi, this means that a large-scale reconstruction of the anomalous area through the use of artificial dermis (Integra®) and skin grafts, which is standard operating procedure at our clinic, may only be conducted at a point in time when the cooperation of the child can be counted on. On the other hand, there is, even in infancy and early childhood, an increased risk of malignant transformation associated with a large-surface nevus. In this regard, vacuum therapy as a fixation system has led to our ability to operate even on infants without incurring problems. Hence, the age at which the excision of a nevus can be conducted and covered by means of large-scale skin replacement procedures has been reduced significantly.

During the past three years, we have employed vacuum therapy in 50% of the cases ($n = 45$) to aid in the fixation of artificial dermis (Integra®) and skin grafts.

Case Study 4



Fig. B10.15 Large soft tissue defect in a seven-year-old girl following run-over trauma in the area of the right leg. The dislocated fracture of the femur was treated by means of external fixation.



Fig. B10.16 Coverage of the defect with vacuum therapy accoutrements.

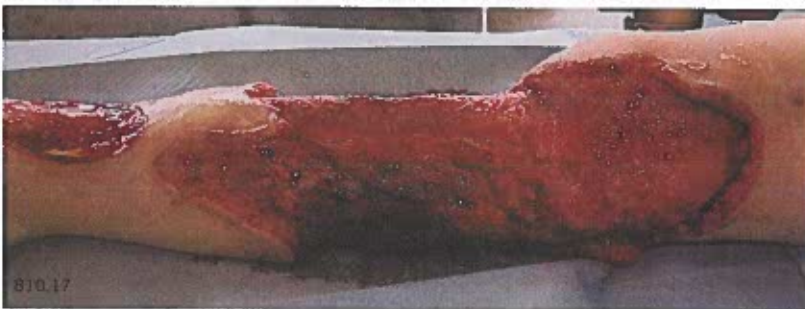


Fig. B10.17 Condition of the wound four days after the start of vacuum therapy.



Fig. B10.18 After 14 days of vacuum therapy, the wound has been prepared such that artificial dermis (Integra®) can be implanted.



Fig. B10.19 After a further three weeks, the defect has been filled by the neodermis that has evolved from the Integra®. For the entire three-week period, vacuum therapy served as a means of affixing the artificial dermis.



Fig. B10.20-23 Subsequent result after nine months. The skin in the area of the right leg is soft and pliable; the walking pattern of the child draws no attention.

Case Study 5



Fig. B10.24 Congenital nevus in the area of the right elbow in a three-year-old boy.

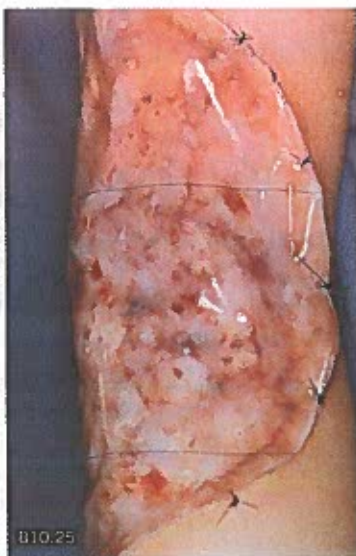


Fig. B10.25 The same boy after excision of the nevus down to the fascia and implantation of artificial dermis (Integra®). The shiny surface is attributable to the silicone layer that covers the Integra® for a three-week period. The rough fixation is accomplished with single-knot sutures placed in 2 cm intervals. The actual fixation occurs as a result of the vacuum therapy system.



Fig. B10.26 The artificial dermis (Integra®) is fixated by means of the vacuum therapy system.



Fig. B10.27 A neodermis has evolved from the Integra®. The silicone layer has already been removed.



Fig. B10.28-29 Subsequent result 12 months after the implantation of the artificial dermis (Integra®). The skin over the elbow joint is soft, very pliable and of uniform texture.



Case Study 6



Fig. B10.30 Monstrous hamartoma in the area of the right leg of an 11-month-old female infant.

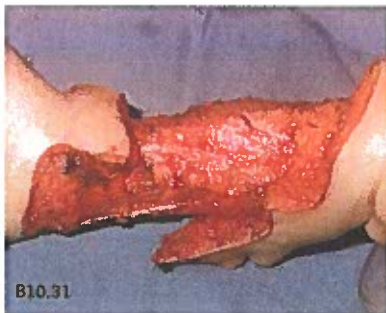


Fig. B10.31 After removal of the hamartoma, a circular defect down to the muscle fascia has resulted.

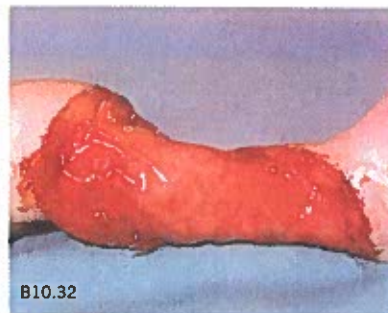


Fig. B10.32 The total excision was followed by implantation of artificial dermis (Integra®). At that point, fixation was not yet accomplished by means of the vacuum therapy system.



Fig. B10.33 After just a few days, infection set in and the artificial dermis (Integra®) was rejected due to the strong lymphatic flow from the base of the wound. The bandage was totally soaked 24 hours after the operation.



Fig. B10.34 Following removal of the infected Integra®, the wound was pre-treated for four days with vacuum therapy. Afterward, a second application of artificial dermis (Integra®), this time with vacuum therapy employed for fixation and drainage.



Fig. B10.35 After three weeks' time, the artificial dermis (Integra®), under the influence of the vacuum therapy system, has evolved without complication into a neodermis. At this point, the neodermis is still covered with the silicone layer. Following removal of the silicone layer, a thin autologous epidermal graft is made and fixated once again by means of the vacuum therapy system.



Fig. B10.36 After four days, the autologous graft has healed without irritation under the influence of vacuum therapy.



Fig. B10.37 Postoperative result two weeks after the concluding epidermal transplant over the neodermis.



Fig. B10.38 Postoperative result 18 months after removal of the hamartoma. The skin in the area of the lower leg is soft and pliable; the walking pattern of the child draws no attention.

In the field of paediatric plastic and reconstructive surgery, vacuum therapy is focused on the treatment of severe soft tissue trauma, the buildup of a two-layer surface of replacement skin, as well as the fixation of skin grafts and artificial dermis. With regard to the treatment of chronic wounds, our clinic has mainly attended to children with wound-healing disturbances in the lower extremities related to spina bifida. The advantages of ambulatory vacuum therapy for this patient group should not go unmentioned here. After five years of experience with vacuum therapy, once we had passed a certain learning curve, working without this system – be it for wound treatment or dermal fixation – has become quite inconceivable.

Part B / Chapter 11

Continuous Vacuum Therapy for Prefabrication of Three-Dimensional Flaps for Tumor Reconstruction of Defects of the Head and Neck

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Continuous computer-assisted vacuum therapy can be used to accelerate prefabrication of three-dimensional flaps (composite flaps). Changes of the actual structure of such flaps are induced by implantation of autologous or heterologous transplants alone or in combination with alloplastic materials as a supportive element. Application of vacuum therapy is useful for accelerating the process of prefabrication by the induction of angiogenesis. In addition, the continuous removal of wound exudate, possible seroma or hematoma and secondary compression of the different tissue layers improve the modelling of the three-dimensional construction. This article describes the technique of vacuum therapy for the prefabrication of three-dimensional pedicled or free flaps for reconstruction of defects after tumor resection in the head and neck area.

Introduction

Continuous vacuum therapy for delay or prefabrication of pedicled or free flaps is a well established technique for plastic surgical reconstruction of tissue defects^{2,7,11,12,22,23,32}. For the reconstruction of large soft tissue defects caused by tumors in the head and neck area flaps have to be created with two or even more surfaces and prefabricate them according to any special functional requirements. The goal, therefore, is to create and prefabricate a customized three-dimensional autologous flap for defect reconstruction. Ideally, the prefabricated flap should restore the lost organ function as well²⁵⁻²⁹. The prefabricated flap should have long term stability but also sufficient elasticity to achieve a good reconstructive result.

Our research has shown that application of topical negative pressure during the time of prefabrication could reduce the incidence of infection and tissue necrosis^{11,12}. In addition, the blood flow in flaps is improved and the prefabrication process is less timely. Flap prefabrication itself is a well established procedure in plastic surgery^{4,5,25,33,37}.

Application of vacuum therapy during the procedure of flap prefabrication can accelerate the process and can improve the technique. To improve the stability of such constructs, autologous elements (sternal or fibular bone, rib cartilage) are integrated into the flap^{30,31,34}. In addition, allogenic materials, such as titanium or resorbable polylactide-containing materials, can also be integrated. However, because of possible foreign body reaction or (pseudo-)allergic reactions autologous tissue is preferred whenever available³⁵.

For partial laryngeal reconstruction three-dimensional flaps were prefabricated using vacuum therapy and reshaped rib cartilage or polylactide-based matrix. We used a free fasciocutaneous radial forearm flap, a free TRAM-flap or a pedicled myocutaneous pectoralis major island flap. To create a second surface vacuum therapy and split-thickness skin grafting was performed prior to transplantation.

Patients and Methods

Patients

We performed plastic reconstruction of head and neck defects after tumor resection in eight cases. Three patients suffered from a partial laryngeal loss after laryngeal

fissure with a two-thirds resection of the ventral parts of the larynx. The reconstructive aim was to restore the ability to speak and swallow.

Laryngeal and soft tissue reconstruction after radiation therapy was performed in two cases by individual prefabrication of a free radial forearm composite flap (cases 1 and 2). In case 3 the reconstructive aim was to create an autologous "neo-trachea" for tracheal replacement in combination with the defect closure using a pedicled myocutaneous composite pectoralis major flap to enable postoperative radiation therapy.

Methods

First, fabrication and modelling of the stabilizing elements was done using either autologous rib cartilage or a resorbable polylactide polymer matrix (Lactosorb® SE, Lorenz Surgical), 100 x 100 millimeters large and 1.5 mm thick, or a titanium mesh grid. The Lactosorb® matrix was already perforated with about 100 holes to allow growth of the surrounding tissue into the matrix. Similarly the cartilage transplants were perforated and sutured together to create a new cartilage frame resembling the cricoid and thyroid cartilage.

Because of its new function as a stabilizing element the cartilage was formed in order to allow a small amount of flexibility for the deglutition but not for inspiration and exhalation. After the shaping procedure the cartilage was inserted into a tissue pocket between the dermal layer and the fascia of the radial forearm flap. The distal radial artery was ligated to enhance and establish the new blood flow pattern in the flap. Afterwards, a *split-thickness* skin graft (0.4 mm thick) was transplanted to the donor site and onto the lower surface of the elevated flap. Between both skin grafts a polyvinyl alcohol foam was applied and drained to the surface. At the end of this procedure the elevated flap was sutured into the donor site, the whole flap area was occluded with adhesive plastic drape and a continuous negative pressure of 125 mmHg applied.

Modelling of the polylactide polymer was done with heat application using the Lactosorb® heat pack in one case. In order to create a stabile "neo-trachea" tissue with a high tensile strength was needed to stretch an epithelialized tube. A pedicled myocutaneous pectoralis major flap was prefabricated in order to create two half-tubes facing each other. After completion of the prefabrication process the two half-tubes were folded up and an epi-

thelialized “neo-trachea” was created. Simultaneously the tumor defect was closed with a natural skin surface. Prelamination is safely done with vacuum therapy on a planar surface. Therefore, Lactosorb® plates were formed to create a half-tube and placed into the muscular tunnel of the elevated pectoralis major flap. The lower surface of the muscle and the donor site were then covered with a split-thickness skin graft. To set up the vacuum therapy a polyvinyl alcohol foam was provided with a drainage tube and placed into the wound bed. In correspondence to the half-tubes the central part of a 10 ml injection syringe was put into the foam as a placeholder. The prelaminate was able to snuggle firmly against the concave surface of the implants. Afterwards, the flap was sutured to its donor site and a vacuum drape was applied for initiation of negative pressure therapy (125 mmHg). After completion of the prefabrication process the composite flap was elevated. The prefabricated flap was folded up and fixed with resorbable sutures. The half-tube implants were folded in such a way that an epithelialized stable tunnel was obtained, which could serve as a “neo trachea”. All prefabrication procedures were performed under sterile conditions.

As a clinical example the reconstruction of the complete lower lip with a prefabricated bilaminated radial forearm flap with integrated palmaris longus tendon is demonstrated (Fig. B11.1-6) and a schematic drawing of the vacuum prefabrication of free functional three-dimensional composite flaps is presented (Fig. B11.7).

