```
                        $q (Ruth Wilhelme),
                        $d 1910-
```

130 Main entry -- Uniform title -- (NR)

Indicator 1: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including spaces)

Indicator 2 undefined.

Indicator 2 became obsolete in 1990. (See 100 above.)

Subfields used most often:

$a -- Uniform title
$p -- Name of part/section of a work (R)
$l -- Language of a work
$s -- Version
$f -- Date of a work

```
Example:    130 0# $a Bible.
                   $p O.T.
                   $p Psalms.
```

240 Uniform title (NR)

Indicator 1: Uniform title printed or displayed

0 -- Not printed or displayed
1 -- Printed or displayed (most common)

Indicator 2: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including spaces)

Subfields used most often:

$a -- Uniform title
$l -- Language of a work
$f -- Date of a work

```
Example:    240 10 $a Ile mystérieuse.
                   $l English.
                   $f 1978
```

245 Title Statement (NR)

Indicator 1: Title added entry

(Should the title be indexed as a title added entry?)

0 -- No title added entry

(indicates a title main entry; i.e. no author is given)

1 -- Title added entry

(the proper indicator when an author given in 1XX; the most common situation)

Indicator 2: Nonfiling characters

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 87 of 309

0-9 -- Number of nonfiling characters present, including spaces; usually set at zero, except when the title begins with an article; e.g., for *The robe*, the second indicator would be set to 4. The letters *T*, *h*, *e*, and the space following them are then ignored in alphabetizing titles. The record will be automatically filed under "*r*" -- for *Robe*.

Subfields used most often:

$a -- Title proper
$h -- Medium (often used for non-book media)
$p -- Name of part/section of a work (R)
$b -- Reminder of title (subtitles, etc.)
$c -- Remainder of title page transcription/Statement of responsibility

```
Example:    245 14 $a The DNA story :
                   $b a documentary history of gene
                      cloning /
                   $c James D. Watson, John Tooze.
```

246 Varying form of title (R)

Indicator 1: Note/title added entry controller
1 -- Note, title added entry
3 -- No note, title added entry

Indicator 2: Type of title
-- No information provided
0 -- Portion of title
1 -- Parallel title
4 -- Cover title
8 -- Spine title

Subfield used most often:
$a -- Title proper

```
Example:    246 3# $a Four corners power review
```

250 Edition statement (NR)

Indicators undefined.

Subfield used most often:
$a -- Edition statement

```
Example:    250 ## $a 6th ed.
```

260 Publication, distribution, etc. (Imprint) (R)

Indicator 1: Sequence of publishing statements
-- No information provided

Indicator 2: Undefined

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 88 of 309

Subfields used most often:

$a -- Place of publication, distribution, etc. (R)
$b -- Name of publisher, distributor, etc. (R)
$c -- Date of publication, distribution, etc. (R)

```
Example:    260 ## $a New York :
                   $b Chelsea House,
                   $c 1986.
```

300 Physical description (R)

Indicators undefined.
Subfields used most often:

$a -- Extent (number of pages) (R)
$b -- Other physical details (usually illustration information)
$c -- Dimensions (cm.) (R)
$e -- Accompanying material (for example, "teacher's guide" or "manual")

```
Example:    300 ## $a 139 p. :
                   $b ill. ;
                   $c 24 cm.
```

440 Series statement / Added entry--Title

This field was made obsolete in 2008 to simplify the series statement. See 490 and 830.

490 Series statement (No added entry is traced from field) (R)

Indicator 1: Specifies whether series is traced (whether an 8XX tag is also present)

0 -- Series not traced
1 -- Series traced (8XX is in record)

Indicator 2 undefined.
Subfield used most often:

$a -- Series statement (R)
$v -- Volume number (R)

```
Example:    490 1# $a Colonial American craftsmen
```

500 General note (R)

Indicators undefined.
Subfield used most often:

$a -- General note (Used when no specialized note field has been defined for the information. Examples: Notes regarding the index; the source of the title; variations in title; descriptions of the nature, form, or scope of the item.)

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 89 of 309

```
Example:    500 ##  $a Includes index.
```

504 Bibliography, etc. note (R)

Indicators undefined.

Subfield used most often:

$a -- Bibliography, etc. note

```
Example:    504 ## $a Includes bibliographical
                     references.
```

505 Formatted contents note (R)

Indicator 1: Type of contents note

0 -- Complete contents

1 -- Incomplete contents (used with multivolume set when some volumes are not yet published)

2 -- Partial contents

Indicator 2: Level of content designation

-- Basic

Subfield used most often:

$a -- Formatted contents note

```
Example:    505 0# $a Pride and prejudice -- Emma
                     -- Northanger Abbey.
```

520 Summary, etc. note (R)

Indicator 1: Display constant controller

-- Summary

1 -- Review

2 -- Scope and content

3 -- Abstract

Indicator 2 undefined

Subfields used most often

$a -- Summary, abstract, or annotation

$b -- Expansion of summary note

```
Example:    520 ## $a This basic guide to parliamentary
                     procedure tells how to conduct
                     and participate in a meeting
                     properly.
```

600 Subject added entry -- Personal name (R)

Indicator 1: Type of personal name entry element

0 -- Forename

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 90 of 309

1 -- Surname (this is the most common form)
3 -- Family name

Indicator 2: Subject heading system/thesaurus (identifies the specific list or file which was used)

0 -- Library of Congress Subject Headings
1 -- LC subject headings for children's literature
2 -- Medical Subject Headings
3 -- National Agricultural Library subject authority file
4 -- Source not specified
5 -- Canadian Subject Headings
6 -- Répertoire de vedettes-matière
7 -- Source specified in subfield $2

(Note regarding Sears subject headings: The MARC 21 format does not provide an assigned indicator for Sears subject headings. Therefore, an indicator of 7 is used, and the MARC defined code "sears" is placed in subfield $2.)

Subfields used most often:

$a -- Personal name (surname and forename)
$b -- Numeration
$c -- Titles and other words associated with a name (R)
$q -- Fuller form of name
$d -- Dates associated with a name (generally, year of birth)
$t -- Title of a work
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term (used with 2nd indicator of 7)

```
Example:    600 10 $a Shakespeare, William,
                   $d 1564-1616
                   $x Comedies
                   $x Stage history.
```

```
Example:    600 10 $a Shakespeare, William,
                   $d 1564-1616
                   $x Knowledge
                   $z Rome
                   $v Congresses.
```

Notice that subfields $v, $x, and $z in the 600 field are repeatable. Subfields $v, $x, $y, and $z do not have to be in alphabetical order. They will be in the order prescribed by the instructions given by the subject heading system.

610 Subject added entry -- Corporate name (R)

*Indicator 1:*Type of corporate name entry element

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 91 of 309

0 -- Inverted name (not used with AACR2)
1 -- Jurisdiction name
2 -- Name in direct order

Indicator 2: Subject heading system/thesaurus.
See indicator 2 under 600

Subfields used most often:
$a -- Corporate name or jurisdiction name as entry element
$b -- Subordinate unit (R)
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term (used with 2nd indicator of 7)

```
Example:    610 10 $a United States.
                   $b Army Air Forces
                   $v Biography.
```

650 Subject added entry -- Topical term (Most subject headings fit here.) (R)

Indicator 1: Level of subject
-- No information provided

Indicator 2: Subject heading system/thesaurus
(identifies the specific list or file which was used)
0 -- Library of Congress Subject Headings
1 -- LC subject headings for children's literature
2 -- Medical Subject Headings
3 -- National Agricultural Library subject authority file
4 -- Source not specified
5 -- Canadian Subject Headings
6 -- Répertoire de vedettes-matière
7 -- Source specified in subfield $2

Note regarding Sears subject headings: The MARC 21 format does not provide an assigned indicator for Sears subject headings. Therefore, an indicator of 7 is used, and the MARC defined code "sears" is placed in subfield $2.)

Subfields used most often:
$a -- Topical term
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term used with 2nd indicator of 7)

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 92 of 309

```
Example:    650 #0 $a Theater
                   $z United States
                   $v Biography
                   $v Dictionaries.
```

Notice that subfields $v, $x, and $z in the 650 field are repeatable. Subfields $v, $x, $y, and $z do not have to be in alphabetical order. They will be in the order prescribed by the instructions given by the subject heading system.

651 Subject added entry -- Geographic name (R)

Indicator 1: undefined.

Indicator 2: Subject heading system/thesaurus.

See indicator 2 under 600

Subfields used most often:

$a -- Geographic name
$v -- Form subdivision (R)
$x -- General subdivision (R)
$y -- Chronological subdivision (R)
$z -- Geographic subdivision (R)
$2 -- Source of heading or term (used with 2nd indicator of 7)

```
Example:    651 #0 $a United States
                   $x History
                   $v Chronology.
```

Notice that subfields $v, $x, and $z in the 651 field are repeatable. Subfields $v, $x, $y, and $z do not have to be in alphabetical order. They will be in the order prescribed by the instructions given by the subject heading system.

700 Added entry -- Personal name (R)

Indicator 1: Type of personal name entry element

0 -- Forename
1 -- Surname (this is the most common form)
3 -- Family name

Indicator 2: Type of added entry

-- No information provided (most common; co-authors, editors, etc.)
2 -- Analytical entry (The values for Indicator 2 changed in 1994 with Format Integration, and older records may display additional values. An analytical entry involves an author/title of an item contained in a work.)

Subfields used most often:

$a -- Personal name
$b -- Numeration
$c -- Titles and other words associated with a name (R)
$q -- Fuller form of name
$d -- Dates associated with a name (generally, year of birth)
$e -- Relator term (such as ill.) (R)
$4 -- Relator code (R)

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 93 of 309

```
Example:    700 1# $a Baldridge, Letitia.
```

710 Added entry -- Corporate name (R)

Indicator 1: Type of corporate name entry element

0 -- Inverted name (not used with AACR2)
1 -- Jurisdiction name
2 -- Name in direct order

Indicator 2: Type of added entry.

See Indicator 2 under 700
-- No information provided
2 -- Analytical entry

Subfields used most often:

$a -- Corporate name or jurisdiction name as entry element
$b -- Subordinate unit (R)

```
Example:    710 2# $a Sunburst Communications (Firm)
```

740 Added entry -- Uncontrolled related/analytical title (R)

Indicator 1: Nonfiling characters

0-9 -- Number of nonfiling characters present (for initial articles, including spaces)

*Indicator 2:*Type of added entry. See Indicator 2 under 700

-- No information provided
2 -- Analytical entry
(This field was redefined in 1994 with Format Integration. Prior to 1994, the field was also used for variant titles, such as a different wording on a spine title. In records created since Format Integration, those variant tiles appear in a 246 field.)

