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~~Solventum Corp. v. Wound Healing Techs., LLC; No IPR2025-01042~~

XIGRIS®

Drotrecogin alfa (activated)

BRIEF SUMMARY: Consult the Xigris package insert for complete prescribing information.

CLINICAL STUDIES: The efficacy of Xigris was studied in an international, randomized, double-blind, placebo-controlled trial (PROWESS) of 1690 patients with severe sepsis. Patients received a 96-hour infusion of Xigris at 24 mcg/kg/hr or placebo started within 48 hours after the onset of the first sepsis-induced organ dysfunction.

The study was terminated after a planned interim analysis due to significantly lower mortality in patients on Xigris than in patients on placebo (21/850, 25% vs 25/840, 31%, p=0.005).

The observed mortality difference between Xigris and placebo was limited to the half of patients with higher risk of death, i.e., APACHE II score ≥ 25 , the 3rd and 4th quartile APACHE II scores. The efficacy of Xigris has not been established in patients with lower risk of death, e.g., APACHE II score < 25 .

This is a short summary of the **CLINICAL STUDIES** section from the complete prescribing information.

INDICATIONS AND USAGE: Xigris is indicated for the reduction of mortality in adult patients with severe sepsis (sepsis associated with acute organ dysfunction) who have a high risk of death (e.g., as determined by APACHE II, see **CLINICAL STUDIES** in the full Prescribing Information).

Xigris is not indicated in adult patients with severe sepsis and lower risk of death (see **CLINICAL STUDIES** in the full Prescribing Information). Safety and efficacy have not been established in pediatric patients with severe sepsis.

CONTRAINDICATIONS: Xigris increases the risk of bleeding. Xigris is contraindicated in patients with the following clinical situations in which bleeding could be associated with a high risk of death or significant morbidity:

- Active internal bleeding
 - Recent (within 3 months) hemorrhagic stroke
 - Recent (within 2 months) intracranial or intraspinal surgery, or severe head trauma
 - Trauma with an increased risk of life-threatening bleeding
 - Presence of an epidural catheter
 - Intracranial neoplasm or mass lesion or evidence of cerebral herniation
- Xigris is contraindicated in patients with known hypersensitivity to drotrecogin alfa (activated) or any component of this product.

WARNINGS: Bleeding—Bleeding is the most common serious adverse effect associated with Xigris therapy. Each patient being considered for therapy with Xigris should be carefully evaluated and anticipated benefits weighed against potential risks associated with therapy.

Under certain conditions, many of which led to exclusion from the Phase 3 trial, are likely to increase the risk of bleeding with Xigris therapy. For individuals with one or more of the following conditions, the increased risk of bleeding should be carefully considered when deciding whether to use Xigris therapy:

- Concurrent therapeutic dosing of heparin to treat an active thrombotic or embolic event (see **PRECAUTIONS, Drug Interactions**)
- Platelet count $< 30,000 \times 10^9/L$, even if the platelet count is increased after transfusions
- Prothrombin time-INR > 3.0
- Recent (within 6 weeks) gastrointestinal bleeding
- Recent administration (within 3 days) of thrombolytic therapy
- Recent administration (within 7 days) of oral anticoagulants or glycoprotein IIb/IIIa inhibitors
- Recent administration (within 7 days) of aspirin > 650 mg per day or other platelet inhibitors
- Recent (within 3 months) ischemic stroke (see **CONTRAINDICATIONS**)
- Intracranial arteriovenous malformation or aneurysm
- Known bleeding diathesis
- Chronic severe hepatic disease
- Any other condition in which bleeding constitutes a significant hazard or would be particularly difficult to manage because of its location

Should clinically important bleeding occur, immediately stop the infusion of Xigris. Continued use of other agents affecting the coagulation system should be carefully assessed. Once adequate hemostasis has been achieved, continued use of Xigris may be reconsidered.

Xigris should be discontinued 2 hours prior to undergoing an invasive surgical procedure or procedures with an inherent risk of bleeding. Once adequate hemostasis has been achieved, initiation of Xigris may be reconsidered 12 hours after major invasive procedures or surgery or restarted immediately after uncomplicated less invasive procedures.