Results

In all patients (n = 8) flap prefabrication was performed with no incidence of major complications (Table B11.1). No seroma or infection was noted. The technique of vacuum therapy was successful in both the pedicled and the free flap. The time required for flap generation was 12 to 16 days, which represents a significant shortening compared to flap prefabrication without vacuum therapy (21 to 28 days). In seven patients a functionally satisfying result was obtained. In the eighth patient reconstruction could not be performed due to a high risk of permanent aspiration although the flap itself had been successfully prefabricated.

Discussion

The results of surgical resection of locally advanced tumors of the head and neck area are no longer evaluated only in terms of prognosis but also of quality of life. Surgical resection has to be compared to the results of primary and secondary radiation and chemotherapy.

The possibility of individually prefabricating and generating three-dimensional composite flaps using vacuum therapy results in a safer and quicker procedure and allows the surgeon to create a stable construct. Our results show that the application of vacuum therapy accelerates the biological prefabrication process³⁴. The delay between the surgical resection of the tumor and the reconstruction of the defect is minimized to a period of

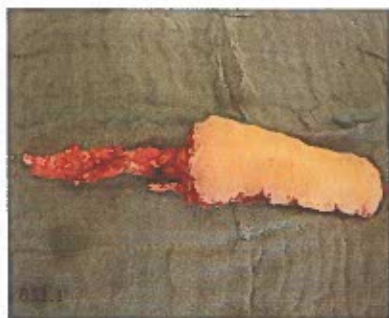


Fig. B11.1 The figure shows a prefabricated bilaminated radial forearm flap after application of vacuum therapy. The palmaris longus tendon was integrated into the flap to stabilize the new lower lip after reconstruction as a suspension band.



Fig. B11.2 Prefabricated dorsal aspect of the flap with generation of split-thickness skin-grafted second surface after vacuum therapy.



Fig. B11.3 The donor site of the radial forearm flap (frequent site of impaired healing) is already almost completely healed under the occlusion. The donor site can be closed in the axis of the vascular pedicle proximally.

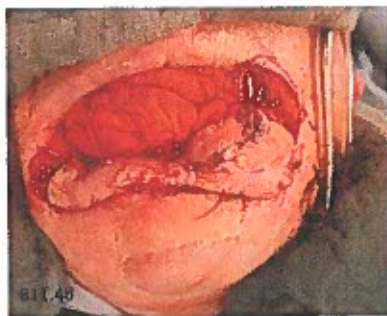


Fig. B11.4a-b

a) Resected specimen of the tumor
b) Tissue defect after resection of a relapsing squamous cell carcinoma of the lower lip with full loss of the lower lip. On the chin the residuals of a tubed flap that had been performed twenty years ago can be seen. The patient had also received radiotherapy.



Fig. B11.5a-c a) Preparation of the recipient vessels for the free flap transfer. b) Arterial and venous anastomosis of the free radial forearm flap was performed. c) Final positioning of the flap into the resectional defect.

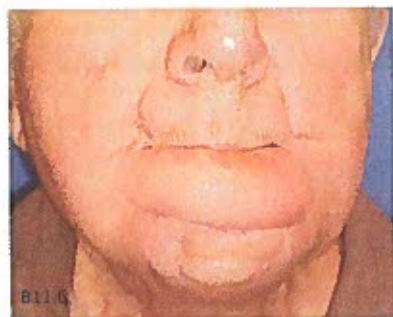


Fig. B11.6 Postoperative situation after transplanteration of the prefabricated flap and visible shrinkage with good functional result of the stable flap (after one year). Further flap contouring is planned to optimize the aesthetic outcome.

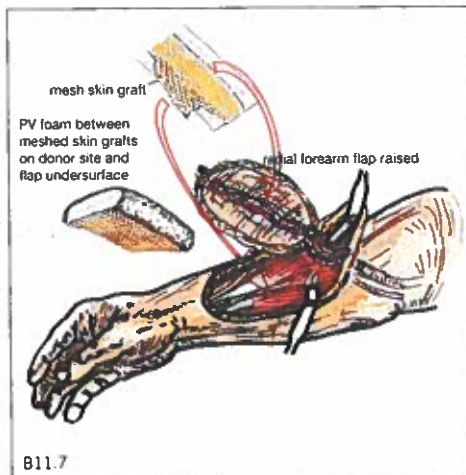


Fig. B11.7 Schematic drawing of the mode of flap prefabrication with skin grafting on the undersurface of the elevated flap and on the wound bed donor site. Foam is interposed between the flap undersurface and the donor site is covered with skin graft. The flap will be sutured back. The whole area will be wrapped with semipermeable film and continuous vacuum is established at -125 mmHg.

approximately 14 days. Based on reports of functionally oriented prefabricated and generated composite flaps^{1,18,25,26} we can report the establishment of prelamination and prefabrication of flaps^{12,13}. Surgical elevation of the flap leads to an increased size of the corresponding angiosome because angiogenesis is stimulated^{3,6}. An explanation could be the opening of arterio-venous shunts that lead to an autonomisation of the local blood flow in the flap. During prefabrication a continuous negative pressure therapy is applied which also leads to a stimulation of angiogenesis. This efficacy of vacuum therapy has al-

ready been shown as applied in chronic wounds to induce granulation tissue^{8,22,25}. Clinical induction of the prelamination technique in combination with the vacuum therapy could create tissue constructs that are epithelialized on two or more surfaces^{13,15,17}. Including autologous bone or cartilage transplants resulted in a stable three-dimensional flap^{18,21,31}. Important properties of continuous vacuum therapy include induction of angiogenesis and drainage of wound secretions, thus preventing seromas. Application of computer-assisted vacuum therapy is more expensive than vacuum therapy using Redon

containers or a wall suction system. The prime advantage of computer-assisted vacuum therapy is that the constant monitoring of therapy enhances safety. In our patient population, we prefer computer-controlled therapy because infection, seroma and dislocation of the skin graft would be major problems that must be avoided, especially in the case of composite flap prefabrication. The continuous negative pressure creates continuous contact between the flap and the new surfaces, leading to a growth of fibroblasts into the tissue and induction of angiogenesis in the composite flap. If possible, we prefer autologous matrices such as bone or cartilage because the polylactide polymer implants can dissolve rapidly through hydrolysis, potentially leading to instability of the flap.

This paper demonstrates the options for prefabrication of newly composed customized compound flaps using vacuum therapy. This procedure expands the reconstructive possibilities for covering defects especially in the head and neck area after tumor surgery. In this context the application of vacuum therapy accelerates the prefabrication process and enables us to create new composite flaps with different surfaces and incorporated stabilizing autologous elements.

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Part B / Chapter 12

The Role of Vacuum Therapy in the Treatment of Stage III and IV Pressure Ulcers*

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Stage III and IV pressure or decubitus ulcers are a frequently encountered clinical entity and represent a significant economic burden on the healthcare system. There is, however, no one "standard" treatment for these lesions. In order to assess the current principles of routine clinical management of more advanced pressure ulcers, we conducted a Medline search for the years 1966 to 2005 and sent questionnaires to members of the German Society of Plastic Surgeons. The present review analyses a total of 270 references on this subject and 91 completed questionnaires.

Our results show that surgery is the treatment of choice for Stage III and IV pressure ulcers. Vacuum therapy is primarily used for the purpose of encouraging healing immediately after debridement and in the treatment of inoperable patients. In these cases, vacuum therapy appears to be superior to other conservative treatment options.

*Stages are defined at the end of this chapter.

Introduction

We can safely assume that the incidence of pressure ulcers in countries of the Western hemisphere is approximately 80 to 1000 cases per 100,000 inhabitants^{47,51,76}. A study that made headlines in many newspapers investigated the prevalence of decubitus ulcers on the basis of 10,222 *post mortem* examinations in a crematorium and reported an overall prevalence of Stage I to IV pressure ulcers of 11.2%³⁰. In acute-care hospitals, the incidence ranged from 1.1 to 36.4% (mean value: 10.8%)^{75,79}. Paraplegic and tetraplegic patients as well as patients in intensive care units are at higher risk of developing pressure sores. Almost 20% of all paraplegic patients and 26-60% of tetraplegic patients have decubitus ulcers. Recent studies reported that 5-27% of intensive care patients exhibited pressure sores. The cumulative risk was 50% at 20 days^{11,43}.

The annual financial costs of decubitus ulcers to the German health care system are estimated at 1 billion EUR. This calculation has been confirmed by analyses in other countries. The financial burden of pressure ulcers is estimated at 1 to 8.5 billion USD in the United States^{2,8,10,41,74}, at approximately 1.1 billion USD in the United Kingdom^{56,78}, and, depending on the care setting (hospital, home care, etc.), between 360 million and 2.8 billion USD (or 1% of the entire health care budget) in the Netherlands^{39,64}.

Per-patient treatment costs of Stage IV ulcers range from 5,000 to 35,000 USD, including the costs of dressings, surgery (if required), nursing care, and hospitalisation^{31,45,63,80}. When pressure sores are complicated by osteomyelitis, treatment costs can increase to an average of 56,000 USD per case³². As a result of demographic trends, these costs can be expected to increase further in Western countries (it is projected that approximately 25% of the population will be older than 65 years in 2025).

Whereas there is general agreement that prevention is the key to success and that problems are associated with the practical application of general guidelines, a wide range of completely different approaches to treating pressure ulcers is available. Moist saline gauze, hydrocolloid and hydrogel dressings, vacuum therapy and plastic surgery, for example, are especially recommended for the treatment of more advanced ulcers. Other treatment options include:

- hyperbaric oxygen (HBO) therapy as an adjunct to conventional dressings in the treatment of osteomyelitis underlying pressure ulcers¹⁹
- high-frequency pulsed electromagnetic therapy as an adjunct to conventional dressings^{23,37}
- topical application of recombinant fibroblast growth factor as an adjunct to conventional dressings⁵⁷
- topical application of recombinant platelet-derived growth factor-BB (rhPDGF-BB) as an adjunct to conventional dressings^{49,58}
- maggot therapy for wound debridement⁶⁵⁻⁶⁷
- ultrasound therapy as an adjunct to conventional dressings^{24,71}
- systemic administration of factor XIII (= blood clotting factor, plasma transglutaminase) as an adjunct to conventional dressings⁷
- infrared and red pulsed monochromatic light as an adjunct to conventional dressings

None of these recommendations are evidence-based but are merely a reflection of empirical data, though they are common practice in different health care settings (university hospitals, district hospitals, hospitals with beds allocated to medical specialists in private practice, nursing homes, residential homes, etc.). Now, there are basically two approaches to evaluating the role of each of the various treatment forms in this complicated system:

1. A review of the literature
2. An analysis of clinical practice

We used both approaches in an attempt to assess our knowledge on this issue. We must admit, however, that the differential treatment of Stage III and IV decubitus ulcers is so complex that it was impossible to make it the central focus of this monograph. Instead, we confined ourselves to a brief overview of findings reported elsewhere. Particular attention was paid to the following questions:

- Is there a treatment of choice for Stage III and IV decubitus ulcers?
- Does vacuum therapy play a role in the management of Stage III and IV decubitus ulcers?
- Is this technique used only during a particular period of treatment or is it also suitable as a monotherapy?

- Is vacuum therapy – provided it is used in the management of decubitus ulcers – superior to other conservative treatment options?
- What is the recommended level of negative pressure?

Material and Methods

Literature Review

Our analysis was based on the results of a computer-assisted search of Medline/PubMed, EMBASE and Cochrane. Medline was searched from 1966 to 31 March 2005 for an analysis of comparative studies using the keywords "pressure sore" and "decubitus". Irrespective of the level of evidence of the studies and with no restriction on language, we searched for randomized clinical and experimental studies, systematic and non-systematic reviews, meta-analyses, expert opinions, case reports, experimental studies (animals and human studies), and consensus conference reports.

Clinical Practice of Stage III and IV Pressure Ulcer Treatment

In cooperation with two authors of this chapter, the Hessian Institute of Nursing Research conducted a survey to collect data on the management of pressure ulcers in everyday clinical practice in Germany³². It was assumed that there is no overtreatment in the clinical setting or, in other words, that conservative approaches are used whenever there is no need for surgery and that the entire spectrum of individual treatment options is available. It was also assumed that, for a variety of reasons, conservative measures are the mainstay of therapy in medical practices, nursing homes and residential homes and that invasive procedures are likely to be used only as a last resort and not for primary therapy. Against this background, all registered members of the German Society of Plastic Surgeons residing in Germany were asked to complete a questionnaire.