Subfield used most often:

$a -- Title

```
Example:    740 02 $a Uncle Vanya.
```

800 Series added entry -- Personal name (R)

Indicator 1: Type of personal name entry element

0 -- Forename
1 -- Surname
3 -- Family name

Indicator 2 undefined.

Subfields used most often:

$a -- Personal name
$b -- Numeration
$c -- Titles and other words associated with a name (R)
$q -- Fuller form of name

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 94 of 309

$d -- Dates associated with a name (generally, year of birth)
$t -- Title of a work (the series)
$v -- Volume number

```
Example:    800 1# $a Fisher, Leonard Everett.
                  $t Colonial American craftsmen.
```

830 Series added entry -- Uniform title (R)
Indicator 1 undefined.
Indicator 2: Nonfiling characters
0-9 -- Number of nonfiling characters present (for initial articles, including spaces)
Subfield used most often:
$a -- Uniform title
$v -- Volume number

```
Example:    830 #0 $a Railroads of America (Macmillan)
```

[Back to Top of Page]

Part VIII:

A List of Other Fields Often Seen in MARC Records

001 Control number
003 Control number identifier
005 Date and time of latest transaction
006 Fixed-length data elements -- additional material characteristics
007 Physical description fixed field
008 Fixed length data elements (See Part X)
022 International Standard Serial Number (ISSN)
037 Source of acquisition
041 Language code
043 Geographic area code
050 Library of Congress call number
060 National Library of Medicine call number
082 Dewey Decimal classification number (the one recommended by the Library of Congress; locally-assigned call numbers may appear elsewhere)
110 Main entry -- Corporate name (less frequent under AACR2 rules)
256 Computer file characteristics
263 Projected publication date (indicates a CIP -- Cataloging in Publication -- record)

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 95 of 309

306 Playing time
508 Creation/production credits note
510 Citation/references note (review sources)
511 Participant or performer note
521 Target audience note (first indicator: 0 = reading grade level, 1 = interest age level, 2 = interest grade level, 3 = special audience characteristics, 4 = motivation interest level)
530 Additional physical form available note
538 System details note
586 Awards note
656 Index term -- Occupation
730 Added entry -- Uniform title
852 Location
856 Electronic location and access
9XX Reserved for local use. (They are used by vendors, systems, or individual libraries to exchange additional data)

[Back to Top of Page]

Part IX:

The Leader

There are 24 positions in the Leader, numbered from 00 to 23. For fuller explanation, see the *MARC 21 Format for Bibliographic Data*.

00-04 Record length (calculated by the computer for each record)
05 Record status
- a = increase in encoding level
- c = corrected or revised
- d = deleted
- n = new
- p = increase in encoding from prepublication (previous CIP)

06 Type of record
- a = language material
- c = printed music
- d = manuscript music
- e = cartographic material
- f = manuscript cartographic material
- g = projected medium
- i = nonmusical sound recording
- j = musical sound recording
- k = 2-dimensional nonprojectable graphic
- m = computer file
- o = kit
- p = mixed materials
- r = 3-dimensional artifact or naturally occurring object
- t = manuscript language material

07 Bibliographic level
- a = monographic component part
- b = serial component part

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 96 of 309

c = collection
d = subunit
i = integrating resource
m = monograph/item
s = serial

08 Type of control
= no specified type
a = archival

09 Character coding scheme
= MARC-8
a = UCS/Unicode

10 Indicator count (always "2")

11 Subfield code count (always "2")

12-16 Base address of data (calculated by the computer for each record)

17 Encoding level
= full level
1 = full level, material not examined
2 = less-than-full level, material not examined
3 = abbreviated level
4 = core level
5 = partial (preliminary) level
7 = minimal level
8 = prepublication level (CIP)
u = unknown
z = not applicable

18 Descriptive cataloging form
= non-ISBD
a = AACR2
i = ISBD
u = unknown

19 Multipart resource record level
= Not specified or not applicable
a = Set
b = Part with independent title
c = Part with dependent title

20 Length of the length-of-field portion (always "4")

21 Length of the starting-character-position portion (always "5")

22 Length of the implementation-defined portion (always "0")

23 Undefined (always "0")

[Back to Top of Page]

Part X:

Field 008 for Books

Field 008 is used for Fixed Length Data Elements ("Fixed Field Codes"). There are 40 character positions in field 008, numbered from 00-39. Undefined positions must contain either a blank (#) or a fill character (|). Positions 00-17 and 35-39 are defined the same way for all media.

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 97 of 309

The information shown here for positions 18-34 applies only to books. For explanation of all the positions below and for positions 18-34 for other media, see the *MARC 21 Format for Bibliographic Data*.

Note that field 008 has no indicators or subfield codes.

00-05 Date entered on file (YYMMDD),
where Y=year, M=month, and D=day

06 Type of date/publication status:
- b = no dates given; B.C. date involved
- e = detailed date
- s = single known date/probable date
- m = multiple dates
- r = reprint/reissue date (Date 1) and original date (Date 2)
- n = dates unknown
- q = questionable date
- t = publication date and copyright date
- | = no attempt to code

07-10 Date 1/beginning date of publication

11-14 Date 2/ending date of publication

Date fields contain the year(s) of publication. The type of date(s) in these elements are specified in fixed field element 06: Type of date/publication status. (For further details, see the field 008 description in the *MARC 21 Format for Bibliographic Data*.)

15-17 Place of publication, production, or execution
For example:
- pk# = Pakistan
- cau = California (US)

(For a full list of codes used in these positions, see the *MARC Code List for Countries*.)

18-21 Illustrations (up to 4 codes):
- # = no illustrations
- a = illustrations
- b = maps
- c = portraits
- d = charts
- e = plans
- f = plates
- g = music
- h = facsimiles
- i = coats of arms
- j = genealogical tables
- k = forms
- l = samples
- m = phonodisc, phonowire, etc.
- o = photographs
- p = illuminations
- | = no attempt to code

22 Target audience:
- # = unknown or not specified
- a = preschool

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 98 of 309

b = primary
c = pre-adolescent
d = adolescent
e = adult
f = specialized
g = general
j = juvenile
| = no attempt to code

23 Form of item:
= none of the following
a = microfilm
b = microfiche
c = microopaque
d = large print
f = braille
r = regular print reproduction
s = electronic
| = no attempt to code

24-27 Nature of contents (up to 4):
= no specified nature of contents
a = abstracts/summaries
b = bibliographies (is one or contains one)
c = catalogs
d = dictionaries
e = encyclopedias
f = handbooks
g = legal articles
i = indexes
j = patent document
k = discographies
l = legislation
m = theses
n = surveys of literature
o = reviews
p = programmed texts
q = filmographies
r = directories
s = statistics
t = technical reports
u = standards/specifications
v = legal cases and notes
w = law reports and digests
z = treaties
| = no attempt to code

28 Government publication:
= not a government publication
i = international intergovernmental
f = federal/national
a = autonomous or semi-autonomous component
s = state, provincial, territorial, dependent, etc.
m = multistate
c = multilocal

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 99 of 309

l = local
z = other type of government publication
o = government publication -- level undetermined
u = unknown if item is government publication
| = no attempt to code

29 Conference publication:
0 = not a conference publication
1 = conference publication
| = no attempt to code

30 Festschrift:
0 = not a festschrift
1 = festschrift
| = no attempt to code

31 Index:
0 = no index
1 = index present
| = no attempt to code

32 Undefined (since 1990) (Earlier records may contain the values 0 or 1)
= Undefined
| = no attempt to code

33 Literary form:
0 = not fiction (not further specified)
1 = fiction (not further specified)
c = comic strips
d = dramas
e = essays
f = novels
h = humor, satires, etc.
i = letters
j = short stories
m = mixed forms
p = poetry
s = speeches
u = unknown
| = no attempt to code

34 Biography:
= no biographical material
a = autobiography
b = individual biography
c = collective biography
d = contains biographical information
| = no attempt to code

35-37 Language:
A three-letter code. For example: eng fre ger spa rus ita

(For a full list of codes used in these positions, see the *MARC Code List for Languages*.)

38 Modified record:
= not modified
x = missing characters (because of characters unavailable in MARC character set)
s = shortened
d = "dashed-on" information omitted

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 100 of 309

r = completely romanized/printed cards in script
o = completely romanized/printed cards romanized
| = no attempt to code

39 Cataloging source:
= national bibliographic agency
c = cooperative cataloging program
d = other sources
u = unknown
| = no attempt to code

[Back to Top of Page]

[Back to Table of Contents] -- [Continue to Part 11]



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Library of Congress Help Desk (10/27/2009)

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 101 of 309

EXHIBIT 1005

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Cited By (35)

Figures (1)



Tables (4)

TABLE I

TABLE II

Urology

Volume 62, Issue 4, October 2003, Pages 689-692

Adult urology

Pain assessment after original transperineal prostate biopsy using a coaxial needle

Giovanni Novella [a], Vincenzo Ficarra [a], Antonio Galfano [a], Riccardo Ballario [a], Giacomo Novara [a], Stefano Cavalleri [a], Walter Artibani [a]

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Received 3 March 2003, Accepted 23 April 2003, Available online 30 September 2003.

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PAIN ASSESSMENT AFTER ORIGINAL TRANSPERINEAL PROSTATE BIOPSY USING A COAXIAL NEEDLE

GIOVANNI NOVELLA, VINCENZO FICARRA, ANTONIO GALFANO, RICCARDO BALLARIO, GIACOMO NOVARA, STEFANO CAVALLERI, AND WALTER ARTIBANI

ABSTRACT

Objectives. To assess whether the use of a coaxial needle reduces discomfort in patients undergoing multiple-core transperineal prostate biopsy to detect prostate cancer.

Methods. From October 2002 to January 2003, we enrolled 102 consecutive patients with a suspicion of prostate cancer. In every case, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance. The patients were randomized into two groups: group 1 (n = 51) in which we used the 17-gauge coaxial TruGuide needle, and group 2 (n = 51) in which the conventional transperineal technique was used. At the end of the procedure, patients were asked to complete a questionnaire regarding the level of pain experienced.

Results. The studied groups were comparable in age, total prostate-specific antigen value, and prostate volume. The whole procedure was significantly less painful in group 1 (2.20 ± 1.20 versus 2.90 ± 1.73, $P = 0.01$). We failed to show any significant pain score differences during rectal probe insertion ($P = 0.10$), transrectal ultrasonography ($P = 0.16$), and execution of local anesthesia ($P = 0.11$). The pain score recorded during the multiple-core prostate sampling was significantly lower in group 1 (1.53 ± 1.5 versus 2.43 ± 1.86, $P = 0.009$). No statistically significant differences were found in the complication rates between the two groups.