Mortality in Patients with Single Organ Dysfunction and Recent Surgery—Among the small number of patients enrolled in PROWESS with single organ dysfunction and recent surgery (surgery within 30 days prior to study treatment) all-cause mortality was numerically higher in the Xigris group (28-day: 10/49; in-hospital: 14/48) compared to the placebo group (28-day: 3/49; in-hospital: 8/47).

In an analysis of the subset of patients with single organ dysfunction and recent surgery from a separate, randomized, placebo-controlled study (ADDRESS) of septic patients not at high risk of death all-cause mortality was also higher in the Xigris group (28-day: 67/323; in-hospital: 76/325) compared to the placebo group (28-day: 44/313; in-hospital: 62/314). Patients with single organ dysfunction and recent surgery may not be at high risk of death irrespective of APACHE II score and therefore not among the indicated population.

PRECAUTIONS: Laboratory Tests—Most patients with severe sepsis have a coagulopathy that is commonly associated with prolongation of the activated partial thromboplastin time (APTT) and the prothrombin time (PT). Xigris may variably prolong the APTT. Therefore, the APTT cannot be reliably used to assess the status of the coagulopathy during Xigris infusion. Xigris has minimal effect on the PT and the PT can be used to monitor the status of the coagulopathy in these patients.

Immunogenicity—As with all therapeutic proteins, there is a potential for immunogenicity. The incidence of antibody development in patients receiving Xigris has not been adequately determined, as the assay sensitivity is inadequate to reliably detect all potential antibody responses. One patient in the Phase 2 trial developed antibodies to Xigris without clinical sequelae. One patient in the Phase 3 trial who developed antibodies to Xigris developed superficial and deep vein thrombi during the study and died of multi-organ failure on day 36 post-treatment but the relationship of this event to antibody is not clear.

Xigris has not been readministered to patients with severe sepsis.

Drug Interactions—Drug interaction studies with Xigris have not been performed in patients with severe sepsis. However, since there is an increased risk of bleeding with Xigris, caution should be employed when Xigris is used with other drugs that affect hemostasis (see **CLINICAL PHARMACOLOGY, WARNINGS** in the full Prescribing Information). Approximately 23% of the patients in the Phase 3 study received either prophylactic low dose heparin (unfractionated heparin up to 15,000 units/day) or prophylactic doses of low molecular weight heparins as indicated in the prescribing information for the specific products. Concomitant use of prophylactic low dose heparin did not appear to affect safety, however, its effects on the efficacy of Xigris have not been evaluated in an adequate and well-controlled clinical trial.

Drug/Laboratory Test Interaction—Because Xigris may affect the APTT assay, Xigris present in plasma samples may interfere with one-stage coagulation assays based on the APTT (such as factor VIII, IX, and XI assays). This interference may result in an apparent factor concentration that is lower than the true concentration. Xigris present in plasma samples does not interfere with one-stage factor assays based on the PT (such as factor II, V, VII, and X assays).

Carcinogenesis, Mutagenesis, Impairment of Fertility—Long-term studies in animals to evaluate potential carcinogenicity of Xigris have not been performed. Xigris was not mutagenic in an *in vivo* micronucleus study in mice or in an *in vitro* chromosomal aberration study in human peripheral blood lymphocytes with or without rat liver metabolic activation.

The potential of Xigris to impair fertility has not been evaluated in male or female animals.

Pregnancy Category C—Animal reproductive studies have not been conducted with Xigris. It is not known whether Xigris can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Xigris should be given to pregnant women only if clearly needed.

Nursing Mothers—It is not known whether Xigris is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, and because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use—The safety and effectiveness of Xigris have not been established in the age group nearest pediatric use (36 weeks gestational age) to 18 years. The efficacy of Xigris in adult patients with severe sepsis and high risk of death cannot be extrapolated to pediatric patients with severe sepsis.

Geriatric Use—In clinical studies evaluating 1821 patients with severe sepsis, approximately 50% of the patients were 65 years or older. No overall differences in safety or effectiveness were observed between these patients and younger patients.