Contents of the Questionnaire

Particular emphasis was placed on the following aspects:

- annual number of cases of Stage III and IV pressure ulcers
- treatment regimen
- number and type of surgical procedures

- method and length of preoperative wound bed preparation
- modalities for the use of vacuum therapy (type of foam, level of pressure, type of suction)
- postoperative positioning
- length of inpatient stay after surgery
- primary healing rate
- rates and types of postoperative complications
- estimated speed of healing without surgery
- percentage of patients suitable for treatment with non-surgical methods
- use of vacuum therapy for wound bed preparation on an outpatient basis
- comments on our own treatment regimens

Design

Data were collected using a quantitative descriptive design. The standardised questionnaire contained 19 closed- and seven open-ended questions. Due to the method of questioning and the qualitative information from the relatively large number of open questions, this study was understood to be "explorative".

Survey

We are grateful to the German Society of Plastic Surgeons for providing us with a list of members' addresses. We distributed a total of 491 questionnaires.

Study Procedure

Questionnaires were mailed and returned by post from 28 June to 26 July 2004. Reminders were sent out in order to increase the response rate.

Ethics

All respondents received an accompanying letter in which they were informed about the nature of the study, their rights and the questioning procedure. Participation in the study was voluntary. The respondents had the right not to answer some or all questions. All data were anonymised for analysis. Prepaid, addressed return envelopes were provided so that the respondents incurred no costs.

Data Analysis

The final analysis included only questionnaires with an affirmative response to the first question (treatment of Stage III and IV sacral pressure ulcers) and with answers to at least 50% of the questions. The data were analysed

with the SPSS statistical package, version 11.5. We calculated a set of descriptive statistics including frequency, mean, median, and mode. Due to the explorative nature of this study, we did not conduct a basic analysis in order to investigate relationships and differences. If group differences appeared to be relevant, they were analysed with a focus on the number of pressure ulcer patients treated annually and the percentage of patients who underwent surgery for Stage III and IV ulcers. We did not determine statistical significance levels due to the study design.

Results

Literature Review

Number and "Quality" of the Articles

We were especially interested in whether vacuum therapy had been used successfully and how effective it was compared to alternative treatment options. A Medline search (1966 to 31 March 2005) using the keywords "decubitus" and "pressure sore" found 6449 articles. Only 270 of articles published in the past fifteen years (1990 to 2005) were explicitly devoted to the treatment of decubitus ulcers. By contrast, a large portion of these articles dealt only with the prevalence/incidence and prevention of pressure ulcers.

A total of 125 studies were case series and 17 were case reports. Forty-seven other publications were general investigations. Only 34 studies were controlled (different qualities) and three studies were reviews conducted by the Cochrane Wounds Group. In addition, the search found two meta-analyses. All other articles belonged to several or none of these groups. On the basis of the data provided, we calculated that a total 7,112 patients had been treated in the 270 studies that focused on pressure ulcer treatment. Of these patients, 3,336 underwent surgery, 1,811 were treated conservatively with different types of dressings, 750 received conservative treatment such as ultrasound or electromagnetic therapy, and 1,215 were treated with vacuum therapy.

Study Contents

It was interesting to note that the few multicenter studies and the majority of RCTs (randomized-controlled studies) were conducted for the sole purpose of comparing the outcomes of different conservative methods. There are no studies comparing different types of plastic sur-

gery or comparing plastic surgery with conservative methods. Only two studies focused on the use of plastic surgery after unsuccessful conservative treatment. We found the following comparative studies:

- conventional therapy *versus* conventional and adjunctive therapies (electromagnetic therapy, ultrasound): a few studies, two Cochrane reviews^{23,24}
- conventional therapy *versus* vacuum therapy: two studies, one Cochrane review (Table B12.1)^{22,25,27}
- vacuum therapy *versus* conventional and adjunctive therapies: no study
- plastic surgery *versus* conventional therapy: no study
- plastic surgery *versus* vacuum therapy: no study
- plastic surgery *versus* conventional and adjunctive therapies: no study

The most important aspects of the studies or analyses that investigated in detail the treatment of decubitus ulcers with vacuum therapy are summarised in Table B12.1. Not included are reviews, general investigations, case reports or case series. Apart from a wide range of case reports, there are at least four case series in renowned scientific journals, two randomized-controlled studies, and one review article (see below) on the use of vacuum therapy for pressure ulcers in the literature. Thus, there are also articles with a high level of evidence (1b and 3a).

Since a comparison of conventional therapy *versus* conventional and adjunctive therapies is not relevant in this context, the eligible studies are not treated in detail here. It should only be noted, however, that both Cochrane reviews come to the conclusion that the results suggest no evidence of any benefit from ultrasound or electromagnetic therapy in the treatment of pressure sores^{23,24,37,71}.

There is only one Cochrane review that examined the effectiveness of vacuum therapy in comparison to conventional methods:

Evans D, Land L. Topical negative pressure for treating chronic wounds (Cochrane Review). In: *The Cochrane Library*, Issue 2, 2003. Oxford: Update Software²².

Search strategy

The Cochrane Wounds Group Specialised Trials Register was searched through November 2003. Experts in the field and relevant companies were contacted to enquire about ongoing and recently completed relevant trials. In addition, citations within identified papers were scrutinised to identify additional studies. The vacuum therapy website (www.vacuumtherapy.co.uk/index.htm) and the Health Technology Assessment (HTA) database of the Cochrane Library were also searched through November 2003. Selection criteria were as follows: All randomized controlled trials that evaluated the effectiveness of topical negative pressure in treating chronic wounds were considered.

Authors' Conclusions

The results provide weak evidence suggesting that topical negative pressure may be superior to saline gauze dressings in healing chronic human wounds. However, due to the small sample sizes and methodological limitations of these trials, the findings must be interpreted with extreme caution.

In addition, the results of non-comparative studies are provided in Table B12.2. Due to methodological limitations, however, these findings also require cautious interpretation. In order to provide a better overview, we summarised the results of a total of 39 studies for each therapeutic approach. Instead of specifying, for example, that complete wound closure was achieved in "70% of patients in six months, 80% in six months, 84% in seven months, 100% in six weeks", the table says that complete wound closure was established in "70% in six months to 100% in six weeks". The small sample sizes (with a median of only 27 patients per study), however, limit the conclusions that can be drawn from the studies. None of the studies placed major emphasis on factors well known to be significant for interpretation (nutrition, wound age, protein level). Unfortunately, different primary and secondary endpoints were used in the

studies. It was therefore only rarely possible to make comparisons on the basis of endpoints. Moreover, there were no clear definitions of endpoints such as "complete wound closure". We were nevertheless able to collect a vast array of individual data and to gain a general overview.

Of the few reviews that included all available forms of treatment in their analysis, none singled out one particular therapy as the "method of choice"²⁴.

Clinical Practice of Stage III and IV Pressure Ulcer Treatment in Germany – Results of a Nationwide Survey

Altogether, 125 of 491 questionnaires were returned, giving a response rate of 25%. A total of 34 respondents stated that they currently did not treat patients with sacral pressure ulcers. Among the reasons were that pressure ulcers were not included in the regional hospital bed requirement plan, the hospital only provided aesthetic plastic surgery, the respondent had a private practice and was only affiliated with a hospital, and the treatment facility was a day-care centre. These questionnaires were excluded from the analysis. Since all other respondents had answered at least 50% of the questions, it was possible to include the remaining 91 questionnaires (19%) in the analysis. Where a question had not been answered by all respondents, the analysis of responses is based on less than 91 answers.

Annual Number of Patients

Our survey revealed that many facilities had only few cases but that a few facilities had many cases. According to the questionnaires, three quarters of the respondents (75.8%, $n = 69$) every year provide pressure ulcer treatment for less than 30 patients, 16.5% ($n = 15$) for 31 to 50 patients, 1.1% ($n = 1$) for 61 to 90 patients (70 cases), 5.5% ($n = 5$) for 91 to 120 patients, and 1.1% ($n = 1$) for 121 to 150 patients (150 cases).

Surgery Rate

Surgery appears to be the most common method of treating Stage III and IV sacral pressure ulcers. Altogether 52% of the respondents ($n = 47$) use surgery for treating 91–100% of all patients with these ulcers. Three of four clinicians (75%, $n = 68$) usually treat at least 71% of pressure ulcer patients with surgery. It is interesting to note, however, that 13% of the respondents ($n = 12$) use surgery to treat Stage III and IV pressure ulcers in a mere 0–10% of cases.

Table B12.1 Vacuum therapy of stage III and IV decubitus ulcers; study protocols and results

Year, Authors, Journal, Setting	Evidence Level	Number / Age	Method / Treatment Groups	Treatment Duration / Follow-up	Healing Speed	Healing Rate	Other Results	Comments
1997 Müllner et al. ⁴⁸ <i>Br J Plast Surg</i> HOSPITAL (1994-1996)	Case series 4 (Oxford Centre)	n = 17 (femur fracture, paraplegic patients) gender: 12 f, 5 m age: Ø 82 y (71-88)	wound size: Ø 43 ml (12-72) wound age: Ø 2 w(1-4 w) stage: III/IV	frequency of foam dressing changes: approx. 6 x (3-12)	Ø 21 d (16-46) using a vacuum bottle Ø 23 d (12-37) using a (Medela*) pump	1/17 secondary closure 8/17 treatment of superficial wounds 3/17 reduction in volume to 20%, then plastic surgery (flap) 5/17 no effect	wound infection: initially 100%, later no signs of infection	healing speeds were reported for 12/17 patients
1999 Philbeck et al. ⁵¹ <i>Ostomy Wound Management</i> HOSPITAL	Case series 4 (Oxford Centre)	n = 1032 patients stage: III/IV	wound size: Ø 22.2 cm compared to earlier study: Ø 4.3 cm	n/a	wound healing: 97 d; 0.23 cm ² /d compared to earlier study: 247 d; 0.09 cm ² /d	n/a	cost of treatment: 14,546 USD compared to earlier study: approx. 23,465 USD	Results were compared to a study conducted by Ferrel et al (1993).
2000 Deva et al. ⁵⁰ <i>Med J Australia</i> HOSPITAL (1997-1998)	Case series 4 (Oxford Centre)	n = 30 spinal cord injury and cerebrovascular disease patients gender: 10 f, 20 m age: Ø 50.7 y stage: III	wound size: Ø 171 ml (16-2228) wound age: Ø 418 d (8-1650 d) acute: (< 6 w): Ø 28 d (n = 17) chronic: 43 d (n = 13)	follow-up: 3 months after the end of treatment	Ø 35d(8-124 d) acute: Ø 28 d chronic: Ø 43 d	26/30 successful, 7/30 direct closure, 11/30 reduction in wound cavity size, making plastic surgery possible	wound infection: 100% of wounds contaminated; 25/26 reduction in bacterial load (8/26 from severe to moderate; 17/26 from severe to low)	only Stage III pressure ulcers
2002 Ford et al. ²⁵ <i>Ann Plast Surg</i> HOSPITAL	RCT (poor quality) 1b(Oxford Centre)	n = 41 wounds (28 patients) age: 21-80 y stage: III-IV wound age: ≥ 4 w wound size: 10-150 ml	group 1: VAC (n = 20) group 2: Iodosorb / Panafil hydrogels (n = 15) osteomyelitis (bone biopsy, MRI, PMN count): systemic antibiotics	treatment duration: 6 w follow-up: 3 to 10 months 22 patients (< 80% of patients)	group 1: volume reduction: Ø 51.8% in 6 w (p=0.46) group 2: volume reduction: Ø 42.1% in 6 w	group 1: 2/20 complete healing 6/20 plastic surgery group 2: 2/15 complete healing 6/15 plastic surgery	group 1: decrease in the number of PMNs and lymphocytes (p = 0.13) increase in the number of capillaries (p = 0.75). group 2: increase in the number of PMNs and lymphocytes (p=0.41) whereas 3 of 15 cases of osteo-myelitis improved in group 1, none improved in group 2	