Conclusions. The use of a coaxial needle reduces the procedure's invasiveness and patient's pain compared with the conventional transperineal prostate biopsy. UROLOGY **62:** 689–692, 2003. © 2003 Elsevier Inc.

The transrectal ultrasound (TRUS)-guided transperineal prostate biopsy is a simple and well-tolerated procedure with a low complication rate. This technique allows optimal sampling of the peripheral and transition zones of the prostate with a greater detection rate.[1] In recent years, the transperineal approach for prostate biopsy has had more limited diffusion than transrectal biopsy, probably because of the supposed greater invasiveness and execution complexity.

In the conventional transperineal technique, the needle is repeatedly inserted through the perineal plane under local anesthesia. To minimize the invasiveness, we recently introduced the use of a 17-gauge coaxial needle (TruGuide Bard) in our clinical practice. The use of coaxial needles has been described for liver, kidney, pancreas, and breast biopsies.[2–4] However, to the best of our knowledge, this is the first experience concerning the utility of this device for prostate biopsy.

The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.

The purpose of the present study was to evaluate whether the use of this new device results in a reduction in the pain patients experience during multiple-core prostate biopsy compared with during the traditional transperineal approach.

MATERIAL AND METHODS

From October 2002 to January 2003, we enrolled 102 consecutive patients with a suspicion of prostate cancer (prostate-specific antigen greater than 4 ng/mL and/or positive digital rectal examination findings). All patients underwent TRUS-guided transperineal prostate biopsy. The patients were adequately informed of mode of execution of the procedure and

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Submitted: March 3, 2003, accepted (with revisions): April 23, 2003

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0090-4295/03/$30.00
doi:10.1016/S0090-4295(03)00483-7

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 104 of 309

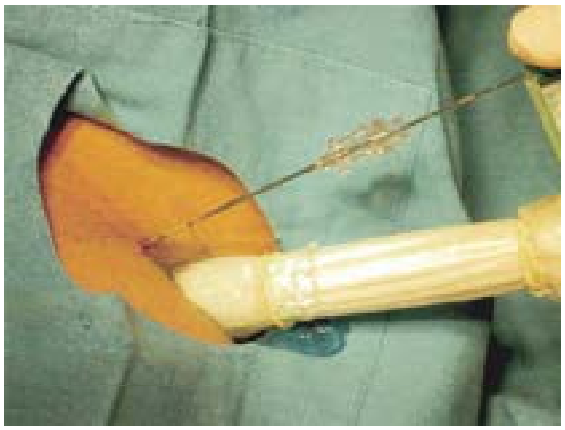


FIGURE 1. *An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.*

its potential complications and were asked to provide written consent. Internal review board approval was not required at our institution to perform this type of study.

The patients were randomized into two groups in relation to the use of the coaxial 17-gauge TruGuide needle during prostate biopsy. We used the coaxial needle in 51 patients (group 1) and carried out the conventional transperineal technique in the other 51 patients (group 2). In both groups, we evaluated age, digital rectal examination findings, total prostate-specific antigen value, and prostate volumes as estimated by TRUS (with the ellipse method: length $\times$ depth $\times$ width $\times \pi/6$).

Bioptical Technique

All patients stopped anticoagulant therapy 7 days before the procedure and took a prophylactic antibiotic (fluoroquinolone or co-trimoxazole) 12 hours before. An enema was given the same morning of the procedure.

All biopsies were performed by a single urologist (G.N.). TRUS was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear probe. The patient was placed in the lithotomy position, and the perineal area was disinfected. A single, 22-gauge spinal needle was inserted transperineally 1.5 cm above the rectum on the median line. The needle passage through perineal planes was guided by TRUS.

The needle was introduced posteriorly to the bulbar urethra up to the prostate apex and laterally to the membranous urethra. In this area, 2 mL of 1% mepivacaine was released. The needle was progressively retracted and 2 mL of anesthetic was administered along the needle path. An identical procedure was done contralaterally through the same median hole. In group 1, a 17-gauge coaxial needle (TruGuide Bard, 13 cm long) was inserted up to the prostate apex through the anesthetized perineal path under TRUS guidance. On the removal of the blunt tip stylet, the guiding cannula of the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle (18-gauge Tru-Cut, 20 cm long), loaded on a spring-driven biopsy gun (Magnum Bard Biopsy Instruments) with a cutting length of 22 mm (Fig. 1).

In group 2, the same biopsy needle was repeatedly inserted through the anesthetized perineal plane, according to the conventional transperineal technique.

Fourteen cores were sampled in every patient (double sextant biopsy from the peripheral and two cores from the transition zone). The progression and inclination of the needle was controlled by transverse and longitudinal TRUS, respectively. In both groups, at the end of the sampling, an ice bag was placed on the perineal area for about 15 minutes. All the procedures were performed on an outpatient basis.

At the end of the biopsy, every patient received an institutional questionnaire to assess the level of pain during the different steps of the procedure. Thorough instructions for form compilation were provided. The form consisted of six questions:

1. How painful was the whole procedure?
2. How painful was the probe insertion?
3. How painful was the presence of the probe during the procedure?
4. How painful was local anesthetic administration?
5. How painful was the prostate sampling?
6. If medically necessary, how willing would you be to repeat the procedure?

The pain level was evaluated by a visual analog scale/numeric analog scale), in which 0 corresponds to "no pain" and 10 to "the worst pain imaginable."[5] A total pain score of 0 was evaluated as "no pain," a score from 1 to 4 as "mild pain," a score from 5 to 7 as "moderate pain," and any score greater than 7 as "severe pain."[6] For question 6, 0 corresponded to "very willing" and 10 to "never, for no reason."

All patients were clinically evaluated 30 days after biopsy to record the complications related to the procedure.

The Pearson chi-square test and the Student *t* test was used to compare categorical and continuous variables, respectively. In statistical analysis, a $P < 0.05$ was considered significant. The data were collected in a database and analyzed using Statistical Package for Social Sciences, version 10.1, software by one of us (V.F.).

RESULTS

The analyzed groups were comparable in age, digital rectal examination findings, prostate volume, and total prostate-specific antigen value (Table I). The whole procedure (question 1) was significantly less painful in group 1 (2.2 ± 1.20 versus 2.90 ± 1.73, $P = 0.01$). In group 1, 49 (96.1%) had mild pain and 2 (3.9%) had moderate pain. No group 1 patients reported a score greater than 6. In group 2, 42 patients (82.4%) recorded mild pain, 8 (15.6%) moderate pain, and 1 (2%) severe pain (Table II).

For the different procedure steps, we failed to show any statistically significant pain score differences during rectal probe insertion (question 2; $P = 0.10$), TRUS (question 3; $P = 0.16$), or local anesthesia execution (question 4; $P = 0.11$). The pain scores concerning the multiple-core prostate sampling were significantly different. The mean score (question 5) was 1.53 ± 1.51 in group 1 and 2.43 ± 1.86 in group 2 ($P = 0.009$). During this step, 14 patients (27.5%) in group 1 (coaxial needle technique) had no pain, 35 (68.5%) had mild pain, and 2 (4%) had moderate pain. In group 2 (conventional transperineal technique), only 6 patients (11.8%) recorded no pain during the prostate sampling step; 37 (72.5%) reported mild pain, 7 (13.7%) moderate pain, and 1 (2%) severe pain (Table II).

The mean score for question 6 was 2.16 ± 1.60 in group 1 and 3.06 ± 2.14 in group 2 ($P = 0.01$).

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 105 of 309

TABLE I. *Clinical characteristics*

Variable	Group 1 (n = 51)	Group 2 (n = 51)	*P* Value
Mean age (yr)	63.76 ± 7.14	65.90 ± 7.54	0.14
Positive DRE (%)	27.5	39.2	0.20
Total PSA (ng/mL)	7.88 ± 3.37	9.26 ± 8.42	0.28
Prostate volume (cm^3)	46.74 ± 27.68	41.81 ± 21.35	0.31

KEY: DRE = digital rectal examination; PSA = prostate-specific antigen.

TABLE II. *Difference in subjective measures between studied groups*

	Group 1 (%)	Group 2 (%)
Whole procedure		
No pain (0)	0	0
Mild pain (1–4)	49 (96.1)	42 (82.4)
Moderate pain (5–7)	2 (3.9)	8 (15.6)
Severe pain (>7)	0	1 (2)
Multiple-core sampling		
No pain (0)	14 (27.5)	6 (11.8)
Mild pain (1–4)	35 (68.5)	37 (72.5)
Moderate pain (5–7)	2 (4)	7 (13.7)
Severe pain (>7)	0	1 (2)

TABLE III. *Mean score (± standard deviation) recorded for each question*

Question	Group 1 (n = 51)	Group 2 (n = 51)	*P* Value
(1) Whole procedure	2.20 ± 1.20	2.90 ± 1.73	0.01
(2) Probe insertion	1.02 ± 1.27	1.43 ± 1.30	0.10
(3) TRUS	1.02 ± 1.34	1.41 ± 1.45	0.16
(4) Local anesthesia	2.29 ± 1.31	2.80 ± 1.87	0.11
(5) Multiple-core sampling	1.53 ± 1.51	2.43 ± 1.86	0.009
(6) Procedure repetition	2.16 ± 1.60	3.06 ± 2.14	0.01

KEY: TRUS = transrectal ultrasonography.

Table III summarizes the reported scores for each question.

The complication rates overlapped in both groups (Table IV).

TABLE IV. *Reported complications (30 days after prostate biopsy; chi-square = not statistically significant in any case)*

Complication	Group 1 (n = 51)	Group 2 (n = 51)
Perineal hematoma	0	1 (2)
Hematuria (lasting >3 days)	30 (59)	23 (45)
Hemospermia	27 (53)	24 (47)
Acute urinary retention	0	3 (6)
Urinary tract infection	0	3 (6)
Fever (>38°C)	0	1 (2)

Numbers in parentheses are percentages.

COMMENT

The TRUS-guided transperineal prostate biopsy is a suitable alternative to the more widespread transrectal approach. The transperineal approach with external ultrasound guidance has been proposed as the optimal way to perform prostate biopsy, mainly in patients who have undergone abdominoperineal resection.[7] Recently, Emiliozzi *et al.*[1] showed that the transperineal technique allowed optimal prostate sampling and had relevant cancer detection rates with acceptable morbidity also in patients who had not undergone any previous abdominoperineal resection. In the transperineal approach, the needle is inserted through the prostate apex along a longitudinal plane parallel to the prostate axis. This eases the needle orientation and provides optimal sampling of the peripheral and transition zones.