ADVERSE REACTIONS: Bleeding—Bleeding is the most common adverse reaction associated with Xigris. In the Phase 3 study, serious bleeding events were observed during the 28-day study period in 3.5% of Xigris-treated and 2.0% of placebo-treated patients, respectively. The difference in serious bleeding between Xigris and placebo occurred primarily during the infusion period and is shown in Table 1. Serious bleeding events were defined as any intracranial hemorrhage, any life-threatening bleed, any bleeding event requiring the administration of ≥ 3 units of packed red blood cells per day for 2 consecutive days, or any bleeding event assessed as a serious adverse event.

Table 1: Number of Patients Experiencing a Serious Bleeding Event by Site of Hemorrhage During the Study Drug Infusion Period* in PROWESS†

	Xigris N=850	Placebo N=840
Total	20 (2.4%)	8 (1.0%)
Site of Hemorrhage		
Gastrointestinal	5	4
Intra-abdominal	2	3
Intra-thoracic	4	0
Retroperitoneal	3	0
Intracranial	2	0
Genitourinary	2	0
Skin/soft tissue	1	0
Other*	1	1

* Study drug infusion period is defined as the date of initiation of study drug to the date of study drug discontinuation plus the next calendar day.

† Patients requiring the administration of ≥ 3 units of packed red blood cells per day for 2 consecutive days without an identified site of bleeding.

In PROWESS, 2 cases of intracranial hemorrhage (ICH) occurred during the infusion period for Xigris-treated patients and no cases were reported in the placebo-treated patients. The incidence of ICH during the 28-day study period was 0.2% for Xigris-treated patients and 0.1% for placebo-treated patients. ICH has been reported in patients receiving Xigris in non-placebo controlled trials with an incidence of approximately 1% during the infusion period. The risk of ICH may be increased in patients with risk factors for bleeding such as severe coagulopathy and severe thrombocytopenia (see **WARNINGS**).

In PROWESS, 25% of the Xigris-treated patients and 18% of the placebo-treated patients experienced at least one bleeding event during the 28-day study period. In both treatment groups, the majority of bleeding events were ecchymoses or gastrointestinal bleeding.

Other Adverse Reactions—Patients administered Xigris as treatment for severe sepsis experience many events which are potential sequelae of severe sepsis and may or may not be attributable to Xigris therapy. In clinical trials, there were no types of non-bleeding adverse events suggesting a causal association with Xigris.

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1. Bernard GR, et al. Efficacy and Safety of Recombinant Human Activated Protein C for Severe Sepsis. *N Engl J Med*. 2001;344:699-709.

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CLINICAL SURGERY—INTERNATIONAL

141 Phyllodes Tumors of the Breast: A Case Series of 106 Patients

Jamel Ben hassouna, Tarak Damak, Amor Gamoudi, Riadh Chargui, Fethi Khomsi, Slim Mahjoub, Maher Slimene, Tarak Ben Dhiab, Monia Hechiche, Hamouda Boussen, and Khaled Rahal

Phyllodes tumors (PTs) of the breast are rare, and their prognosis and treatment are still subject of discussion. According to our results, we recommend for malignant PT a simple mastectomy, whereas for borderline and benign PT, treatment is based rather on wide excision passing in healthy tissue.

148 Cystic Lesions of the Pancreas: An Appraisal of an Aggressive Resectional Policy Adopted at a Single Institution During 15 Years

Brian K.P. Goh, Yu-Meng Tan, Peng-Chung Cheow, Yaw-Fui Alexander Chung, Pierce K.H. Chow, Wai-Keong Wong, and London L.P.J. Ooi

One hundred nine consecutive patients who underwent surgical resection of a cystic lesion of the pancreas at a single institution adopting an aggressive resectional approach during a 15-year period were retrospectively reviewed. Thirty-nine percent of pancreatic cysts resected were incidental, and these were less likely to be premalignant or malignant compared with symptomatic cysts. Reliance on preoperative characteristics alone such as the presence of symptoms, cyst size, and patient age were not sufficiently reliable in determining malignant potential and thus management approach toward a pancreatic cyst.