Year, Authors, Journal, Setting	Evidence Level	Number / Age	Method / Treatment Groups	Treatment Duration / Follow-up	Healing Speed	Healing Rate	Other Results	Comments
2003 Isago et al. ⁵⁶ <i>J Dermatol</i> HOSPITAL	Case series 4 (Oxford Centre)	n = 10 stage: IV ^a		6 w	55.1% reduction in wound size during the period under observation, 61.2% reduction in ulcer depth	n/a	n/a	small patient population
2003 Wanner et al. ⁷⁷ <i>Scand J Plast Reconstr Surg Hand Surg</i> HOSPITAL (1998-1999)	RCT 1b (poor quality) (Oxford Centre)	n=22 (paraplegic and tetraplegic patients) stage: III-IV	group 1: vacuum-assisted closure Ø 49 y (25-73) Ø 50 ml ± 33 (3-132 ml) group 2: gauze soaked in Ringer's solution Ø 53 y (34-77) Ø 42 ml ± 16 (5-68 ml)	treatment duration: 3-8 w	group 1: time to reach 50% of the initial wound volume: Ø 27 d (±10) group 2: time to reach 50% of the initial wound volume: Ø 28 d (±7)	n/a	no difference in granulation tissue formation	Small patient groups. The authors emphasise that vacuum therapy is associated with much lower costs and more patient comfort.
2004 Smith et al. ⁶⁸ <i>Br J Nurs</i> HOSPITAL (1998-1999)	Meta-analysis of 3 studies (no comparative studies) 3b (Oxford Centre)	n = 281 stage: III ^a -IV ^a	comparison: VAC, alginate or hydrocolloid dressings (n = 141+92+48)	treatment duration: n/a	wound closure: < 3 w satisfactory signs of wound healing: VAC: 43% alginate: 0% hydrocolloid: 0%	wound closure: (satisfactory: 60-80%) VAC: 93% alginate: 0% hydrocolloid: 63%	VAC appears to be significantly superior to alginate and hydrocolloid dressings with regard to the endpoints investigated.	No analysis of comparative studies although such studies are available.

d = days; w = weeks; m = months; y = years; f = female; m = male; n/a = not available;

VST = vacuum sealing technique; VAC = vacuum-assisted closure;

RCT = randomised controlled trial;

Table B12.2 Comparison of outcomes using different methods of treating pressure ulcers

	Plastic Surgery	Conventional Therapy	Conventional + Adjunctive Therapies	Vacuum Therapy
Stage	III, IV	I, II, III, IV	II, III	III, IV
Ø Reduction in Wound Size after 4 w	n/a	n/a	29-40% of baseline	52.6%
Ø Reduction in Wound Size after 8 w	n/a	III, IV – 9-34%	n/a	76.2%
40% Reduction in Wound Size after 4 w	n/a	22.6-74% of patients	n/a	62.5% of patients (median)
40% Reduction in Wound Size after 8 w	n/a	42-75% of patients	n/a	76.9% of patients (median)
Ø Reduction in Wound Size in 12 w	n/a	26-64%	n/a	80.6%
Rate and Time of Wound Closure	70% in 6 m to 100% in 7 w	27% in 7.5 w to 56.6% in 26 w	40% in 12 w to 100% in 9 w	25% in 4 to 6 w
Use as Interim Treatment	-----	60% ⁴⁶	n/a	60%
Open at Discharge	0 - 10%	n/a	n/a	n/a
Reduction in Bacterial Load	n/a	n/a	n/a	96-100%
Recurrence Rate	4.44-82%	n/a	n/a	n/a
Complications	21-50%	n/a	n/a	n/a
Literature References	5,12,13,28,38,42,46,55,60,61,68,70	9,14,17,21,27,33,39,40,44,58,59,73	23,24,26,37,49,71,72	34,6,35,46,48,50,75,36,51

w = weeks

m = month

n/a = not available

Table B12.3 Comparison of outcomes reported in five studies on the treatment of pressure ulcers using vacuum therapy in a home care setting and in a hospital setting

	Home Care	Hospital	Hospital	Hospital	Hospital
Stage	III, IV	III	III, IV	IV	III, IV
Number of Patients	104	30	20	10	11
Wound Size and Age	wound size: Ø 170 ml (± 317 ml; 2 - 2700 ml) wound age: Ø 189 d (± 396 d; 13 d - 8 y)	wound size: Ø 171 ml (16.1-2228 ml) wound age: Ø 418 d (8 - 1650 d)	wound size: 10 - 150 ml wound age: > 4 w	n/a	wound size: Ø 50 ml (± 33 ml; 3 - 132 ml)
Wound Closure Rate	24 / 104 (23.1%)	23.3%	10%	n/a	
Time until Wound Closure	60 d (20 - 106 d)	8 - 124 d	42 d	n/a	n/a
Ø Wound Size Reduction in 6 w	65.3%	n/a	51.8%	55.1%	n/a
Ø Time until 50% Wound Size Reduction	26 d	n/a	n/a	n/a	n/a
Literature References	2001 - 2003 reports by 35 physicians in private practice (see auth. for source)	2000 Deva et al. ³⁰ <i>Med J Australia</i>	2002 Ford et al. ³⁵ <i>Ann Plast Surg</i>	2003 Isago et al. ^{35,36} <i>J Dermatol</i>	2003 Wanner et al. ⁷⁷ <i>Scand J Plast Reconstr Surg Hand Surg</i>
Evidence Level	Case series 4 (OC)	Case series 4 (OC)	RCT (poor quality) 1b (OC)	Case series 4 (OC)	RCT (poor quality) 1b (OC)

w = weeks

m = months

y = years

n/a = not available

OC = Oxford Centre

RCT = randomized controlled trial

Preoperative Wound Preparation

Almost one out of every two respondents (48%) does not apply special methods of wound preparation. Vacuum therapy is the most commonly used method for preparing the wound bed (69%, $n = 63$). Hydrocolloid/hydrogel dressings (32%, $n = 29$) and gauze soaked in lactated Ringer's solution (26%, $n = 24$) are far less frequently used. Altogether 53% of the clinicians ($n = 46$) apply preoperative methods of optimising the wound environment for a period of one to two weeks. Almost one out of three respondents (31%, $n = 27$) stated that wound preparation took approximately one week. When both groups are taken together, 84% of the respondents usually apply preoperative methods of preparing the wound for a period not exceeding two weeks.

Modalities for the Use of Vacuum Therapy

When using vacuum therapy, three out of four respondents (74%, $n = 67$) prefer black foam to white foam (32%, $n = 29$). The levels of negative pressure range between 50 and 400 mmHg. The majority of clinicians use 125 mmHg (68%, $n = 45$). Whereas most of the respondents (71%, $n = 62$) use continuous suction, a mere 6% apply intermittent suction ($n = 5$).

The Course of Wound Healing after Surgery and Conservative Therapy

Surgery usually involves using a V-Y flap. The majority of clinicians state that the average postoperative length of stay is three weeks. Primary healing is achieved in as many as 60-80% of cases. Postoperative complications occur in 11-20% or less of patients. The most common complication is secondary healing, followed by surgery for recurrence and infection.

How do respondents assess alternative methods regarding their potential for achieving primary healing? Conservative methods are assessed rather pessimistically for their healing potential and healing rate. Of these, vacuum therapy is considered to have the highest healing potential and to require the shortest length of time to achieve healing. Altogether 63% of the respondents ($n = 57$) regard vacuum therapy as superior to other treatment options such as hydrocolloid and hydrogel dressings (38%, $n = 30$) and gauze soaked in lactated Ringer's solution (28%, $n = 22$). Likewise, clinicians assess alternative methods rather pessimistically for their healing rate. Although the ranges of values for the various methods are large, all medians are low (0-10%).

Vacuum therapy is again considered to have the highest healing rate (10%). The majority of respondents regard the use of gauze soaked in lactated Ringer's solution or hydrocolloid/hydrogel dressings as hardly capable of achieving wound closure.

Outpatient Treatment Options

Two-thirds of respondents (66%, $n = 55$) believe that vacuum therapy can be effectively used for creating an optimal wound-healing environment once initial debridement is performed on an inpatient basis. The clinicians emphasise, however, that the outpatient use of vacuum therapy is subject to limitations and, in particular, requires specially trained nursing personnel, good nursing care in the home environment, good general practitioner care, a satisfactory level of patient compliance, and the presence of a clean wound.

Discussion

The objective of this review was to assess the role of different forms of treatment for Stage III and IV pressure ulcers. There is a wide variety of plastic surgical and conservative options that can be used for the differential treatment of pressure ulcers. Because the focus of this book is the role of vacuum therapy, we conducted a literature search to identify published studies and carried out a survey to collect data on the treatment of pressure ulcers in everyday clinical practice in Germany. It should be emphasised that the differential treatment of Stage III and IV decubitus ulcers is a complex subject with a wide variety of clinical, sociomedical and economic implications that cannot be covered exhaustively in a book chapter whose sole intention is to assess the role of vacuum therapy. Likewise, a non-response rate of 75% limits the conclusions that can be drawn from the responses received. Since response rates to questionnaire surveys are usually around 25-30%, however, the number of respondents is less important than the knowledge gaps that were revealed by the questionnaire.

Our results show that the overall situation of pressure ulcer treatment is unsatisfactory. The choice of therapy depends less on the clinical condition of the pressure ulcer or the patient than on the resources available at the treatment facility. It appears that surgical centres with expertise in plastic surgery prefer surgical debridement and flap coverage. By contrast, clinical facilities with less experience in plastic surgery seem to provide

only conservative outpatient treatment for the same condition.

Primary healing of Stage III and IV sacral pressure ulcers is achieved in both treatment settings, but there are no comparative studies with a high level of evidence. The following conclusions, however, could be drawn from what is reported in the literature and by clinicians from treatment centers that offer the entire spectrum of treatment options. Surgical treatment achieves a high primary healing rate of 60-80% (a V-Y flap is most commonly used in the treatment of sacral pressure ulcers; the length of hospital stay is usually three weeks post surgery). The majority of clinicians reported a complication rate of 11-20%. There are, however, a number of references in the literature suggesting complication rates as high as 50%. In an article published in a German surgical journal in 2002, for example, Brenner et al.¹², in an analysis of 16 years' experience, found that only about one-third of all flaps healed uneventfully, complications were seen in more than 50% of cases for a wide variety of reasons. In addition, partial necrosis of the flap occurred in approximately 6% and complete necrosis in 2%¹². Nevertheless, the generally positive results reported in the literature and in our nationwide survey suggest that surgical treatment is the method of choice for Stage III and IV sacral decubitus ulcers. Conservative methods, including vacuum therapy, are considered to have only a low potential for healing more advanced ulcers. Vacuum therapy, however, is generally regarded as having the highest primary healing rate compared to other conservative treatments^{62b}.

The literature review and our survey show that vacuum therapy (plus radical debridement) allows approximately 10-15% of Stage III and IV decubitus ulcers to heal without surgical intervention. This means that if conservative treatment is used to treat pressure ulcers that are inoperable or cannot be managed surgically for other reasons, vacuum therapy offers the best chance of success and should therefore be the first choice^{27b,33b,40b,62b}. In this context, it is interesting to highlight demographic trends showing that the average age of patients with pressure ulcers and thus the number of inoperable cases are likely to increase in the future.

Initial radical debridement is a basic prerequisite for successful pressure ulcer treatment. When this method of wound cleansing is used for inpatients in a surgical setting, debridement is usually more extensive and performed with greater frequency than is the case in an out-

patient setting. Although there is no concrete evidence for this assumption, it is nevertheless safe to conclude that conservative therapy is likely to achieve a higher success rate than previously reported if treatment commences with radical debridement under optimum conditions. In the future, providers of outpatient surgery will be able to offer this service. It would thus be possible to further improve the outcome of vacuum therapy in the primary treatment of Stage III and IV pressure ulcers.

Both our literature review and our survey show that vacuum therapy is considered to be superior to other conservative methods in preparing the wound bed for healing. Vacuum therapy is the preferred interim treatment because it offers the advantages of reducing the bacterial load, aiding debridement, removing exudate, promoting a clean and healthy wound environment, increasing patient comfort and requiring a low level of nursing care. Although this has thus far not been proved in comparative studies, there are many case series and case reports (evidence levels: 4 and 5) that come to this conclusion. The majority of clinicians estimated the time from radical surgical debridement to the definitive flap procedure to be one to a maximum of two weeks.

The strong pressure of healthcare economics today requires that outpatient and inpatient care be compared in terms of treatment costs and success. It is assumed that vacuum therapy has the same physical effects in the treatment of pressure ulcers, irrespective of whether it is provided in an outpatient or an inpatient setting. Equal success, however, can only be achieved if the quality of initial debridement and subsequent decisions on whether or not to take more invasive measures (e.g. re-debridement) are identical. A scientific comparison of treatment options in terms of outcome quality is not available. An assessment can only be made on the basis of a home care study (see Table B12.3) and the responses received from centers for plastic surgery. These data suggest that it is generally possible to provide vacuum therapy in an outpatient setting either as primary conservative treatment for 10-20% of patients with Stage III and IV pressure ulcers or for wound bed preparation.