Systematic transperineal prostate biopsies need local anesthesia. Although the use of local anesthesia has not been considered mandatory in transrectal prostate biopsy, an increasing number of reports have been showing a relevant reduction of discomfort in patients undergoing transrectal prostate biopsy with local anesthesia.[6,8–10] The prostatic plexus block is the most commonly used technique of local anesthesia during transrectal prostate biopsy. Since the first report of Costello and Costello,[11] several technical modifications have been proposed, mainly involving the dosage and sites of anesthetic injection.[10–13] A recent prospective, randomized study showed that an anesthetic injection at the level of the prostate apex was easier, less painful, and more effective than prostatic plexus block during transrectal prostate biopsy.[6] To administer local anesthesia and to perform transperineal biopsies, double-sided access is often used, on both the left and the right of the median line, 1.5 cm above the rectum, on a line at a 45° angle with the median line.[1] The transperineal access further simplifies anesthetic injection at the prostate apex.

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 106 of 309

The use of a single median transperineal access was described by Milani *et al.*[14] Although it involves a greater risk of bulbar urethra injury, this approach allows the reduction of bulbourethral artery injuries and perineal hematoma development and increases procedure tolerability.[14]

To the best of our knowledge, the use of a coaxial needle has not been reported during prostate biopsy. This device makes the procedure easier and quicker. The guiding cannula forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.

Our data showed that the use of a coaxial needle significantly reduced the experienced pain during prostate sampling and improved patient compliance compared with the conventional transperineal biopsy technique. Our results support the widespread use of a coaxial needle during transperineal prostate biopsy.

An additional possible issue could be the comparison between the use of the perineal coaxial needle and the standard TRUS-guided biopsy. No data are currently available about this topic. Indirect evidence could be gained by comparing our data with those recently published by Stirling *et al.*[15] in a group of 50 patients undergoing TRUS-guided biopsy with periprostatic nerve blockade. Using a similar question about discomfort during prostate sampling and the same visual analog pain scale, the investigators reported a mean score of 2.8 $\pm$ 1.9, significantly greater than our score ($P < 0.001$). Moreover, although in the patients in the study by Stirling *et al.*, a mean number of nine cores was sampled, we performed 14 biopsies in every patient. However, this issue could be better assessed by a randomized prospective trial.

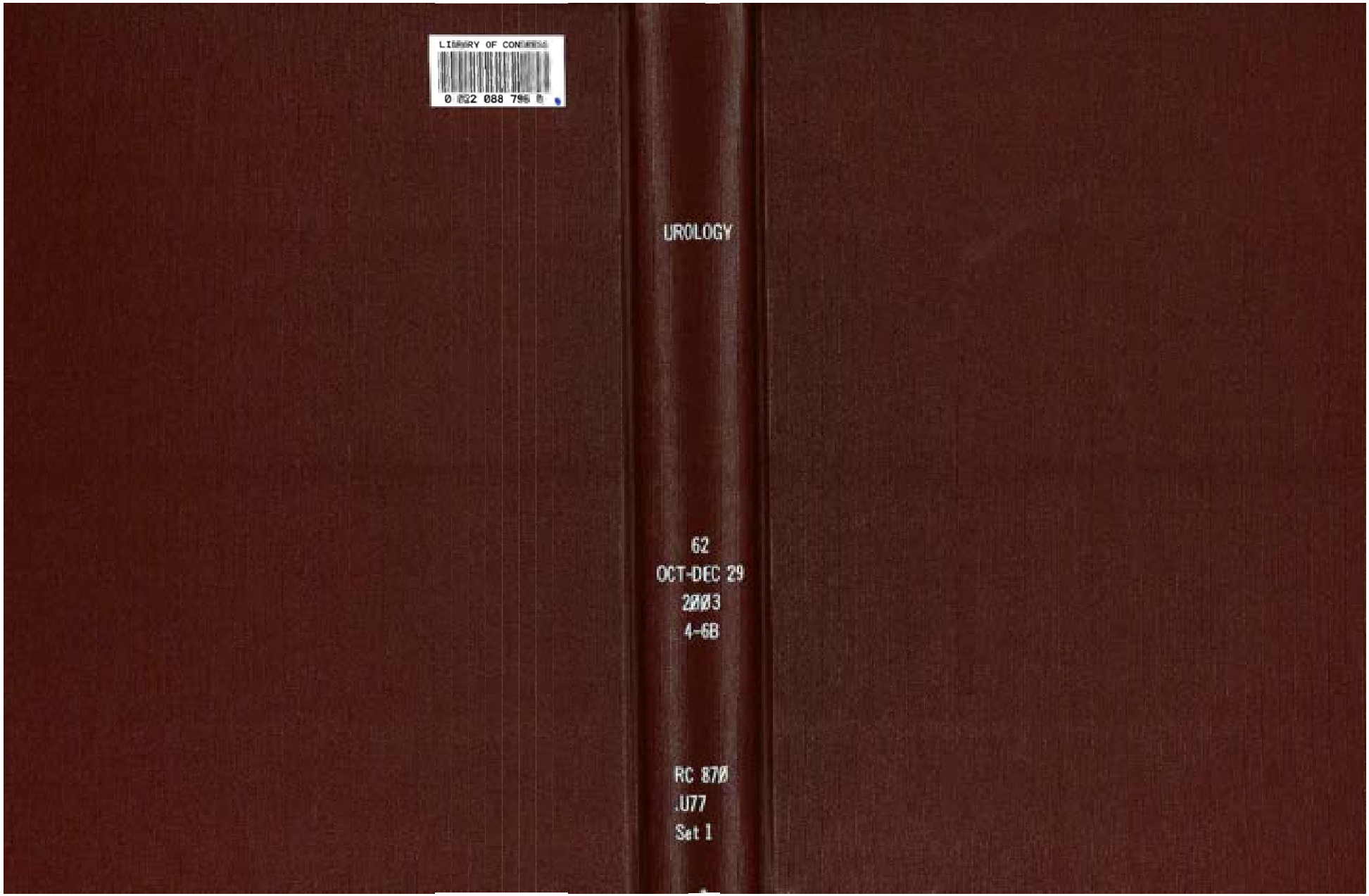
The role of transperineal approach might become more relevant as acceptance of an increase in the number of cores needed to maximize prostate cancer detection rates grows.

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Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 107 of 309

APPENDIX 1005A


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In This Issue

■

Levofloxacin for Chronic Prostatitis/CPPS in Men
J. Nickel, J. Downey, J. Clark, et al

■

Nephrectomy for Metastatic Renal Cell Carcinoma: Indiana University Experience
A. Mosharafa, M. Koch, A. Shalhav, et al

■

Contemporary Evaluation of Operative Parameters and Complications Related to Open RRP
H. Lepor and L. Kaci

■

Outcomes After Single or Double-Cuff Artificial Urinary Sphincter Insertion
R. O'Connor, G. Gerber, D. Avila, et al

■

Risk Factors for Spontaneous Bladder Perforation After Augmentation Cystoplasty
W. DeFoor, L. Tackett, E. Minevich, et al

■

Rapamycin Preserves Renal Function After Ischemia/Reperfusion Injury
S. Inman, N. Davis, K. Olson, et al

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Brief Summary of Prescribing Information
(No. 3683)
03-5055-R3-Brf. Rev. November, 2001

LUPRON DEPOT® – 4 Month 30 mg

(leuprolide acetate for depot suspension)

4-MONTH FORMULATION
IM only

INDICATIONS AND USAGE
LUPRON DEPOT–4 Month 30 mg is indicated in the palliative treatment of advanced prostatic cancer.

CONTRAINDICATIONS
1. Hypersensitivity to GnRH, GnRH agonist analogs or any of the excipients in LUPRON DEPOT. Reports of anaphylactic reactions to synthetic GnRH (Fiachel) or GnRH agonist analogs have been reported in the medical literature.
2. This formulation is not indicated for use in women. (See LUPRON DEPOT 3.75 mg and LUPRON DEPOT-3 Month 11.25 mg package inserts.)
3. All formulations of LUPRON DEPOT are contraindicated in women who are or may become pregnant while receiving the drug. LUPRON DEPOT may cause fetal harm when administered to a pregnant woman. Major fetal abnormalities were observed in rabbits but not in rats after administration of LUPRON DEPOT throughout gestation. There was increased fetal mortality and decreased fetal weights in rats and rabbits. The effects on fetal mortality are expected consequences of the alterations in hormonal levels brought about by this drug. Therefore, the possibility exists that spontaneous abortion may occur if this drug is used during pregnancy, or if the patient becomes pregnant while taking any formulation of LUPRON DEPOT. The patient should be apprised of the potential hazard to the fetus.

WARNINGS
Initially, LUPRON DEPOT, like other LH-RH agonists, causes increases in serum levels of testosterone to approximately 50% above baseline during the first week of treatment. Transient worsening of symptoms, or the occurrence of additional signs and symptoms of prostate cancer, may occasionally develop during the first few weeks of LUPRON DEPOT treatment. A small number of patients may experience a temporary increase in bone pain, which can be managed symptomatically. As with other LH-RH agonists, isolated cases of ureteral obstruction and spinal cord compression have been observed, which may contribute to paralysis with or without fatal complications.

For patients at risk, initiation of therapy with daily LUPRON® (leuprolide acetate) Injection (See **DOSAGE AND ADMINISTRATION** section in the LUPRON injection labeling.) for the first two weeks to facilitate withdrawal of treatment may be considered. If spinal cord compression or renal impairment develops, standard treatment of these complications should be instituted.

PRECAUTIONS
Information for Patients An information pamphlet for patients is included with the product.

General Patients with metastatic vertebral lesions and/or with urinary tract obstruction should be closely observed during the first few weeks of therapy. (See **WARNINGS** section.) **Laboratory Tests** Response to LUPRON DEPOT–4 Month 30 mg should be monitored by measuring serum levels of testosterone as well as prostatic-specific antigen. In the majority of patients, testosterone levels increased above baseline during the first week, declining thereafter to baseline levels or below by the end of the second week. Castrate levels were reached within two to four weeks and once achieved were maintained in most (45/49) patients for as long as the patients received their injections. (See **ADVERSE REACTIONS**.)

Drug Interactions No pharmacokinetic-based drug-drug interaction studies have been conducted with LUPRON DEPOT. However, because leuprolide acetate is a peptide that is primarily degraded by peptidase and the drug is only about 46% bound to plasma proteins, drug interactions would not be expected to occur.