155 Randomized Controlled Study: Radiofrequency Coagulation and Plication Versus Ligation and Excision Technique for Rectal Mucosal Prolapse

Pravin J. Gupta

A novel technique of radiofrequency ablation and plication of the rectal mucosa as a treatment for rectal mucosal prolapse is reported. The results of this technique are compared with the conventional ligature and excision procedure. The procedure of radiofrequency ablation and plication of rectal mucosa is safe, effective, and swift. It can be proposed as an effective alternative to conventional surgical procedures.

161 Therapeutic Approach to Tumors of the Ampulla of Vater

Akihiko Kobayashi, Masaru Konishi, Toshio Nakagohri, Shinichiro Takahashi, and Taira Kinoshita

The present study evaluated suitable treatments for patients with tumors of the ampulla of Vater, and the

implications for surgical treatment of such tumors are discussed.

165 Predictive Risk Score for Infection After Inguinal Hernia Repair

Patrick Pessaux, Emilie Lermite, Eric Blezel, Simon Msika, Jean-Marie Hay, Yves Flamant, Varma Deepak, and Jean-Pierre Arnaud, for the French Associations for Surgical Research

This study identified a subgroup of patients at high risk for global infectious complications after inguinal hernia repair without mesh. An antibiotic prophylaxis in this high-risk subgroup of patients was demonstrably efficient.

172 The Value of Magnetic Resonance Imaging in Diagnosis and Size Assessment of In Situ and Small Invasive Breast Carcinoma

Arjan P. Schouten van der Velden, Carla Boetes, Peter Bult, and Theo Wobbes

To assess the value of magnetic resonance imaging (MRI) in diagnosis of ductal carcinoma-in-situ (DCIS) and DCIS with small (<10 mm) invasive carcinoma, mammographic and MRI images were retrospectively reviewed. MRI detects DCIS with high sensitivity, although tumor extent is overestimated in approximately one third of cases.

179 Heat Fixation of Cancer Cells Ablated with High-Intensity-focused Ultrasound in Patients with Breast Cancer

Feng Wu, Zhi-Biao Wang, You-De Cao, Zhong-Lin Xu, Qiang Zhou, Hui Zhu, and Wen-Zhi Chen

As a noninvasive ablation, high-intensity-focused ultrasound (HIFU) was used to treat 23 patients with breast cancer. Histological examinations were performed to evaluate therapeutic effects of HIFU on both cellular structures and viability of ablated tumors. The results revealed that HIFU could cause the heat fixation of breast cancer through thermal effect, and the combination of both H&E and nicotinamide adenine dinucleotide-diaphorase histochemical stains could provide a reliable assessment for histological analysis of ablated tumor.

185 Clinical and Diagnostic Significance of Preoperative Computed Tomography Findings of Ascites in Patients with Advanced Gastric Cancer

Kazuhiro Yajima, Tatsuo Kanda, Manabu Ohashi, Toshifumi Wakai, Satoru Nakagawa, Ryuta Sasamoto, and Katsuyoshi Hatakeyama

This retrospective study evaluated the relationship between preoperative CT findings of ascites and

surgical findings of peritoneal metastasis in 293 patients with advanced gastric cancer. The results show that the presence of ascites on CT suggests the presence of peritoneal metastasis with high specificity and it indicates a very poor prognosis of the patients. The presence of peritoneal metastasis should be confirmed by diagnostic laparoscopy in gastric patients with ascites preoperatively.

CLINICAL SURGERY-AMERICAN

191 High-Frequency Percussive Ventilation Improves Oxygenation in Trauma Patients With Acute Respiratory Distress Syndrome: A Retrospective Review

Alexander Eastman, Dean Holland, Jason Higgins, Brian Smith, Jennifer Delagarza, Craig Olson, Scott Brakenridge, Kousta Foteh, and Randall Friese

This retrospective chart review addresses the use of high-frequency percussive ventilation (HFPV) in injured patients with respiratory distress syndrome. The authors found that although mean airway pressure remained unchanged, oxygenation parameters improved when patients were converted from conventional mechanical ventilation techniques to HFPV.