A comparison of the outcomes of conservative treatment in an outpatient and an inpatient setting (see Table B12.3) shows that vacuum therapy can be successfully used in the home care setting and can achieve results as favourable as those obtained in an inpatient setting. We can assume that identical standards of treatment can be

met in outpatient and inpatient settings. The results, obtained in a relatively large home care patient population (Table B12.3), show, however, that the success of outpatient treatment depends on two conditions. In individual cases, for example, vacuum therapy was used for an excessively long period without clinical success. The wounds of two patients were unsuccessfully treated for more than 160 days. Eventually the wound area was 155.6% and 322.5% respectively compared to the initial size of the wound. The reasons for these extremely long treatment courses were insufficient radical debridement at the beginning of treatment and a lack of communication with the physician who had initially considered it appropriate for the patient to undergo vacuum therapy. The mainstays of successful treatment with vacuum therapy in both inpatient and outpatient settings are radical debridement, personnel with special training in vacuum therapy, and close cooperation between hospital physicians, general practitioners and nursing personnel.

Overall results suggest that surgery is the method of choice for Stage III and IV pressure ulcers. This treatment always involves initial surgical debridement. Definitive closure of the wound is performed either immediately after debridement, after wound bed preparation or after second-look surgery. A maximum period of two weeks is usually sufficient to prepare the wound bed, where required. There is general agreement that vacuum therapy is better suited for wound bed preparation than alternative methods and thus plays a special role in this respect.

Both a literature review and a survey of clinical practice show that conservative methods are indicated as primary treatment for approximately 10-15% of pressure ulcers. The majority of clinicians consider vacuum therapy to have a higher healing potential than other conservative methods. A specific indication for vacuum therapy is the treatment of pressure ulcers in elderly patients who are inoperable.

According to the results of the literature review and the survey, vacuum therapy most commonly involves the application of continuous negative pressure at 125 mmHg. This, however, appears to contradict theoretical expectations (see previous chapters). If vacuum therapy is used primarily to promote the formation of granulation tissue in poorly perfused areas, low intermittent suction should be applied (for example 100 mmHg with cycles 10 minutes ON and 10 minutes OFF).

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Several systems for staging decubitus ulcers have been proposed. The National Pressure Ulcer Advisory Panel (NPUAP, www.npuap.org)¹ staging system has achieved the widest acceptance and distinguishes four stages:

- | | |
|-------------------|--|
| Stage I: | Skin redness |
| Stage II: | Partial thickness skin loss involving the epidermis and/or dermis.
The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater. |
| Stage III: | Full thickness skin loss involving damage to subcutaneous tissue that may extend down to, but not through underlying fascia. No damage to muscle and bone tissue. |
| Stage IV: | Open wound with damage to muscle and bone tissue. Exposed muscle or bone tissue. |

Part B / Chapter 13

Vaginal Reconstruction for Aplasia and Strictures with Free Skin Grafts and Vacuum-Assisted Closure

H. Hallberg and H. Holmström

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Probably the most common method of constructing a vagina in patients with the Mayer-Rokitansky-Küster syndrome is the technique popularised by McIndoe and Banister in 1938. A cavity is created between the rectum and urethra-bladder complex and lined with split-thickness skin grafts. One of the disadvantages of using split-thickness skin grafts is the incidence of late contraction of the neovagina. To avoid this problem, full-thickness skin grafts have been used, but their take is less reliable. A new technique to improve the take of skin grafts is the vacuum-assisted closure or vacuum therapy system which has proven to be particularly valuable in grafting difficult anatomical sites. We have used the vacuum therapy system in the construction of a neovagina in three cases with split-thickness skin grafts and in two cases with full-thickness skin grafts on patients with primary vaginal aplasia. In all cases, the graft take was excellent with little discomfort for the patients. It was not necessary in any case to stent the neovagina regularly except in one case in the immediate postoperative period and coitus was possible within a month of operation in most of the cases. We have also used the same technique in treating four cases with secondary strictures due to various reasons with good results but with some minor postoperative problems.

Introduction

Congenital absence of the vagina, part of the Mayer-Rokitansky-Küster syndrome, is a rare occurrence with an incidence of about one in 5,000 live-born female infants. The malformation also includes a hypoplastic non-functioning uterus and rudimentary fallopian tubes. As the ovaries are not affected, the female secondary sexual characteristics are normal. The aetiology of the disorder is thought to be a failure of the Müllerian ducts to respond to hormonal secretion. As the vulva is derived from the urogenital pit and not from the Müllerian ducts, the vaginal introitus is normal.

In a case report published in 1898, Abbe described a method for creating a vagina with split-thickness skin grafts.¹ In 1938, McIndoe and Banister further investigated this technique², which, with small variations, has been the standard procedure at our department for constructing a vagina.^{3,4} In a series of 17 patients, six had incomplete take of the grafts with an extended healing

period of up to six months, during which period a vaginal mould was used most of the time. At operation the neovaginal cavity was made 12 cm deep, but the usual depth of the vaginas at follow-up was 6-10 cm with a mean of 8 cm despite a long period of postoperative stenting. Sexual activity was therefore delayed until six months postoperatively. Obviously, the limited take of the grafts is the most difficult problem with the McIndoe technique and the advent of vacuum therapy, which improves the take of grafts in difficult anatomical sites, inspired us to test it in the construction of a vagina with skin grafts.

Patients and Methods

Patients

To date, we have treated five patients with congenital vaginal aplasia using the vacuum therapy system. Three women were treated with split-thickness skin grafts at age



Fig. B13.1 H-shaped incision in the vaginal pit.



Fig. B13.2 Full-thickness skin graft 17 x 8 cm taken from the groin.



Fig. B13.3a-c Semisolid silicone rubber (Silastic) rod (a); wrapped with a vacuum therapy foam, greased gauze (b), and skin graft (c).



Fig. B13.4a Vacuum therapy device with split-thickness skin graft.

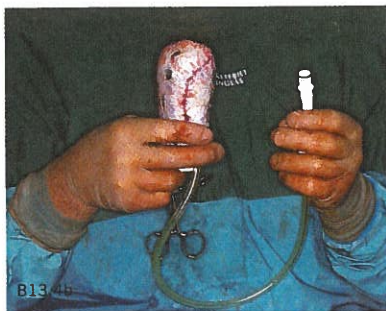


Fig. B13.4b Vacuum therapy device with full-thickness skin.

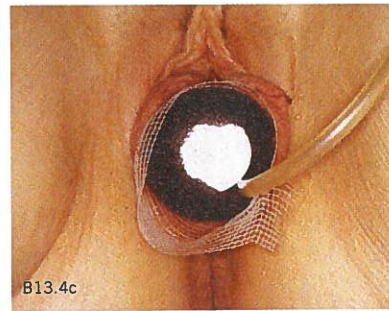


Fig. B13.4c The device has been inserted into the surgically prepared vaginal cavity.

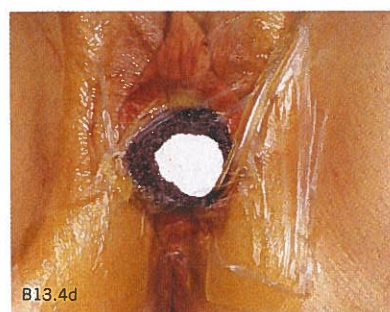


Fig. B13.4d Air-tight sealing with hydrocolloid dressing (Duoderm®) and semipermeable adhesive dressing (Tegaderm®).



Fig. B13.5a On removal of the foam at day 6 the meshed split skin graft is well healed.

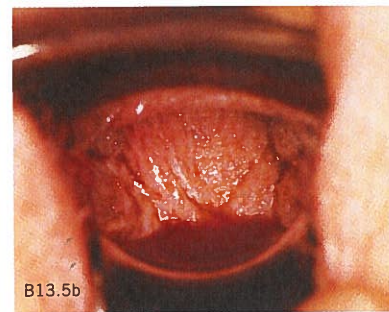


Fig. B13.5b On day 13 the healing is more mature.



Fig. B13.6a Full-thickness skin graft in the vaginal cavity at three months. The graft retains most of its skin characteristics.

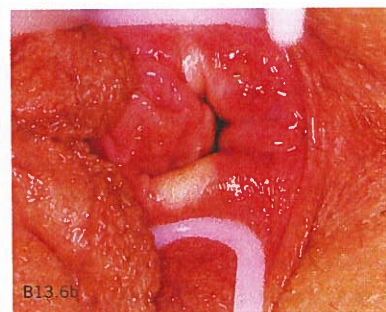


Fig. B13.6b The border between the pink introital mucosa and the full-thickness graft is clearly seen.



Fig. B13.7 At six months the donor areas of full-thickness skin grafts in the groins are still hyperaemic but not hypertrophic.

Table B13.1 Published literature on the subject of the treatment of gynaecological wounds by vacuum therapy

Year	Author/Journal	Evidence-Level	Number of Patients/ Indication	Vacuum Therapy	Course
2003	Hallberg et al. ¹ <i>Scand J Plast Reconstr Surg Hand Surg</i>	5 (case report)	n = 4, young girls (Mayer-Rokitansky- Küster-Syndrome) split-thickness skin graft (n = 2) full-thickness skin graft (n = 2)	5 days p.o. intra- cavitary	good results, high take rate of the mesh-graft, no contraction of the neovagina
2004	Schimp et al. ³ <i>Gyn Oncol</i>	4 (case series)	n = 14, maligne gynaecological disease, chronic wound healing problems at the vagina	median 32 days (3-88)	96 % reduction of wound surface, 1 complication: hematoma, painful dressing change in 67% of all patients
2005	Shvartsman et al. ¹⁰ <i>Obstet Gynecol</i>	5 (case report)	n = 1, Paget's disease of the vulva	16 days	safely temporize wound closure until the final histopathologic results, helped secure the skin graft to the large and irregular surface.

17, 18 and 21, respectively, while two others underwent treatment at age 16 and 18, respectively, with full-thickness skin grafts taken from the groin. The five patients met full criteria for the diagnosis of Mayer-Rokitansky-Küster syndrome.

We have also treated four cases with secondary strictures. The first case was a patient with primary vaginal aplasia who had undergone surgery in 1977 with split-thickness skin graft. She developed a stricture more than ten years after primary surgery. The second case was a 15-year-old girl who in early childhood had introduced a mercury battery into the vagina and subsequently developed a severe stricture. The third case was a 57-year-old woman who, after having undergone several laser treatments of the vagina, developed a stricture that was operated on three times with split-thickness skin graft with no success. The fourth case was a stricture in the vagina secondary to surgery to correct anal atresia.

Surgical Technique

The operation is done under general anaesthesia and the patient is positioned with leg supports. The pubic region is shaved carefully so that the vacuum therapy system can be sealed tightly. A 16-Ch urethral catheter is introduced and after the bladder has been filled with saline, a suprapubic catheter is inserted percutaneously. The inner labia are sutured to the inner thigh for better expo-

sure of the surgical field. An "H"-shaped incision is marked in the introitus and the area is infused with adrenaline solution (Fig. B13.1). After sharp mucosal incisions, blunt finger dissection is used in the perineum in the lateral aspects of the "H". Centrally, a distinct "raphe" connects the urethra to the rectum, and this is divided with scissors guided by a stent in the urethra and a finger in the rectum to make the dissection safe. Once the vesicorectal space has been reached, the dissection is easy and preferably blunt until a depth of about 12-14 cm has been reached. Bleeders are usually confined to the superficial structures. In case of vaginal strictures the dissection is modified according to the type of defect. Skin grafts are taken either from the gluteal-femoral region (split-thickness grafts) or from both groin areas (full-thickness grafts). The full-thickness grafts are 8 x 16-17 cm (Fig. B13.2). All grafts are meshed. The vaginal mould is composed of a central core of a semisolid silicone rubber (Silastic) rod 3 cm in diameter which is covered with a 1 cm thick foam. In our first cases we used the black polyurethane foam covered with Mepitel® (silicon) but we have changed this strategy and are now using the white polyvinyl alcohol foam instead without the Mepitel®. The reason for this is that the black foams have a tendency to adhere to the introitus with a risk for tear injuries when the dressings are removed. The skin grafts are positioned on top of the mould/foam (Figs. B13.3a-c).