Drug/Laboratory Test Interactions Administration of LUPRON DEPOT in therapeutic doses results in suppression of the pituitary-gonadal system. Normal function is usually restored within three months after treatment is discontinued. Due to the suppression of the pituitary-gonadal system by LUPRON DEPOT, diagnostic tests of pituitary gland-adrenal and gonadal functions conducted during treatment and for up to three months after discontinuation of LUPRON DEPOT may be affected.

Carcinogenesis, Mutagenesis, Impairment of Fertility Two-year carcinogenicity studies were conducted in rats and mice. In rats, a dose-related increase of benign pituitary hyperplasia and benign pituitary adenomas was noted at 24 months when the drug was administered subcutaneously at high daily doses (0.6 to 4 mg/kg). There was a significant but not dose-related increase of pancreatic islet-cell adenomas in females and of testicular interstitial cell adenomas in males (highest incidence in the low dose group). In mice no pituitary abnormalities were observed at a dose as high as 60 mg/kg for two years. Patients have been treated with leuprolide acetate for up to three years with doses as high as 10 mg/day and for two years with doses as high as 20 mg/day without demonstrable pituitary abnormalities.

Mutagenicity studies have been performed with leuprolide acetate using bacterial and mammalian systems. These studies provided no evidence of a mutagenic potential.

Clinical and pharmacologic studies in adults (≥18 years) with leuprolide acetate and similar analogs have shown reversibility of fertility suppression when the drug is discontinued after continuous administration for periods of up to 24 weeks.

Pregnancy, Teratogenic Effects Pregnancy Category X. (See **CONTRAINDICATIONS** section.)

Pediatric Use Safety and effectiveness of LUPRON DEPOT – 4 Month 30 mg have not been established in pediatric patients. See LUPRON DEPOT-PED® (leuprolide acetate for depot suspension) labeling for the safety and effectiveness of the monthly formulation in children with central precocious puberty.

ADVERSE REACTIONS
Clinical Trials
The 4-Month formulation of LUPRON DEPOT 30 mg was utilized in clinical trials that studies the drug in 49 nonorchiectomized prostatic cancer patients for 32 weeks or longer and in 24 orchiectomized prostatic cancer patients for 20 weeks.

In the majority of nonorchiectomized patients, testosterone levels increased 50% or more above baseline during the first week of treatment with LUPRON DEPOT, declining thereafter to baseline levels or below by the end of the second week of treatment. Therefore, potential exacerbations of signs and symptoms during the first few weeks of treatment are of concern in patients with vertebral metastases and/or urinary obstruction or hematuria which, if aggravated, may lead to neurological problems such as temporary weakness and/or paresthesia of the lower limbs or worsening of urinary symptoms. (See **WARNINGS** section.)

In the above described clinical trials, the following adverse reactions were reported in ≥ 2% of the patients during the treatment period regardless of causality.

Adverse Events Reported in ≥ 5% of Patients Regardless of Causality
LUPRON DEPOT–4 Month 30 mg

	Nonorchiectomized N = 49 Study 032		Orchiectomized N = 24 Study 032	
	N	(%)	N	(%)
Body As a Whole				
Asthenia	6	(12.2)	1	(4.2)
Flu Syndrome	6	(12.2)	0	(0.0)
General Pain	19	(38.7)	1	(4.2)
Headache	3	(6.2)	1	(4.2)
Injection Site Reaction	4	(8.2)	0	(0.0)
Cardiovascular System				
Hot Flashes/Sweats*	23	(46.9)	2	(8.3)
Digestive System				
GI Disorders	5	(10.2)	3	(12.5)
Metabolic and Nutritional Disorders				
Dehydration	3	(6.2)	0	(0.0)
Edema	4	(8.2)	3	(20.8)
Musculoskeletal System				
Joint Disorder	3	(6.2)	1	(4.2)
Myalgia	4	(8.2)	0	(0.0)
Nervous System				
Dizziness/Vertigo	3	(6.2)	2	(8.3)
Neuromuscular Disorders	3	(6.2)	1	(4.2)
Paresthesia	4	(8.2)	1	(4.2)
Respiratory System				
Respiratory Disorder	4	(8.2)	1	(4.2)
Skin and Appendages				
Skin Reaction	6	(12.2)	0	(0.0)
Urogenital System				
Urinary Disorders	3	(6.2)	4	(16.7)

In these same studies, the following adverse reactions were reported in less than 5% of the patients on LUPRON DEPOT–4 Month 30 mg.

Body As a Whole - Abscess, Accidental injury, Allergic reaction, Cyst, Fever, Generalized edema, Hernia, Neck pain, Neoplasm; *Cardiovascular System* - Atrial fibrillation, Deep thrombophlebitis, Hypertension; *Digestive System* - Anorexia, Eructation, Gastrointestinal hemorrhage, Gingivitis, Gum hemorrhage, Hepatomegaly, Increased appetite, Intestinal obstruction, Peridontal abscess; *Hemic and Lymphatic System* - Lymphadenopathy; *Metabolic and Nutritional Disorders* - Healing abnormal, Hypoxia, Weight loss; *Musculoskeletal System* - Leg cramps, Pathological fracture, Ptosis; *Nervous System* - Abnormal thinking, Amnesia, Confusion, Convulsion, Dementia, Depression, Insomnia/ sleep disorders, Libido decreased*, Neuropathy, Paralysis; *Respiratory System* - Asthma, Bronchitis, Hiccup, Lung disorder, Sinusitis, Voice alteration; *Skin and Appendages* - Herpes zoster, Melanosis; *Urogenital System* - Bladder carcinoma, Epididymitis, Impotence*, Prostate disorder, Testicular atrophy*, Urinary incontinence, Urinary tract infection.

* Due to the expected physiologic effects of decreased testosterone levels.

Laboratory: Abnormalities of certain parameters were observed, but their relationship to drug treatment is difficult to assess in this population. The following were recorded in ≥ 5% of patients: Decreased bicarbonate, Decreased hemoglobin/hematocrit/RBC, Hyperlipidemia (total cholesterol, LDL-cholesterol, triglycerides), Decreased HDL-cholesterol, Eosinophilia, Increased glucose, Increased liver function test (ALT, AST, GGTP, LDH), Increased phosphorus, Abnormal laboratory abnormalities were reported: Increased BUN and PT, Leukopenia, Thrombocytopenia, Urinaciduria.

Postmarketing
During postmarketing surveillance, which includes other dosage forms and other patient populations, the following adverse events were reported. Symptoms consistent with an anaphylactoid or asthmatic process have been reported: Rash, urticaria, and photosensitivity reactions have also been reported. Localized reactions including induration and abscess have been reported at the site of injection.

Cardiovascular System - Hypotension; *Hemic and Lymphatic System* - Decreased WBC; *Central/Peripheral Nervous System* - Peripheral neuropathy, Spinal fracture/paralysis; *Musculoskeletal System* - Tenosynovitis-like symptoms; *Urogenital System* - Prostate pain.

Changes in Bone Density: Decreased bone density has been reported in the medical literature in men who have had orchiectomy or who have been treated with an LH-RH agonist analog. In a clinical trial, 25 men with prostate cancer, 10 of whom had been treated previously with leuprolide acetate for at least six months, underwent bone density studies as a result of pain. The leuprolide-treated group had lower bone density scores than the nontreated control group. It can be anticipated that long periods of medical castration in men will have effects on bone density.

See other LUPRON DEPOT and LUPRON injection package inserts for other events reported in women and pediatric populations.

OVERDOSAGE
In clinical trials using daily subcutaneous leuprolide acetate in patients with prostate cancer, doses as high as 20 mg/day for up to two years caused no adverse effects differing from those observed with the 1 mg/day dose.

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Ref. 03-5055-R3: Revised: June, 2000

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ADVERSE REACTIONS

Clinical Trials

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In the majority of nonorchiectomized patients,
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UROLOGY®

Aims and Scope

The mission of **UROLOGY**, the "GOLD JOURNAL", is to provide practical, timely, and relevant clinical and basic science information to physicians and researchers practicing the art of urology worldwide. **UROLOGY** publishes original articles relating to adult and pediatric clinical urology as well as to clinical and basic science research. Topics in **UROLOGY** include pediatrics, surgical oncology, radiology, pathology, erectile dysfunction, infertility, incontinence, transplantation, endourology, andrology, female urology, reconstructive surgery, and medical oncology, as well as relevant basic science issues. Special features include rapid communication of important timely issues, surgeon's workshops, interesting case reports, surgical techniques, clinical and basic science review articles, guest editorials, letters to the editor, book reviews, historical articles in urology, and a postgraduate continuing medical education program.

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Publisher: UROLOGY (ISSN 0090-4295) (GST #128741063) (IPM #0388203) is published monthly (For Post Office use only: Volume 03, issue 10 of 12) by Elsevier Inc., 360 Park Avenue South, New York, NY 10010-1710; telephone (212) 633-3927, FAX (212) 633-3913.

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Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 113 of 120

UROLOGY

VOLUME 62, NUMBER 4 OCTOBER 2003

EDITORIAL

Indications for Early Cystectomy . . . 591
John P. Stein

REVIEWS

Measuring Self-Reported Sexual Function in Men with Prostate Cancer . . . 596
Penny S. Brucker and David Cella

Molecular Genetic Aspects of Prostate Transition Zone Lesions . . . 607
Jasminka Pavelić, Žarko Zeljko, and Maja Herak Bosnar

RAPID COMMUNICATION

Levofloxacin for Chronic Prostatitis/Chronic Pelvic Pain Syndrome in Men: A Randomized Placebo-Controlled Multicenter Trial . . . 614
J. Curtis Nickel, Joe Downey, Janet Clark, Richard W. Casey, Peter J. Pommerville, Jack Barkin, Gary Steinhoff, Gerald Brock, Allan B. Patrick, Stanley Flax, Bernard Goldfarb, Bruce W. Palmer, and Joseph Zadra

ADULT UROLOGY

Identification of Common Themes from After-Hour Telephone Calls Made to Urology Residents . . . 618
John T. Stoffel, Alireza Moinzadeh, and Moritz Hansen

Management of Encrusted Ureteral Stents Impacted in Upper Tract . . . 622
Matthew F. Bultitude, Richard C. Tiptaft, Jonathan M. Glass, and Prokar Dasgupta

Laparoscopy for the Diagnosis and Treatment of Radiologically Occult but Symptomatic Hypoplastic Kidneys . . . 627
M. S. Ansari, A. K. Hemal, N. P. Gupta, and P. N. Dogra