196 Improvement in Gastrointestinal Symptoms and Quality of Life After Cholecystectomy

Kelly R. Finan, Ruth R. Leeth, Bryan M. Whitley, Joshua C. Klapow, and Mary T. Hawn

The effectiveness of elective cholecystectomy on reduction of symptoms and the effect on quality of life (QOL) was studied. The gastrointestinal symptom score showed highly significant improvement in biliary-type symptoms but not reflux or irritable bowel symptoms after cholecystectomy ($P < .05$). Significant improvement was also seen in QOL ($P < .01$).

CLINICAL IMAGE

203 Transverse Colon Volvulus and Associated Chilaiditi's Syndrome

Kazuhide Matsushima and Yoshikazu Suzuki

Hepatodiaphragmatic interposition of the intestine is a rare and often asymptomatic anomaly. An elongated and hypermobile colon with long mesentery is the most important predisposing factor for Chilaiditi's syndrome and colonic volvulus.

205 Spontaneous Cyst-Cutaneous Fistula: An Extremely Rare Presentation of Hydatid Liver Cyst

George H. Sakorafas, Vania Stafyla, and George Kassaras

We describe a patient with hydatid liver disease who presented with a spontaneous cyst-cutaneous fistula. The treatment and potential pathogenic mechanisms of this very rare presentation are discussed.

207 Small-Bowel Obstruction Secondary to Incarcerated Obturator Hernia

Kwok Kay Yau, Wing Tai Siu, Kai Hung Fung, and Michael Ka Wah Li

Obturator hernia is an unusual but important cause of small-bowel obstruction. Various imaging modalities have been applied to achieve correct preoperative diagnosis. Herein we describe a case of incarcerated obturator hernia diagnosed by preoperative multiplanar computed tomography that was managed successfully by laparoscopic treatment.

209 Virilizing Adrenocortical Carcinoma with Cavoatrial Extension

Michael W. Yeh, Dean Lisewski, and Peter Campbell

Adrenocortical carcinomas may involve the inferior vena cava in up to 30% of patients. We present a case of a virilizing tumor with extension into the vena cava and right atrium. A successful palliative resection was performed using cardiopulmonary bypass.

REVIEW

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renting the KCI system. We have developed a method of creating negative pressure in wounds by using widely available off-the-shelf components that is easy to construct and appears to provide nearly equivalent effects on wound healing. We use this system whenever negative pressure therapy is indicated and the KCI system is not available.

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Negative pressure wound therapy with off-the-shelf components

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Abstract

Background: The KCI Wound VAC system (Kinetic Concepts, Inc, San Antonio, TX) for providing negative-pressure therapy for wounds is expensive and may not be available for patients without insurance. We have examined the feasibility of using off-the-shelf components to provide comparable negative pressure therapy at less cost.

Methods: Adhesive iodine-impregnated drape, a flat Jackson-Pratt drain (Cardinal Health, McGaw Park, IL), and foam prep sponges stapled together are used to assemble a dressing connected to wall suction (negative 75–100 mm Hg) to create negative pressure wound therapy that is relatively inexpensive (<\$60 component cost).

Results: We have used this system in more than 40 cases with results that seem comparable to the commercial system and have not seen bleeding or other complications.

Conclusion: Off-the-shelf components can be safely employed to provide effective negative pressure therapy for wounds and skin grafts. © 2006 Excerpta Medica Inc. All rights reserved.

Keywords: Negative pressure therapy; Wound, Skin graft; Vacuum assisted closure; Off-the-shelf system

The application of negative pressure to promote wound healing first was described in the Russian medical literature for patients with infected breast wounds. These original reports described the topical application of a suction-cup–type apparatus to the wound surface to create negative pressures of 80 mm Hg [1,2]. Subsequent reports have described the successful management of enterocutaneous fistulae and open abdominal wounds using flat drains delivering negative pressure under compliant plastic films [3–5]. In these early reports surgical gauze was used to create an interface between the wound surface and the vacuum source.