The urethral catheter is removed and the stent with the skin graft introduced into the vaginal cavity. To prevent leakage in the vacuum therapy system, strips of hydrocolloid dressing (Duoderm®) are used between the anus and the vagina and around the labia. The mould and foam are then sealed with a semipermeable adhesive dressing (Tegaderm®) and negative pressure of -125 mmHg is applied. The pressure is decreased to -75 mm Hg after one day (Figs. B13.4a-d).

Results

In four cases with primary vaginal aplasia the grafts took completely, but in our most recently treated patient, despite an almost 100% graft take at removal of the mould, a stricture developed within one month postoperatively for unclear reasons. This patient underwent a second surgery with an 80% graft take and with minor tendency to stricture handled with dilatation on a regular basis. The margin of the full-thickness skin graft became detached from the introital mucosa in one case when the mould was removed due to adherence between the graft and the black foam. This had healed at two months.

Patients remained in bed during the first postoperative day and then were allowed to ambulate freely. In the first case (split-thickness skin graft), the mould was removed after six days. The patient was advised to use the retaining stent after operation, which was our routine procedure, but for psychological reasons she refused this regimen. On check-up six months postoperatively there was no contraction of the cavity, which remained 12-13 cm deep and after 35 months follow up there is still no tendency to stricture or other problems. She reported regular vaginal intercourse with full satisfaction from one month postoperatively. The other case with split-thickness graft was completely healed at follow-up four months postoperatively. We recommended that the two patients who had received full-thickness grafts should test the patency of the vagina daily with a mould. One of them had vaginal intercourse 28 days postoperatively, while the patient with a introital wound had intercourse after six to seven weeks with minor problems. The maximum follow-up to date is 41 months, and the shortest is two months.

On inspection the split-thickness grafts looked more like a normal vaginal cavity with a soft and pliable lining (Fig. B13.5). The full-thickness grafted neovaginas were

pale and showed a few hairs. In no case has the vaginal cavity contracted (Fig. B13.6).

Secondary strictures in the vagina are more complicated and in the case with a stricture secondary to childhood insertion of a mercury battery we first did a split-thickness skin graft transplant that initially healed without any complications. She quite soon developed a stricture and was operated on again, this time with full thickness skin graft. Unfortunately, there was just minor graft take due to a rotation of the mould and the patient underwent a final surgery with split-thickness skin graft with complete graft take. In the other three cases with secondary strictures there have been minor problems but all are healed at the present time and have not yet developed any further strictures.

Discussion

There are three principal methods of creating a neovagina in congenital cases. There is a non-surgical method involving pressure on the vaginal pit by vaginal stents of increasing volume. Success with this technique has been claimed in cooperative patients. Another technique is to use intestinal segments drawn down through a space created between the bladder and the rectum to the perineum. This method is of course intra-abdominal and complicated, and problems may be encountered during and after operation. The third and, perhaps, most common technique is to line the neovagina with free skin grafts. Split-thickness skin grafts have been used most often, and long-term follow up has shown a patent and functional vagina; most patients have reported a normal sex life. In the long-term, the split skin retains most of its original morphological and histochemical characteristics, but atrophy of sweat glands and hair follicles has been observed⁴. The main disadvantage with the split-thickness technique is inadequate take of the graft and late stenosis or contraction of the neovagina. In a recently published case report fibrin tissue adhesives were used to secure the split-thickness graft in neovagina reconstruction in two cases with a reported graft take of 80% and no complications². We have also used this technique in burn injuries and other diagnoses for securing grafts with good results but not in construction of a neovagina. One disadvantage of using fibrin tissue adhesives alone for securing the graft in creating a neovagina is the risk of fluid retention in the cavity, which is prevented using the vacuum therapy system.

If full-thickness skin grafts, which are well known to resist contracture, are substituted for split-thickness skin grafts the vagina does not contract but grows at the rate of the remainder of the body without requiring prolonged stenting or care⁷. It may also be more acceptable to the patient to have a linear scar in the groins than split-thickness donor site scars in the thigh or buttocks (Fig. B13.7).

The vacuum therapy system increases local blood flow, encourages the formation of granulation tissue, increases bacterial clearance, and minimises local oedema⁸. Those factors considerably improve the take of skin grafts particularly in the case of vaginal construction, where the evacuation of fluid as well as mechanical securing of the graft are key points. Others have shown good take of grafts in difficult anatomical regions with the vacuum therapy system⁹ (see Table B13.1). Another advantage of the vacuum therapy system is that patients can be ambulated shortly after surgery and with more comfort compared to the original McIndoe and Banister method.

The white polyvinyl alcohol foam is recommended because of the polyurethane foam's tendency to strongly adhere to the graft with risk of tearing injuries when removing the foam.

Altogether, the main objections to using split-thickness grafts include a poor take rate and late contraction of the neovagina. Both of these objections seem to be counteracted by vacuum therapy. This treatment also increases the take of full-thickness grafts in the cavity. The use of vacuum-assisted closure together with healing of skin grafts in the vaginal cavity has been proven to be promising. However, as the full-thickness grafts seem to retain most of their skin characteristics including hair growth and thicker, less pliable skin, split-thickness skin grafts may actually be better in the long run. The problem of late contracture cannot be evaluated yet given our maximum follow-up period of only 41 months (range: 2-41 months).

In conclusion, VAC treatment together with skin-lined vaginoplasties seems to solve the problems of delayed healing and late contracture of the vaginal cavity. It is, however, important to follow the patients for a few years more to see if the promising initial results will stand the test of time.

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Part B / Chapter 14

Vacuum Therapy for Necrotising Fasciitis – A Review and Case report

S. Meiners, W. Schwarz and C. Willy

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Eight publications (level 5 evidence) in the literature discuss the use of vacuum therapy for necrotising fasciitis. The majority of patients presented with soft-tissue infection of the inguinal, mediastinal or cervical regions of the trunk. In the reported cases, vacuum therapy was particularly effective in covering large, heavily exuding wounds in a clean and hygienic manner between debridements and for the preparation of the wound bed for split-thickness skin grafting at a later stage of treatment.

Introduction

Necrotising fasciitis is a life-threatening infection of the soft tissues. It is characterised by fulminant necrosis of fascia that may extend to the skin and subcutaneous tissue¹⁸. Secondary muscle involvement may occur in advanced cases^{5,10,16,23,24}. Infection is caused by bacteria and can affect all fascial structures of the body. In 1977, necrotising fasciitis was, for the first time, classified into two different types: Infections are caused either by a mixture of aerobic and anaerobic organisms that act synergistically (type 1) or by *group A streptococcus* (GAS) alone (type 2)⁹. The most common causative agents of necrotising fasciitis are anaerobic organisms present in polymicrobial infections. The most frequent anaerobes are *Peptostreptococcus* (75-80%) and *Bacteroides species* (58%). By contrast, *group A streptococcus* accounts for only 10-18% of cases¹⁵. The organisms usually extend to the fascia from a small wound after minor trauma or from ulcers. In addition, many cases of iatrogenic inoculation during intramuscular injection have been described in the literature^{1,7,8,16}.

The cardinal symptom of necrotising fasciitis is severe local pain caused by ischemia of the fascia. Inspection reveals erythema without distinct margins that is usually accompanied by marked tissue edema extending beyond the erythema. With progression, livid discolouration may develop especially in the central region and can give the skin a map-like appearance. This eventually results in necrosis. Fascial necrosis is far more extensive than cutaneous changes, which may be accompanied by the development of bullae. Crepitation is found in approximately 50% of cases and is a sign of mixed infection^{15,16,23,25}. Necrotising fasciitis is typically characterised by the absence of lymphadenopathy.

Without treatment, necrotising fasciitis leads to fulminant septic shock with deterioration in mental status (confusion and somnolence) and eventual multi-organ failure (MOF). Fisher⁵ defined the following diagnostic criteria for necrotising fasciitis:

- extensive necrosis of fascia with widespread undermining of surrounding tissue
- moderate to severe systemic toxic reaction and deterioration in mental status
- failure to demonstrate clostridia in wound cultures
- absence of primary muscle involvement

- absence of vascular occlusion
- pathological examination of debrided tissue showing leukocyte infiltration, focal necrosis of fascia and surrounding tissues and thrombosis of microvasculature.

The diagnosis of necrotising fasciitis is primarily clinical. Early diagnosis is crucial to patient survival. Key roles in making the diagnosis are played not only by clinical signs and symptoms but also by comprehensive microbiological tests that are carried out to identify the causative organisms. Ultrasonography reveals a hypoechoic space between the subcutis and underlying musculature, which, morphologically, is liquefactive necrosis of the fascia^{5,16,17}. Roentgenographic examination of the involved site may disclose gas as in cases of gas gangrene. Computed tomography and magnetic resonance imaging seldom provide additional information. Fascial biopsy is an invasive method that can be useful in diagnosing necrotising fasciitis. It shows the greenish fluid remains of tissue that are typical of liquefactive necrosis. A manual dissection of the fascia is easy to perform in this case. Thrombosis of small blood vessels with branch-like structures may occur^{9,11,16}. Erysipelas, gas gangrene, streptococcal myositis, which primarily affects muscular tissue, and streptococcal toxic shock syndrome (STSS) should be considered in the differential diagnosis. Treatment of necrotising fasciitis must be instituted as soon as possible and consists of radical surgical debridement and removal of all necrotic tissue. Only the complete removal of toxic bacterial decomposition products can prevent the development of septic shock. Surgeons must avoid insufficiently extensive surgery, irrespective of how large the resulting defect might be.

Incision and drainage alone are contraindicated in necrotising fasciitis. The mainstays of treatment are initial and repeated surgical debridements together with the intensive treatment of septic complications. Hyperbaric oxygen therapy (HBO), which involves breathing pure oxygen in a pressure chamber, may serve as an adjunct to surgical cleansing, antibiotic treatment and intensive care. HBO therapy should be commenced after initial debridement and repeated several times a day in the early phase of treatment. Once the wound conditions have improved, the number of hyperbaric oxygenation sessions can be reduced²⁷. This form of treatment not only inhibits the growth of obligate anaerobic bacteria but also improves the supply of oxygen to ischemic tissue.

It thereby aids the oxygen-dependent destruction of microbes by phagocytes and encourages repair mechanisms.

At a later stage of treatment, a variety of plastic surgery procedures are available for the coverage of large defects. These procedures include but are not limited to secondary suture, split-thickness skin grafts, and rotational flaps. Strict adherence to the relevant therapeutic principles can help achieve a low mortality rate from necrotising fasciitis. The most important prognostic factor is the time from the onset of symptoms to the first surgical intervention. The average mortality rate of necrotising fasciitis is approximately 30%^{4,19,26,28,29}. Radical surgical management and standardized treatment can reduce mortality to less than 20%^{16,26}. Infections of the extremities have a better prognosis than those in the periphery of the trunk. Intra-abdominal extension of the infection is usually fatal^{8,22,26}.

Literature Review

The majority of publications on the treatment of necrotising fasciitis with vacuum therapy are case reports^{2,3,6,9b,12,14,20,21,21b}. The first articles on this indication for vacuum therapy were published in 2000. Most patients presented with soft-tissue infection of the inguinal, mediastinal or cervical regions of the trunk. In the reported cases, vacuum therapy was particularly effective in closing large, heavily exuding wounds in a clean and hygienic manner between debridements and for the preparation of the wound bed for skin grafting at a later stage of treatment.

Case Presentation

Medical History

In mid-February 2001, a 54-year-old woman was admitted to hospital and treated conservatively for acute lumbago and sciatica with S1 radiculopathy. During the course of treatment, the patient received at least one, but possibly more intramuscular injections of diclofenac and corticosteroids into the gluteal muscle. Commencing on 6 March 2001, the patient complained of trunk pain that progressively worsened. As her general condition deteriorated, the patient was referred to a larger hospital on the following day with a suspected diagnosis of abscess formation and in order to rule out an acute abdomen.

Chemical laboratory tests showed elevated levels of creatine kinase (1018 U/l), C-reactive protein (43.7 mg/dl) and serum creatinine (1.7 mg/dl). An abdominal CT was taken and showed marked phlegmonous inflammation in the region of the right lateral chest and abdominal wall, the presence of an extensive right retroperitoneal phlegmon and swelling of the psoas and lumbar quadratus muscles. Since the patient was suspected of having severe necrotising soft-tissue infection, extensive surgical debridement was performed on the same day. She then developed severe sepsis with respiratory and circulatory insufficiency and disseminated intravascular coagulation. Once group A *beta-hemolytic streptococci* were identified, antibiotic treatment with clindamycin, penicillin G and gentamycin was instituted. Over the following three days, intensive treatment and two further surgical revisions helped combat sepsis. Then, however, there was a significant increase in the severity of local signs and symptoms, including muscle necrosis, a marked inflammatory response of the skin, and an increase in inflammatory parameters. Since a mixed anaerobic infection was suspected, the patient was referred to us on 16 March 2001 for hyperbaric oxygen therapy and for further surgical and intensive care treatment.