Modified Renal Morcellation for Renal Cell Carcinoma: Laboratory Experience and Early Clinical Application . . . 632
Jaime Landman, Ramakrishna Venkatesh, Adam Kibel, and Richard Vanlangendonck
Editorial Comment: Louis Eichel

Nephrectomy for Metastatic Renal Cell Carcinoma: Indiana University Experience . . . 636
Ashraf Mosharafa, Michael Koch, Arieh Shalhav, Thomas Gardner, Theodore Logan, Richard Bihrle, and Richard Foster

Nephron-Sparing Surgery for Renal Cell Carcinoma: Clinicopathologic Features Predictive of Patient Outcome . . . 641
Kent G. Krejci, Michael L. Blute, John C. Cheville, Thomas J. Sebo, Christine M. Lohse, and Horst Zincke

Detrusor Resistive Index Evaluated by Doppler Ultrasonography as a Potential Indicator of Bladder Outlet Obstruction . . . 647
A. Belenky, Y. Abarbanel, M. Cohen, O. Yossepowitch, P. M. Livne, and G. N. Bachar

Distinguishing Neurogenic from Non-neurogenic Detrusor Overactivity: A Urodynamic Assessment of Lower Urinary Tract Symptoms in Patients With and Without Parkinson's Disease . . . 651
Gina A. Defreitas, Gary E. Lemack, Philippe E. Zimmern, Richard B. Dewey, Claus G. Roehrborn, and Padraig E. O'Suilleabhain

Accuracy of Bladder Volume Determinations by Ultrasonography: Are They Accurate Over Entire Bladder Volume Range? . . . 656
Seok-Soo Byun, Hyeon Hoe Kim, Eunsik Lee, Jae-Seung Paick, Weechang Kang, and Seung-June Oh

Reducing Time to Oral Diet and Hospital Discharge in Patients Undergoing Radical Cystectomy Using a Perioperative Care Plan . . . 661
Raj S. Pruthi, Judy Chun, and Marc Richman
Editorial Comment: Marcus L. Quek and John P. Stein

Weak Correlation Between Bladder Outlet Obstruction and Probability to Void to Completion . . . 667
Ries Kranse and Ron van Mastrigt

Comparison of Outcomes of Transurethral Prostate Resection in Urodynamically Obstructed Versus Selected Urodynamically Unobstructed or Equivocal Men . . . 672
Ger E. P. M. van Venrooij, Harm H. E. van Melick, and Tom A. Boon

Dietary Manipulation, Ethnicity, and Serum PSA Levels . . . 677
James A. Eastham, Elyn Riedel, Lianne Latkany, Martin Fleisher, Arthur Schatzkin, Elaine Lanza, Moshe Shike, and the Polyp Prevention Trial Study Group

Clinical Correlates to PSA Spikes and Positive Repeat Biopsies After Prostate Brachytherapy . . . 683
Daniel Reed, Ken Wallner, Gregory Merrick, Steven Butler, and Lawrence True

Continued on page A12

0090-4295(200310)62:4;1-X

UROLOGY

TABLE OF CONTENTS

Continued from page A8

Pain Assessment After Original Transperineal Prostate Biopsy Using a Coaxial Needle . . . 689
Giovanni Novella, Vincenzo Ficarra, Antonio Galfano, Riccardo Ballario, Giacomo Novara, Stefano Cavalleri, and Walter Artibani

Prospective Evaluation of Pain Medication Requirements and Recovery After Radical Perineal Prostatectomy . . . 693
Alon Z. Weizer, Ari D. Silverstein, Matthew D. Young, Johannes Vieweg, David F. Paulson, and Philipp Dahm

Comparison of the American Society of Anesthesiologists Physical Status Classification with the Charlson Score as Predictors of Survival After Radical Prostatectomy . . . 698
Michael Froehner, Rainer Koch, Rainer Litz, Axel Heller, Sven Oehlschlaeger, and Manfred P. Wirth

Contemporary Evaluation of Operative Parameters and Complications Related to Open Radical Retropubic Prostatectomy . . . 702
Herbert Lepor and Ledia Kaci

Quality-of-Life Questionnaire Results 2 and 3 Years After Radiotherapy for Prostate Cancer in a Randomized Dose-Escalation Study . . . 707
Darryn J. Lisle, Deborah A. Kuban, Lawrence B. Levy, Gunar K. Zagars, and Alan Pollack

Simple Sling Incision for the Treatment of Iatrogenic Urethral Obstruction . . . 714
Howard B. Goldman

Failed Posterior Urethroplasty: Lessons Learned . . . 719
Mamdouh M. Koraitim

Comparison of Outcomes After Single or Double-Cuff Artificial Urinary Sphincter Insertion . . . 723
R. Corey O'Connor, Glenn S. Gerber, Desiderio Avila, Andrew A. Chen, and Gregory T. Bales

Biochemical Screening in the Assessment of Erectile Dysfunction: What Tests Decide Future Therapy? . . . 727
Carolyn M. Earle and Bronwyn G. A. Stuckey

Reoperative Retroperitoneal Surgery for Nonseminomatous Germ Cell Tumor: Clinical Presentation, Patterns of Recurrence, and Outcome . . . 732
James M. McKiernan, Robert J. Motzer, Dean F. Bajorin, Jennifer Bacik, George J. Bosl, and Joel Sheinfeld

PEDIATRIC UROLOGY

Risk Factors for Spontaneous Bladder Perforation After Augmentation Cystoplasty . . . 737
William DeFoor, Leslie Tackett, Eugene Minevich, Jeffrey Wacksman, and Curtis Sheldon

Adolescent Varicocele: Is It a Unilateral Disease? . . . 742
Yigal Gat, Zvi Zukerman, Gil N. Bachar, Dov Feldberg, and Michael Gornish
Editorial Comment: Stanley J. Kogan

CASE REPORT ABSTRACTS (Full Text Available Only at http://www.goldjournal.net)

Two Secondary Malignancies After Radiotherapy for Seminoma: Case Report and Review of the Literature . . . 748
Michael A. Hughes, Alice Wang, and Theodore L. DeWeese

Obstructive Nephropathy Secondary to Sulfasalazine Calculi . . . 748
Paul J. Russinko, Saraub Agarwal, Michael J. Choi, and Patrick J. Kelly

Extensive Palliative Surgery for Advanced Mesothelioma of the Tunica Vaginalis . . . 748
Peter C. Black, Paul H. Lange, and Thomas K. Takayama

Distinguishing Splenosis from Renal Masses Using Ferumoxide-Enhanced Magnetic Resonance Imaging . . . 748
Adam J. Berman, Michael P. Zahalsky, Stephen A. Olson, and Joseph R. Wagner

Prostate Carcinoma Presenting as Multiple Pulmonary Nodules in an Asymptomatic Patient with a History of Testicular Nonseminomatous Germ Cell Tumor . . . 748
Francis D. Sheski, John D. Henley, Richard S. Foster, and Lawrence H. Einhorn

Transitional Cell Carcinoma in a Fused Crossed Ectopic Kidney . . . 748
Uri Gur, Ofer Yossepowitch, and Jack Baniel

Renal-Ovarian Axis: A Case Report and Review . . . 749
George Garallos, Ossama Tawfik, Duke Herrell, and Peter Langenstroer

Large Cerebellar Lesion as Original Manifestation of Transitional Cell Carcinoma of the Bladder . . . 749
Benjamin J. Davies, Sheldon Bastacky, and Steve Y. Chung

BASIC SCIENCE

Rapamycin Preserves Renal Function Compared with Cyclosporine A After Ischemia/Reperfusion Injury . . . 750
Sharon R. Inman, Nancy A. Davis, Kristen M. Olson, Victoria A. Lukaszek, Marc R. McKinley, and Jennifer L. Seminerio

Continued on page A14

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 115 of 120

UROLOGY

TABLE OF CONTENTS

Continued from page A12

Effect of Spinal Cord Injury on Urinary Bladder Spinal Neural Pathway: A Retrograde Transneuronal Tracing Study with Pseudorabies Virus . . . 755
X. Yu, L. Xu, X. D. Zhang, and F. Z. Cui

Reperfusion of Ischemic Corporal Tissue: Physiologic and Biochemical Changes in an Animal Model of Ischemic Priapism . . . 760
Ricardo Munarriz, Kwangsung Park, Yue-Hua Huang, Iñigo Saenz De Tejada, Robert B. Moreland, Irwin Goldstein, and Abdulmaged M. Traish

Immature Tumor Angiogenesis in High-Grade and High-Stage Renal Cell Carcinoma . . . 765
Toshiaki Kinouchi, Masayuki Mano, Ikuyo Matsuoka, Sae Kodama, Tomomi Aoki, Mina Okamoto, Hisako Yamamura, Michiyuki Usami, and Katsuhito Takahashi

Quantitative RT-PCR Assay for *MUC3* and *VEGF* mRNA in Renal Clear Cell Carcinoma: Relationship with Nuclear Grade and Prognosis . . . 771
Xavier Leroy, Valerie Gouyer, Charles Ballereau, Farid Zerimech, Guillemette Huet, Marie-Christine Copin, Jean-Pierre Aubert, and Nicole Porchet

NAMES IN GENITOURINARY SURGERY

Urologic Techniques of Serefeddin Sabuncuoglu in the 15th Century Ottoman Period . . . 776
Ayhan Verit, Sahin Aksoy, Hasan Kafali, and F. Ferda Verit

GENERAL

Letter to the Editor
Shortened Pull-String Simplifies Office-Based Ureteral Stent Removal . . . 779
Fred R. Portney
Reply of: J. Stephen Jones

Postgraduate Education . . . 780

Editorial Board . . . A4

Information for Contributors . . . A17–A18

Classified Ads . . . A35–A39

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 116 of 120

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ELSEVIER

PAIN ASSESSMENT AFTER ORIGINAL TRANSPERINEAL PROSTATE BIOPSY USING A COAXIAL NEEDLE

GIOVANNI NOVELLA, VINCENZO FICARRA, ANTONIO GALFANO, RICCARDO BALLARIO, GIACOMO NOVARA, STEFANO CAVALLERI, AND WALTER ARTIBANI

ABSTRACT

Objectives. To assess whether the use of a coaxial needle reduces discomfort in patients undergoing multiple-core transperineal prostate biopsy to detect prostate cancer.

Methods. From October 2002 to January 2003, we enrolled 102 consecutive patients with a suspicion of prostate cancer. In every case, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance. The patients were randomized into two groups: group 1 (n = 51) in which we used the 17-gauge coaxial TruGuide needle, and group 2 (n = 51) in which the conventional transperineal technique was used. At the end of the procedure, patients were asked to complete a questionnaire regarding the level of pain experienced.