Kinetic Concepts, Inc. (KCI; San Antonio, TX) markets a modular negative pressure system (Wound VAC) that is based on the system developed by Argenta and Morykwas [6] and Morykwas et al [7] by using foam sponges connected to suction tubing and a vacuum pump containing a small canister. Other commercial vendors market similar systems. The KCI system has been used very successfully to treat a large variety of wound problems such as dehiscent incisions, leg ulcers, and skin

grafts, and has been adopted very rapidly into surgical practice across many disciplines [8–13]. The advantages of negative pressure therapy appear to include better control of wound secretions, reduction of wound edema, promotion of granulation, improved patient comfort, and, based on some clinical trial data, more rapid healing [8–13]. The foam sponges used in the commercial system provide a good, possibly optimal, interface between the wound and the vacuum source because of the even distribution of suction exerted by the porous foams and their ability to capture secretions.

We have been using the KCI Wound VAC system with good results, but because of financial considerations we have tried to develop a method of providing patients with similar negative-pressure therapy without the significant costs of purchasing or renting the KCI system, which can cost more than \$100 per day. We have developed a method of creating negative pressure in wounds by using widely available off-the-shelf components that is easy to construct and apply and, based on our experience in more than 40 cases, appears to provide nearly equivalent effects on wound healing. We use this system whenever negative-pressure therapy is indicated and the KCI system is not available.

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Fig. 1. Elements of an off-the-shelf negative-pressure dressing. Shown clockwise, starting at the top left corner, are the stapler, sponge raft, Acticoat, JP drain, and tubing connector. The Loban adhesive film is underneath these items.

Techniques

As shown in Fig. 1, the construction of our off-the-shelf system requires materials commonly used in the operating room: (1) a surgical stapler (model PXW35; Ethicon, Cincinnati, OH); (2) foam sponges used for dressings or for surgical preparation (model 4463; Cardinal Health, McGaw Park, IL); (3) a 10-mm Jackson Pratt (JP) drain (model SU130-1311; Cardinal Health); (4) Ioban adhesive film and Ioban iodine-impregnated transparent surgical drape (model 6651EZ; 3M, St. Paul, MN), and (5) a wall suction connector (model P361; Cardinal Health) for the JP drain to adapt into standard suction tubing. The system, once con-

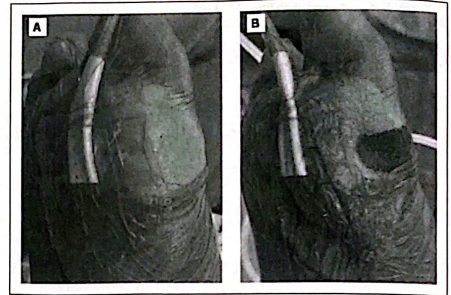


Fig. 3. (A) After sealing the sponge raft to the foot with a layer of Ioban adhesive film, a 1-cm diameter defect is made directly in the adhesive film over the middle of the raft. The JP drain, cut to a short segment, is placed over the perforation and sealed with a second layer of adhesive film. Vacuum has not yet been applied. (B) The tubing now is connected to a vacuum and the characteristic collapse of the sponge raft, indicating effective delivery of negative pressure, is present.

structed, routinely is connected to a 1-L suction canister and to standard wall suction at 75 to 100 mm Hg negative pressure. We use the lower pressure for skin grafts and higher pressures when wound drainage is indicated.

In general, the wound to be treated is debrided to remove necrotic or infected tissue before the application of negative-pressure dressings (Fig. 2A). To ensure an adequate seal with the overlying adhesive film, the surrounding skin must be as dry as possible. In many cases, particularly with split-thickness skin grafts, we place a porous silver mesh between the wound and the sponges (Fig. 2B). We have used either multilayer 7-day release silver mesh (7-day Acticoat; Smith & Nephew, Largo, FL) or several layers of the silver mesh from the standard 1-layer Acticoat (Smith & Nephew). Such silver mesh barriers provide a sustained antimicrobial environment and seem particularly apt for use with negative-pressure dressings over skin grafts [14]. We have used a variety of other topical products between the sponge and the wound tissue including antibiotic ointments, papain preparations, and growth factor gel, all of which seem to be compatible with negative-pressure therapy [15].