Findings on Admission

The patient had undergone incision and debridement of skin and subcutaneous tissue in the entire region of the right flank from the scapular line to the iliac crest (Fig. B14.1-2).

Treatment and Course

Treatment commenced with further surgical debridement of the skin and subcutaneous tissue. Beginning in the gluteal region, an incision to the deep fascia was made and continued over the greater tuberosity in cranial direction to the iliac crest where devitalised tissue of the transverse abdominal muscles had to be removed. Necrotic fatty tissue was removed on the dorsal side of the peritoneum, which, however, was not opened. Superficial portions of the psoas muscle were removed, but the muscle mass was preserved. The ilioinguinal and genitofemoral nerves were necrotic and had to be resected. Cranially, it was necessary to remove skin tissue extending to the mid-pelvis at the level of the spinous processes. The area of necrosis extended to the mid-



Fig. B14.1-2 Ventral and dorsal views after previous incision and debridement of skin and subcutaneous tissue in the entire region of the right flank from the scapular line to the iliac crest. In deeper layers, the fascia has a greenish-grey color.



Fig. B14.3-4 Same patient after further extensive debridement. Vacuum therapy was used to cover and hygienically close the large wound.



Fig. B14.5-6 Ventral and dorsal views on the 11th postoperative day. No extension of the infection. The peritoneum is exposed but healthy. The liver is clearly visible.

scapular region in the cranial direction and to the anterior axillary line in the ventral direction. The axilla itself was left intact (Fig. B14.3).

At the end of surgery, the wound area was sealed using vacuum therapy (Fig. B14.4). Postoperatively, the patient was admitted to the intensive care unit and treated for massive volume and catecholamine requirements. On the first, second, third, fifth, eighth and eleventh postoperative days, further wound revisions were performed and foam dressings were changed (Fig. B14.5-6). A special air mattress was used for the patient in order to promote healing of the extremely large and heavily exuding wound. Throughout this period, the patient was under deep sedation and analgesia and was mechanically ventilated. She had eight sessions of treatment in the hyperbaric chamber.

Since it was evident that the patient required long-term ventilation, a tracheotomy was performed. With

time, the patient stabilised. It was therefore possible to use less invasive techniques of ventilation and to reduce the usage of catecholamines, until the patient could finally be transferred to a hospital closer to her home. At the time of transfer, the wound was clean and showed no signs of necrotising fasciitis. After further preparation of the wound bed for improving the wound-healing environment, the wound was covered with autologous split-thickness skin grafts, which took well. Apart from cholestatic jaundice of unknown origin and difficulties in weaning from prolonged mechanical ventilation, the further postoperative course was uneventful. Approximately two months after initial surgery, the patient was referred for further rehabilitation. She had regained complete consciousness, her circulatory system was stable, and she was able to breathe spontaneously. Apart from some small residual defects, the wound showed no signs of inflammation. The peritoneum, which had been covered with

split-thickness skin grafts in the right lower abdomen, also healed without complications and was additionally stabilised by a post-surgery girdle.

Discussion

So far, there are ten publications – nine case reports (level 5 evidence) and one letter – on the use of vacuum therapy for necrotising fasciitis in the literature. No complications are reported. There is general agreement that vacuum therapy is especially effective in covering large wounds safely and hygienically^{2,3,6,9b,12-14,20,21,21b}. Large amounts of fluid exuding from the wound can be removed in a manner that is comfortable for staff and patients alike. During this period of treatment, the purpose of vacuum therapy is to temporarily cover large and heavily exuding wounds. At a later stage of treatment, vacuum therapy is used for wound bed preparation. Finally, it is eminently suitable for improving the take of split-thickness skin grafts that cover large wounds and thus helps achieve a high take rate.

The diagnosis and treatment of necrotising fasciitis primarily depend on the clinical situation. The time and extent of surgical intervention are the key prognostic factors. The mainstays of medical management are the symptomatic treatment of septic shock, antibiotic medication and immunological approaches such as the use of immunoglobulins as an adjunctive therapy. On the basis of an objective risk-benefit analysis, hyperbaric oxygen (HBO) therapy is a suitable complementary therapy in the management of necrotising fasciitis, especially in cases where antibiotic treatment and surgical debridement appear to be insufficient.

Using vacuum therapy it is possible to safely and comfortably cover large soft-tissue defects extending as far as the chest wall or the peritoneum. Whereas continuous suction should be applied initially in order to remove discharge from the wound, intermittent suction can be used later for the preparation of the wound bed.

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Part B / Chapter 15

Vacuum Therapy for Intra- and Perioperative Irradiation of Malignant Soft Tissue Tumors

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Effective treatment of invasive or relapsing extensive malignant soft-tissue tumors remains an interdisciplinary challenge. Especially in cases of advanced or relapsing tumors affecting vital structures, mere surgical excision often does not contribute to lasting success. In the past, the alternative to incomplete tumor resection would have been amputation of an extremity or hemipelvectomy. In order to avoid mutilating operations, multimodal therapeutic approaches (chemotherapy and/or radiotherapy) are required. Intraoperative radiotherapy (IORT) represents a common procedure, especially in cases in which radical resection of the tumor is not foreseen due, for example, to tumor localisation. Difficult wound healing as a side effect of IORT has also been recognized. The significant requirements in terms of facilities and personnel for performing IORT forestall the wider use of this technique. The combination of multimodal therapeutic approaches (e.g. minimally invasive brachytherapy, special plastic implants and mesh) and vacuum therapy for temporary coverage of the tissue defect after tumor operation as well as simultaneous elevation of myocutaneous flaps or fasciocutaneous flaps for flap conditioning (delay procedure) is cost effective and contributes significantly to increasing patients' quality of life. Transplant patients can be easily ambulated without compromising vacuum therapy. This procedure improves the outcome of coverage of patients' plastic surgical defects and, in case of a relapse, allows for further radiotherapy as the tissue above the previous tumor area is well vascularized and not previously irradiated.

To date, no other research groups have presented *peer-reviewed* articles dealing with this indication of vacuum therapy.

Introduction

Malignant and semi-malignant soft tissue tumors have a high risk of recurrence. Especially in cases of advanced or relapsing tumors affecting vital structures, mere surgical excision often does not contribute to lasting success, with the result that multimodal therapeutic approaches are required. These may include chemotherapy or radiotherapy, either consecutively or combined as radio-chemotherapy. Intraoperative radiotherapy (IORT) represents a common procedure, especially in cases in which radical resection of the tumor is not foreseen due, for example, to tumor localization.

Because IORT is restricted to specially equipped surgical suites, its use at present remains limited to only a few centers. Temporary vacuum therapy can circumvent this technical obstacle. Concomitantly, the time required for the intra- and peri-operative radiotherapy can be used to precondition large myo- or fasciocutaneous, axially vascularized flaps. These flaps can then be transposed more safely after the irradiation to cover the defects.

Patients and Methods

This combination of therapies has been used in our department to treat patients with a malignant fibrous histiocytoma, a leiomyo- or liposarcoma and a desmoid tumor. In four patients (three male, one female; age 31-68 years) a temporary vacuum therapy application for perioperative radiotherapy was carried out after it had been determined that radical surgical excision (R0-resection) could not be performed due to tumor localisation and

affected vital structures. In three other patients brachytherapy applicators (tubes and FLABS) were placed on the not yet completely redeveloped tumor area and sealed with vacuum polyurethane foam under continuous computer-controlled suction at a subatmospheric pressure of -125 mmHg.

In one patient vacuum therapy was started after tumor resection; percutaneous radiotherapy was performed postoperatively. In two patients a tensor fasciae



Fig. B15.1 Gluteal soft-tissue defect in a young female patient with relapsing desmoid tumors and renewed operative tumor removal. The microscopically epineurectomized sciatic nerve is marked with a yellow loop.



Fig. B15.2 The so-called "FLAB" as a carrier of the brachytherapy tubes for the later insertion of the radiation tubes is cut to the size of the defect and prepared.



Fig. B15.3 Insertion of the "FLAB" as carrier of the brachytherapy tubes into the resectional defect and directly on to the wound bed to be treated; suture fixation to secure correct position.



Fig. B15.4 After implantation of the FLAB, a PU-vacuum therapy foam is applied onto the plastic FLAB and sealed with an airtight film prior to being connected to the vacuum therapy unit.

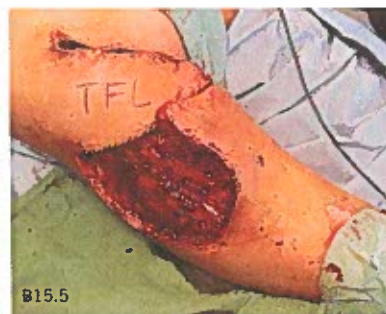


Fig. B15.5 After the brachytherapy has been completed the prepared *tensor fasciae latae* (TFL) flap is raised and transposed into the defect.



Fig. B15.6 The flap donor site is primarily closed and the defect is covered with a non-irradiated TFL flap over the treated region.



Fig. B15.7 Two weeks after the brachytherapy the flap and the donor site have healed.

latae flap was circumcised during the initial operation, elevated and sutured back. In two other patients a myocutaneous vertical rectus abdominis (VRAM) flap, pedicled at the inferior epigastric artery, was elevated and preconditioned. After the radiotherapy had been completed final coverage of the defect was performed by flap transposition over the irradiated area.

Results

In all cases we were able to prevent progression of the tumor and actually achieve tumor remission by using this combined multimodal therapy. Surgical resection was carried out as radically as possible. Thereafter, once brachytherapy had been started, the wounds could be properly sealed using polyurethane foam with continuous local negative pressure of -125 mmHg.

In order to obtain maximum local tissue protection, both brachytherapy and external conventional beams were used in three cases (for details see Kopp et al. 2005¹³). All patients were completely ambulatory during the time of vacuum and radiotherapy. All flaps completely healed into the irradiated area. In one case an additional gluteus maximus myocutaneous flap was necessary due to a gigantic resectional defect to cover the pelvic bones, because the tip of the first flap became necrotic. At the time of follow-up examination all patients were alive and completely ambulatory without any restrictions of their quality of life concerning the flap donor site and the coverage.

Discussion

Effective treatment of invasive or relapsing extensive malignant soft-tissue tumors remains an interdisciplinary challenge. Although desmoid tumors generally grow slowly, because of their invasiveness in breaking through the fascia and muscle structures with involvement of vital neurovascular structures, they may still represent a problematic tumor entity. In our patients the alternative to an incomplete tumor resection would have been amputation of an extremity or hemipelvectomy. Such aggressive treatment was refused by our comparatively young patients as well as by the two older patients, who consistently rejected mutilating operations. Survival rates in malignant fibrous histiocytomas are significantly influenced by factors such as histologic grading, surgical resection margins and tumor size. There is strong

evidence in the literature that adjuvant chemo-radiotherapy is especially advantageous for patients with minimal or marginal residual tumors confined to the surgical resection margins²⁴. This also confirms our experience with the particular cases described here.

While intraoperative radiotherapy was shown to be an effective treatment for a series of malignant tumors^{2-4,7,8,12,15,16,19,20,22-25,26} this procedure was also described as a suitable therapeutic modality for patients with a malignant fibrous histiocytoma. The problematic nature of deteriorated wound healing as a side effect of IORT has also been recognized. The significant requirements in terms of facilities and personnel for performing IORT, not to mention the previously described wound-healing problems, forestall the wider use of this technique in patients with corresponding indications.

By comparison, minimally invasive brachytherapy used in the treatment of soft-tissue tumors can contribute to the protection of the surrounding tissue from the adverse effects of the radiotherapy. This is facilitated by use of special plastic implants and nets that at the same time allow for an adequate apportionment of beams into the tissue. Danger of protracted wound healing is an especially great risk in patients in whom chemotherapy is required in addition to brachytherapy⁹.