Results. The studied groups were comparable in age, total prostate-specific antigen value, and prostate volume. The whole procedure was significantly less painful in group 1 (2.20 ± 1.20 versus 2.90 ± 1.73, $P = 0.01$). We failed to show any significant pain score differences during rectal probe insertion ($P = 0.10$), transrectal ultrasonography ($P = 0.16$), and execution of local anesthesia ($P = 0.11$). The pain score recorded during the multiple-core prostate sampling was significantly lower in group 1 (1.53 ± 1.5 versus 2.43 ± 1.86, $P = 0.009$). No statistically significant differences were found in the complication rates between the two groups.

Conclusions. The use of a coaxial needle reduces the procedure's invasiveness and patient's pain compared with the conventional transperineal prostate biopsy. UROLOGY **62:** 689–692, 2003. © 2003 Elsevier Inc.

The transrectal ultrasound (TRUS)-guided transperineal prostate biopsy is a simple and well-tolerated procedure with a low complication rate. This technique allows optimal sampling of the peripheral and transition zones of the prostate with a greater detection rate.[1] In recent years, the transperineal approach for prostate biopsy has had more limited diffusion than transrectal biopsy, probably because of the supposed greater invasiveness and execution complexity.

In the conventional transperineal technique, the needle is repeatedly inserted through the perineal plane under local anesthesia. To minimize the invasiveness, we recently introduced the use of a 17-gauge coaxial needle (TruGuide Bard) in our clinical practice. The use of coaxial needles has been described for liver, kidney, pancreas, and breast biopsies.[2–4] However, to the best of our knowledge, this is the first experience concerning the utility of this device for prostate biopsy.

The insertion of the coaxial needle up to the prostate apex and the successive blunt tip stylet removal allow the creation of an optimal transperineal path for repeated atraumatic passage of the biopsy needle.

The purpose of the present study was to evaluate whether the use of this new device results in a reduction in the pain patients experience during multiple-core prostate biopsy compared with during the traditional transperineal approach.

MATERIAL AND METHODS

From October 2002 to January 2003, we enrolled 102 consecutive patients with a suspicion of prostate cancer (prostate-specific antigen greater than 4 ng/mL and/or positive digital rectal examination findings). All patients underwent TRUS-guided transperineal prostate biopsy. The patients were adequately informed of mode of execution of the procedure and

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Submitted: March 3, 2003, accepted (with revisions): April 23, 2003

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0090-4295/03/$30.00
doi:10.1016/S0090-4295(03)00483-7

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Page 117 of 120

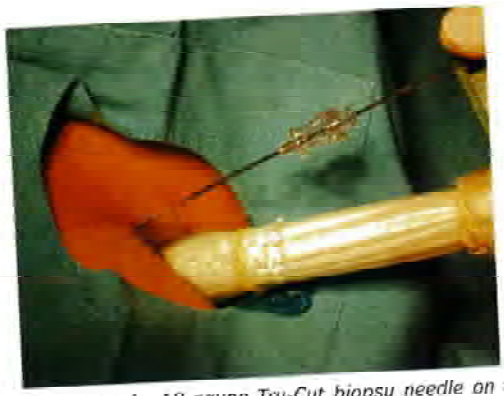


FIGURE 1. *An 18-gauge Tru-Cut biopsy needle on a spring-loaded biopsy gun is inserted into the guiding cannula of the coaxial needle.*

its potential complications and were asked to provide written consent. Internal review board approval was not required at our institution to perform this type of study.

The patients were randomized into two groups in relation to the use of the coaxial 17-gauge TruGuide needle during prostate biopsy. We used the coaxial needle in 51 patients (group 1) and carried out the conventional transperineal technique in the other 51 patients (group 2). In both groups, we evaluated age, digital rectal examination findings, total prostate-specific antigen value, and prostate volumes as estimated by TRUS (with the ellipse method: length × depth × width × $\pi/6$).

Bioptical Technique

All patients stopped anticoagulant therapy 7 days before the procedure and took a prophylactic antibiotic (fluoroquinolone or co-trimoxazole) 12 hours before. An enema was given the same morning of the procedure.

All biopsies were performed by a single urologist (G.N.). TRUS was carried out using the Siemens Sonoline Omnia Diagnostic Ultrasound System, with a 7.75-MHz linear probe. The patient was placed in the lithotomy position, and the perineal area was disinfected. A single, 22-gauge spinal needle was inserted transperineally 1.5 cm above the rectum on the median line. The needle passage through perineal planes was guided by TRUS.

The needle was introduced posteriorly to the bulbar urethra up to the prostate apex and laterally to the membranous urethra. In this area, 2 mL of 1% mepivacaine was released. The needle was progressively retracted and 2 mL of anesthetic was administered along the needle path. An identical procedure was done contralaterally through the same median hole. In group 1, a 17-gauge coaxial needle (TruGuide Bard, 13 cm long) was inserted up to the prostate apex through the anesthetized perineal path under TRUS guidance. On the removal of the blunt tip stylet, the guiding cannula of the coaxial needle was an optimal transperineal path for repeated atraumatic passage of the biopsy needle (18-gauge Tru-Cut, 20 cm long), loaded on a spring-driven biopsy gun (Magnum Bard Biopsy Instruments) with a cutting length of 22 mm (Fig. 1).

In group 2, the same biopsy needle was repeatedly inserted through the anesthetized perineal plane, according to the conventional transperineal technique.

Fourteen cores were sampled in every patient (double sextant biopsy from the peripheral and two cores from the transition zone). The progression and inclination of the needle was controlled by transverse and longitudinal TRUS, respectively. In both groups, at the end of the sampling, an ice bag was placed on the perineal area for about 15 minutes. All the procedures were performed on an outpatient basis.

At the end of the biopsy, every patient received an institutional questionnaire to assess the level of pain during the different steps of the procedure. Thorough instructions for form compilation were provided. The form consisted of six questions:

1. How painful was the whole procedure?
2. How painful was the probe insertion?
3. How painful was the presence of the probe during the procedure?
4. How painful was local anesthetic administration?
5. How painful was the prostate sampling?
6. If medically necessary, how willing would you be to repeat the procedure?

The pain level was evaluated by a visual analog scale/numeric analog scale), in which 0 corresponds to "no pain" and 10 to "the worst pain imaginable."[5] A total pain score of 0 was evaluated as "no pain," a score from 1 to 4 as "mild pain," a score from 5 to 7 as "moderate pain," and any score greater than 7 as "severe pain."[6] For question 6, 0 corresponded to "very willing" and 10 to "never, for no reason."

All patients were clinically evaluated 30 days after biopsy to record the complications related to the procedure.

The Pearson chi-square test and the Student *t* test was used to compare categorical and continuous variables, respectively. In statistical analysis, a $P < 0.05$ was considered significant. The data were collected in a database and analyzed using Statistical Package for Social Sciences, version 10.1, software by one of us (V.F.).

RESULTS

The analyzed groups were comparable in age, digital rectal examination findings, prostate volume, and total prostate-specific antigen value (Table I). The whole procedure (question 1) was significantly less painful in group 1 (2.2 ± 1.20 versus 2.90 ± 1.73, $P = 0.01$). In group 1, 49 (96.1%) had mild pain and 2 (3.9%) had moderate pain. No group 1 patients reported a score greater than 6. In group 2, 42 patients (82.4%) recorded mild pain, 8 (15.6%) moderate pain, and 1 (2%) severe pain (Table II).

For the different procedure steps, we failed to show any statistically significant pain score differences during rectal probe insertion (question 2; $P = 0.10$), TRUS (question 3; $P = 0.16$), or local anesthesia execution (question 4; $P = 0.11$). The pain scores concerning the multiple-core prostate sampling were significantly different. The mean score (question 5) was 1.53 ± 1.51 in group 1 and 2.43 ± 1.86 in group 2 ($P = 0.009$). During this step, 14 patients (27.5%) in group 1 (coaxial needle technique) had no pain, 35 (68.5%) had mild pain, and 2 (4%) had moderate pain. In group 2 (conventional transperineal technique), only 6 patients (11.8%) recorded no pain during the prostate sampling step; 37 (72.5%) reported mild pain, 7 (13.7%) moderate pain, and 1 (2%) severe pain (Table II).

The mean score for question 6 was 2.16 ± 1.60 in group 1 and 3.06 ± 2.14 in group 2 ($P = 0.01$).

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Page 118 of 120

TABLE I. *Clinical characteristics*

Variable	Group 1 (n = 51)	Group 2 (n = 51)	*P* Value
Mean age (yr)	63.76 ± 7.14	65.90 ± 7.54	0.14
Positive DRE (%)	27.5	39.2	0.20
Total PSA (ng/mL)	7.88 ± 3.37	9.26 ± 8.42	0.28
Prostate volume (cm^3)	46.74 ± 27.68	41.81 ± 21.35	0.31

Key: DRE = digital rectal examination; PSA = prostate-specific antigen.

TABLE II. *Difference in subjective measures between studied groups*

	Group 1 (%)	Group 2 (%)
Whole procedure		
No pain (0)	0	0
Mild pain (1–4)	49 (96.1)	42 (82.4)
Moderate pain (5–7)	2 (3.9)	8 (15.6)
Severe pain (>7)	0	1 (2)
Multiple-core sampling		
No pain (0)	14 (27.5)	6 (11.8)
Mild pain (1–4)	35 (68.5)	37 (72.5)
Moderate pain (5–7)	2 (4)	7 (13.7)
Severe pain (>7)	0	1 (2)

TABLE III. *Mean score (± standard deviation) recorded for each question*

Question	Group 1 (n = 51)	Group 2 (n = 51)	*P* Value
(1) Whole procedure	2.20 ± 1.20	2.90 ± 1.73	0.01
(2) Probe insertion	1.02 ± 1.27	1.43 ± 1.30	0.10
(3) TRUS	1.02 ± 1.34	1.41 ± 1.45	0.16
(4) Local anesthesia	2.29 ± 1.31	2.80 ± 1.87	0.11
(5) Multiple-core sampling	1.53 ± 1.51	2.43 ± 1.86	0.009
(6) Procedure repetition	2.16 ± 1.60	3.06 ± 2.14	0.01

Key: TRUS = transrectal ultrasonography.

Table III summarizes the reported scores for each question.

The complication rates overlapped in both groups (Table IV).