Foam sponges are stapled together to form a raft larger than the wound to be treated using 3 to 4 staples to connect each sponge (Fig. 2C). The assembled foam then is cut to match the wound and secured with 1 or 2 staples to the adjacent skin (Fig. 2D). A layer of Ioban adhesive then is wrapped tightly to seal the entire wound. The Ioban adhesive is cut in the center with a scalpel or scissors to create an approximately 1-cm diameter defect. The JP drain, with most of the perforated portion removed, is placed over the defect and secured with another layer of Ioban adhesive (Fig. 3A). Additional layers of Ioban adhesive are wrapped around the JP to seal the wound completely. A wall suction connector (model P361; Cardinal Health) is connected to the JP and wall suction. A negative pressure of 75 mm Hg induces

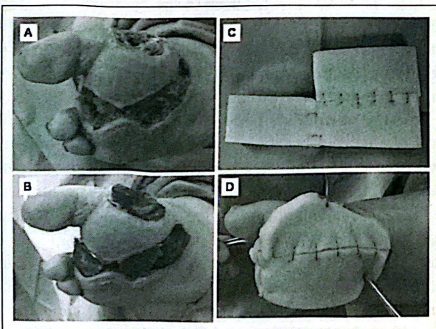


Fig. 2. (A) A complex foot wound that developed in a diabetic patient with arterial occlusive disease. The patient previously underwent revascularization, and the wound has just been debrided sharply. (B) Acticoat has been applied onto the wound. (C) The sponge raft has been assembled by stapling 3 individual foam sponges together. (D) The sponge raft has been placed over the wound and trimmed to accommodate the wound margins just before covering with Ioban adhesive film.

the characteristic collapse of foam sponges seen in other systems (Fig. 3B). Skin graft dressings usually are left in place for 5 days. Our practice with open wounds is to replace the dressing every 2 or 3 days.

Comments

We have used the off-the-shelf system for management of leg ulcers, diabetic foot infections, dehiscent extremity and abdominal incisions, and split-thickness skin grafts in 40 patients in the past 2 years. In general, we have seen very similar local wound responses as observed with the KCI Wound VAC. We have found the off-the-shelf system to be particularly good for skin graft dressings, and we now routinely use either the KCI or the off-the-shelf system without seeing any difference in results.

Based on our hospital purchase expenses, the overall cost required to assemble 1 off-the-shelf system using 1 stapler, 1 box of foam sponges, 1 large sheet of Ioban, 1 JP drain, and 1 connector is less than \$60. This estimate does not take into account charges for using the wall suction apparatus, which also is low.

We believe that only a minor difference in distribution of vacuum suction to the wound results from substituting multiple sponges stapled together versus a single sponge. Our methods allow the foam layer to be tailored easily to match the wound dimensions; in deep wounds the sponges can be piled in layers. The application of the vacuum should be used to test the system in the operating room or at bedside, and rapid compression of the sponge raft when vacuum is applied reliably indicates that no significant leak is present.

Although we have not observed any problems with hemorrhage with this method (eg, discontinuing therapy because of bleeding), there is some concern that large wounds or those oozing at the time of dressing application could bleed excessively into the suction canister, which unlike commercial systems does not have a volume cut-off level. Because of this limitation, we urge caution in using this method for pediatric wounds in which drainage volumes should be monitored carefully, and for very large wounds or those likely to bleed excessively.

Other limitations of the off-the-shelf system include the inability to modify the pressure cycle (eg, intermittent suction) and to treat patients on an outpatient basis because our device uses simple wall suction for negative pressure. Despite these limitations, our system is invaluable for patients who would benefit greatly from negative-pressure therapy but who are unable to obtain access to commercial systems as a result of funding, cost considerations, or unavailability.

A recent clinical trial indicated that negative-pressure therapy is more cost effective than traditional saline-soaked gauze dressings [16]. Unfortunately, in the current health care environment, commercial technology is not always available as a result of cost or insurance authorization issues. The components required in this off-the-shelf system are available in most community hospitals and are easy to apply to manage inpatient wound problems, and based on our experiences it provides results similar to more complex commercial systems.

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