The use of these techniques combined with vacuum therapy makes it possible, on the one hand, to perform high-dose radiotherapy on an incompletely resected soft-tissue tumor. On the other hand, adequately sized myocutaneous flaps or fasciocutaneous flaps can simultaneously be elevated and have their blood flow improved through the so-called delay phenomenon. This means an increase in microcirculation through the change of the vascular flow in an axialized flap. Hence, the tissue destined for future transplant remains at its position and is not exposed to the radiation therapy. After its final transposition, vacuum therapy allows for significantly better coverage of the irradiated area than would be the case with irradiated tissue.

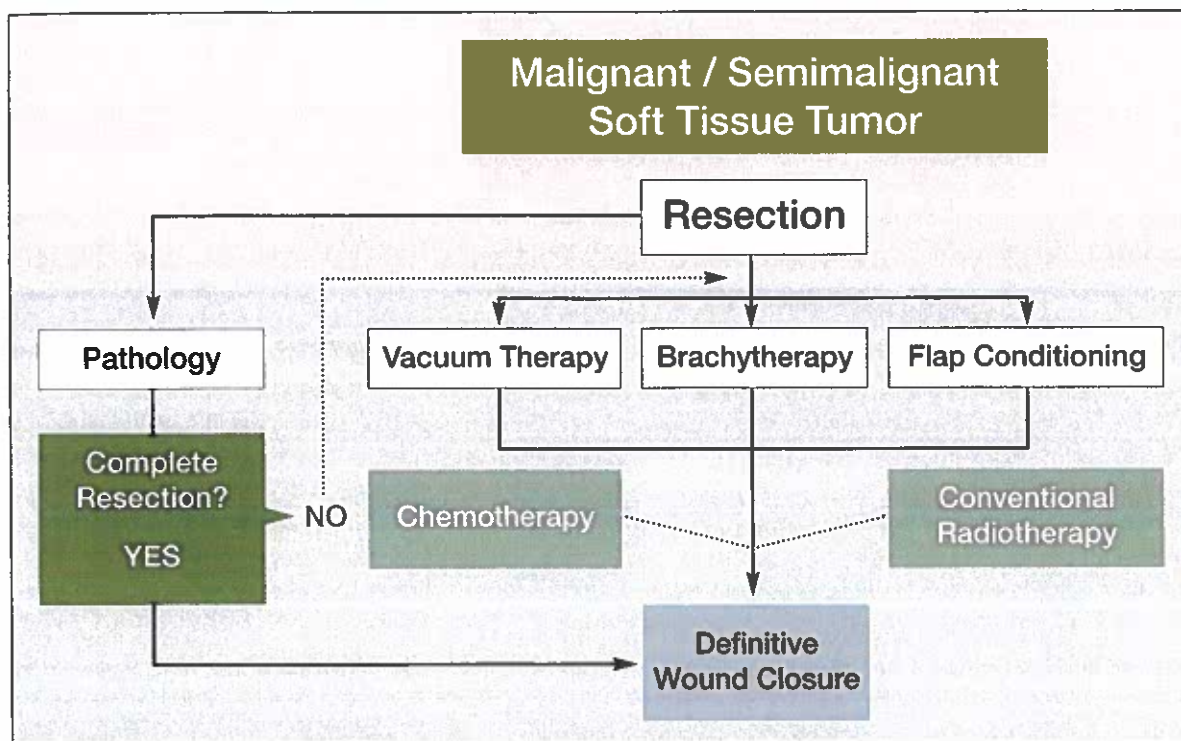


Fig. B15.8 Algorithm for the combined application of brachytherapy and vacuum therapy for treating malignant and semi-malignant soft-tissue tumors.

The combination of the above-described techniques is comparatively simple and has been shown to be safe. It allows for immediate peri-operative radiotherapy in centers without access to cost-intensive IORT equipment. During radiotherapy and until final coverage of the defect patients can be easily ambulated without compromising vacuum therapy. The procedure is cost efficient and contributes significantly to increasing patients' quality of life. Transplanting a conditioned axially circulated flap improves the outcome of the coverage of patients' plastic surgical defects and, in case of a relapse, allows for further radiotherapy as the tissue above the previous tumor area is well vascularized and not previously irradiated.

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Part B / Chapter 16

Vacuum Therapy in the Treatment of Intra- and Extraoral Wounds in Oral and Craniomaxillofacial Surgery

D. Halama

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Over the past decade, chronic wounds of the extremities and trunk have been successfully treated by the application of subatmospheric pressure. Over the course of these 10 years, the initial limits of this method have been overcome by the development of special dressing systems, such as the abdominal dressing system⁶ or the heel dressing kit³. Novel reconstructive therapies such as dermis replacement using Integra® split-thickness skin grafts were made possible in the first place by the use of vacuum therapy⁴.

By comparison, use of vacuum therapy in treating wounds of the head and neck has been relatively rare (up to now, there was no *peer-reviewed* article published dealing on this topic). Reasons include the surface geometry of the face as well as the mobility of the face due to the mimic musculature, both of which make vacuum therapy difficult. Because of the visibility of the dressing, reduction in patient compliance is very rarely seen. The characteristics of the wounds and their surroundings, however, created special demands: for example, in the treatment of chronic wounds after radiation therapy, it is of great importance to avoid maceration of the surrounding skin. The ability to achieve an adequate seal is often compromised by the need to take into account structures such as ears, eyelids or the nostrils. Finally, because the oral cavity is lined with mucous membrane and use of the foam-drape system is not possible, the development of a completely new dressing system was required². The following presentation uses case examples to propose solutions to problems affecting the application of intra- and extraoral vacuum dressings at various localisations in oral and craniomaxillofacial plastic surgery.

Intraoral Application

The oral cavity is one of the regions of the human body with essential functions, including the mastication and moistening of food and phonation; hence, the requirement that an intraoral vacuum therapy system should restrict speaking and food intake as little as possible, since otherwise one could expect significant compliance issues on the part of patients.

Case 1

History

This 52-year-old male patient presented to our clinic for evaluation of a large keratocyst localised in the area of the mandibular angle and the mandibular ramus initially identified on routine dental radiography (Fig. B16.1). Following histological confirmation of the diagnosis, cystectomy followed by transplantation of autologous iliac crest spongiosa to fill the defect was performed. Postoperative wound healing problems, however, resulted in complete loss of the spongiosa transplant. Subsequently, the large osseous intraoral wound surface was irrigated daily and dried. Systemic antibiotics were ordered for prevention of primary chronic osteomyelitis (Fig. B16.2). Under these circumstances, a second spongiosa transplantation was not possible.

One treatment option consisted in a continuous resection of the affected mandibular segment to be bridged over with a stable reconstruction plate for integration of a free bone transplant. Instead, we recommended that the patient undergo intraoral application of vacuum therapy.

Method

Classical vacuum therapy with a self-adhesive foil dressing was not suitable for use in the mouth because of its mucosal lining. In addition, the dressing would require high elasticity in order to withstand the movements of the mimic muscles and the muscles of mastication. For these reasons, an anatomically adapted high-elasticity silicone body was used instead of the foil dressing for wound sealing. The silicone body was created after placement of the foam in the oral cavity by means of spray application around the suction appliance of EPIFORM-Flex (Dreve Dentamid GmbH), an impression material

consisting of polyvinyl siloxane (Fig. B16.3). Upon application of subatmospheric pressure a close seal to the wall of the oral cavity is achieved by means of the capillary forces, which operate in the film of saliva that forms between the silicone body and the mucosal membrane. The complete dressing consisted of an appropriately trimmed polyvinyl alcohol foam and the silicone body of EPIFORM-Flex, which enclosed the *trac-pad connector*. The connection tubes were inserted through the mouth.

Therapy and Clinical Course

After a treatment period of seven days with a dressing change frequency of twice per week the patient exhibited a clean wound bed in the area of the osseous defect, which, after 38 days, had completely filled with granulation tissue. Following renewed preparation of the bony surface, the defect was filled under local anesthesia with about 15 ml of β -tricalcium phosphate granules (β -TCP; pellet size 1.4-2.8 mm; chronOSTM, SYNTHES®) mixed with blood according to the manufacturer's instructions. Wound closure followed using the above described method with dressing change every three to four days and oral antibiotic coverage was ordered. Vacuum therapy was continued on an out-patient basis and the patient visited the clinic only for dressing change.

Over the following weeks, we observed a slow integration of the β -TCP granules starting at the margins of the osseous defect zone. After eight weeks, CT follow-up imaging demonstrated almost complete integration of the β -TCP granules and vacuum therapy was discontinued at this point. The granulated intraoral wound surface quickly epithelialised beneath a small, integrated obturator, which, after have been shortened several times, was able to be removed after only three weeks' wearing time. After one year, radiographic follow-up revealed complete osseous regeneration of the former defect (Fig. B16.4).



Fig. B16.1 Pre-operative panoramic radiograph of the mandible with extensive areas of reduced attenuation secondary to cyst formation in the area of the left mandibular angle and left ascending mandibular ramus.



Fig. B16.2 Probing the wound cavity into the ascending mandibular ramus.

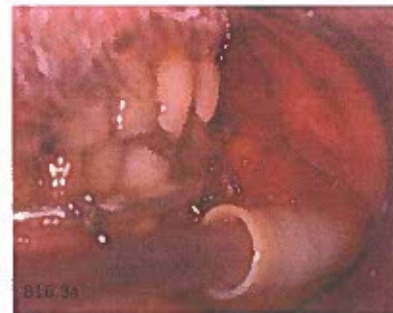


Fig. B16.3a Suction appliance with the anatomically modeled silicone body. *In situ*.



Fig. B16.3b Foam, suction appliance and silicone body following removal during dressing change.



Fig. B16.4 Panoramic radiograph one year after completion of vacuum therapy with complete osseous regeneration of the cyst lumen following integration of the β -tricalcium phosphate granules.

Case 2

Use of the above described dressing system is not feasible in the treatment of defects of the alveolar process of the mandible because the absent pouch formation precludes stable positioning. Fixation, however, is possible using a large-surface-area placement on the mandible. In fact, in patients with large defects, a stable wound covering is desirable for reducing mechanical irritations of the wound surface that occur during food intake.

History

In the present case, the patient required partial resection of the mandible after having been diagnosed with a squamous cell carcinoma of the anterior lateral floor of the mouth. The resulting defect was subsequently bridged with a reconstruction plate and covered with a micro-

vascularised radial flap transplant. The patient subsequently underwent radiation therapy at 60 Gy. After a disease-free interval of two years, the patient underwent pre-prosthetic mandibular reconstruction using a microvascularised iliac crest transplant placed under the radial flap, which remained *in situ*. In the immediate post-operative period the patient suffered complete loss of the radial flap transplant, leaving the transplanted iliac crest bone largely exposed intra-orally (Fig. B16.5).

Method

Because of the large wound surface area affecting the anterior floor of the mouth a different strategy for application of vacuum therapy was required. First, a polyvinyl alcohol foam appropriately trimmed to the wound geometry was placed and dental modeling of the mandible was subsequently obtained. This permitted creation of a

plaster model of the floor of the mouth including the foam that had been placed over the wound, which, in turn, served as the basis for production of a 2-mm thick dressing plate using the deep draw process. The suction appliance was fixed in this dressing plate using a polyvinyl-siloxane impression material (PRESIDENT®), which was also used to seal the plate margin upon application of the system in the mouth (Fig. B16.6). After application of subatmospheric pressure at -125 mmHg, stable fixation of the foam and dressing plate was observed. In this case also, the tube was fed through the mouth (Fig. B16.7).

Therapy and Clinical Course

Dressing change was performed twice weekly; only the polyvinyl alcohol foam required exchange. Debridement was performed at the time of the first two dressing changes. Complete granulation of the wound surface was achieved after twelve days of treatment, at which point vacuum therapy was discontinued (Fig. B16.8). Epithelialisation of the granulated wound surface was achieved by placement of a split-thickness skin graft and fixation with a classical dressing plate without vacuum (Fig. B16.9).



Fig. B16.5 Initial findings after partial debridement of necrotic radialis flap transplant with exposed intraoral iliac crest transplant.



Fig. B16.6a Manufacturing the dressing plate. Situation model of the floor of the mouth with polyvinyl alcohol foam in place.



Fig. B16.6b The dressing plate formed on the plaster model with the suction appliance fixed with silicone.



Fig. B16.7a Dressing system. Polyvinyl alcohol foam placed over the defect.



Fig. B16.7b Dressing plate sealed with silicone for improved seal at edges.



Fig. B16.7c Dressing plate with polyvinyl alcohol foam *ex situ*.



Fig. B16.8 Granulation tissue prior to covering the defect with a split-thickness skin graft.



Fig. B16.9 Results following successful split-thickness skin grafting.