TABLE IV. *Reported complications (30 days after prostate biopsy; chi-square = not statistically significant in any case)*

Complication	Group 1 (n = 51)	Group 2 (n = 51)
Perineal hematoma	0	1 (2)
Hematuria (lasting >3 days)	30 (59)	23 (45)
Hemospermia	27 (53)	24 (47)
Acute urinary retention	0	3 (6)
Urinary tract infection	0	3 (6)
Fever (>38°C)	0	1 (2)

Numbers in parentheses are percentages.

COMMENT

The TRUS-guided transperineal prostate biopsy is a suitable alternative to the more widespread transrectal approach. The transperineal approach with external ultrasound guidance has been proposed as the optimal way to perform prostate biopsy, mainly in patients who have undergone abdominoperineal resection.[7] Recently, Emiliozzi *et al.*[1] showed that the transperineal technique allowed optimal prostate sampling and had relevant cancer detection rates with acceptable morbidity also in patients who had not undergone any previous abdominoperineal resection. In the transperineal approach, the needle is inserted through the prostate apex along a longitudinal plane parallel to the prostate axis. This eases the needle orientation and provides optimal sampling of the peripheral and transition zones.

Systematic transperineal prostate biopsies need local anesthesia. Although the use of local anesthesia has not been considered mandatory in transrectal prostate biopsy, an increasing number of reports have been showing a relevant reduction of discomfort in patients undergoing transrectal prostate biopsy with local anesthesia.[6,8–10] The prostatic plexus block is the most commonly used technique of local anesthesia during transrectal prostate biopsy. Since the first report of Costello and Costello,[11] several technical modifications have been proposed, mainly involving the dosage and sites of anesthetic injection.[10–13] A recent prospective, randomized study showed that an anesthetic injection at the level of the prostate apex was easier, less painful, and more effective than prostatic plexus block during transrectal prostate biopsy.[6] To administer local anesthesia and to perform transperineal biopsies, double-sided access is often used, on both the left and the right of the median line, 1.5 cm above the rectum, on a line at a 45° angle with the median line.[1] The transperineal access further simplifies anesthetic injection at the prostate apex.

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 119 of 120

The use of a single median transperineal access was described by Milani *et al.*[14] Although it involves a greater risk of bulbar urethra injury, this approach allows the reduction of bulbourethral artery injuries and perineal hematoma development and increases procedure tolerability.[14]

To the best of our knowledge, the use of a coaxial needle has not been reported during prostate biopsy. This device makes the procedure easier and quicker. The guiding cannula forms an optimal transperineal path, allowing the repeated insertion of the needle with lower perineal invasiveness and avoiding continual ultrasound control of the needle.

Our data showed that the use of a coaxial needle significantly reduced the experienced pain during prostate sampling and improved patient compliance compared with the conventional transperineal biopsy technique. Our results support the widespread use of a coaxial needle during transperineal prostate biopsy.

An additional possible issue could be the comparison between the use of the perineal coaxial needle and the standard TRUS-guided biopsy. No data are currently available about this topic. Indirect evidence could be gained by comparing our data with those recently published by Stirling *et al.*[15] in a group of 50 patients undergoing TRUS-guided biopsy with periprostatic nerve blockade. Using a similar question about discomfort during prostate sampling and the same visual analog pain scale, the investigators reported a mean score of 2.8 ± 1.9, significantly greater than our score ($P < 0.001$). Moreover, although in the patients in the study by Stirling *et al.*, a mean number of nine cores was sampled, we performed 14 biopsies in every patient. However, this issue could be better assessed by a randomized prospective trial.

The role of transperineal approach might become more relevant as acceptance of an increase in the number of cores needed to maximize prostate cancer detection rates grows.

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Page 122 of 309

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Page 123 of 309

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Page 124 of 309

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Page 130 of 309

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Clinical Trial Urology. 2003 Oct;62(4):689-92. doi: 10.1016/s0090-4295(03)00483-7.

Pain assessment after original transperineal prostate biopsy using a coaxial needle

Giovanni Novella [1], Vincenzo Ficarra, Antonio Galfano, Riccardo Ballario, Giacomo Novara, Stefano Cavalleri, Walter Artibani

Affiliations
PMID: 14550444 DOI: 10.1016/s0090-4295(03)00483-7

Abstract

Objectives: To assess whether the use of a coaxial needle reduces discomfort in patients undergoing multiple-core transperineal prostate biopsy to detect prostate cancer.

Methods: From October 2002 to January 2003, we enrolled 102 consecutive patients with a suspicion of prostate cancer. In every case, we performed a 14-core transperineal prostate biopsy under transrectal ultrasound guidance. The patients were randomized into two groups: group 1 (n = 51) in which we used the 17-gauge coaxial TruGuide needle, and group 2 (n = 51) in which the conventional transperineal technique was used. At the end of the procedure, patients were asked to complete a questionnaire regarding the level of pain experienced.

Results: The studied groups were comparable in age, total prostate-specific antigen value, and prostate volume. The whole procedure was significantly less painful in group 1 (2.20 +/- 1.20 versus 2.90 +/- 1.73, P = 0.01). We failed to show any significant pain score differences during rectal probe insertion (P = 0.10), transrectal ultrasonography (P = 0.16), and execution of local anesthesia (P = 0.11). The pain score recorded during the multiple-core prostate sampling was significantly lower in group 1 (1.53 +/- 1.5 versus 2.43 +/- 1.86, P = 0.009). No statistically significant differences were found in the complication rates between the two groups.

Conclusions: The use of a coaxial needle reduces the procedure's invasiveness and patient's pain compared with the conventional transperineal prostate biopsy.

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Page 132 of 309

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PG - 689-92
AB - OBJECTIVES: To assess whether the use of a coaxial needle reduces c patients undergoing multiple-core transperineal prostate biopsy to prostate cancer. METHODS: From October 2002 to January 2003, we enr consecutive patients with a suspicion of prostate cancer. In every performed a 14-core transperineal prostate biopsy under transrectal guidance. The patients were randomized into two groups: group 1 (n we used the 17-gauge coaxial TruGuide needle, and group 2 (n = 51) conventional transperineal technique was used. At the end of the pr patients were asked to complete a questionnaire regarding the level experienced. RESULTS: The studied groups were comparable in age, tc prostate-specific antigen value, and prostate volume. The whole prc significantly less painful in group 1 (2.20 +/- 1.20 versus 2.90 +/ 0.01). We failed to show any significant pain score differences dur probe insertion (P = 0.10), transrectal ultrasonography (P = 0.16), of local anesthesia (P = 0.11). The pain score recorded during the prostate sampling was significantly lower in group 1 (1.53 +/- 1.5 +/- 1.86, P = 0.009). No statistically significant differences were complication rates between the two groups. CONCLUSIONS: The use of needle reduces the procedure's invasiveness and patient's pain comp conventional transperineal prostate biopsy.
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Page 133 of 309

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Page 134 of 309

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Novella, G., Ficarra, V., Galfano, A., Ballario, R., Novara, G., Cavalleri, S., & Artibani, W., (2003, October), Pain assessment after original transperineal prostate biopsy using a coaxial needle, *Urology*, vol. 62, no. 4, pp. 689-692.

Citations: 2005 – 2010 (in chronological order)

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EXHIBIT 1007

bk medical

User Guide
Type 8808e

Prostate Biplane Transducer



English
BB1856-D
June 2012

CE 0543
For Professional Users Only

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The serial number of a BK Medical product contains information about the year of manufacture. To obtain the date of manufacture of a product, please contact your BK Medical representative or write to us at the email address above, including the product's serial number (SN number).

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If you have comments about the user documentation, please write to us at the email address above. We would like to hear from you.

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Contents

Introduction 5
Indications for Use 5
General Information 5
Service and Repair 6
Caring for the Transducer 6
Cleaning and Disinfection 6
Starting Imaging 7
Connecting the Transducer 7
Changing Frequency 7
Using a Transducer Cover 7
Using the Transducer Control Button 8
Changing Orientation 8
Imaging with Type 8808e 8
Imaging Without Puncture or Biopsy 9
Puncture and Biopsy Facilities 9
For Transrectal Puncture 9
For Transperineal Puncture 12
Performing Puncture and Biopsy 13
Cleaning after Puncture and Biopsy 14
Disposal 14

Advance Medical Designs, Inc. - EX1013
Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 141 of 309

4

Introduction

This is the user guide for Prostate Biplane Transducer Type 8808e and must be used together with *Care, Cleaning & Safety* which contains important safety information.

Indications for Use

Prostate Biplane Transducer Type 8808e is designed for transrectal prostate imaging.



Figure 1. Prostate Biplane Transducer Type 8808e.

Imaging Plane

The transducer contains two convex arrays — one for transverse (T) imaging, and one for sagittal (S) imaging (see Figure 2). The advantage of being able to view two planes simultaneously with one transducer is that the true position of the needle can be seen during puncture and biopsy and a suspicious lesion can be viewed in both planes.

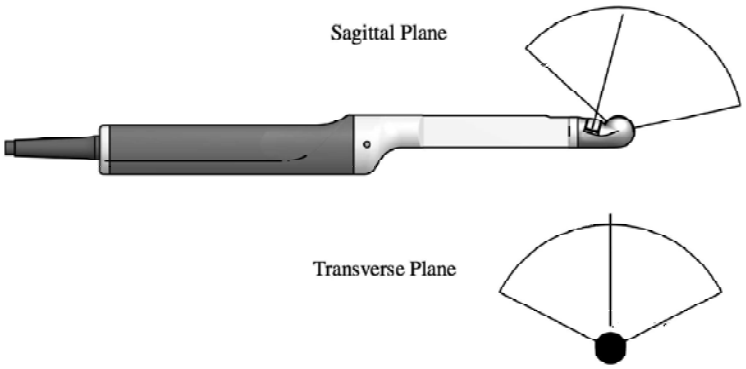


Figure 2. Imaging planes for Prostate Biplane Transducer Type 8808e.

General Information

Product specifications for this transducer can be found in the Product Data sheet that accompanies this user guide.

Acoustic output data and data about EMC (electromagnetic compatibility) for this transducer are in Technical Data (BZ2100) that accompanies this user guide. A full explanation of acoustic output data is given in your system user guide.

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 143 of 309

WARNING

If at any time the system malfunctions, or the image is severely distorted or degraded, or you suspect in any way that the system is not functioning correctly:

- Remove all transducers from contact with the patient.
- Turn off the system. Unplug the system from the wall and make sure it cannot be used until it has been checked.
- Do not try to repair the system yourself.
- Contact your BK Medical representative or hospital technician.

WARNING

Always keep the exposure level (the acoustic output level and the exposure time) as low as possible.

Service and Repair

WARNING

Service and repair of BK Medical electromedical equipment must be carried out only by the manufacturer or its authorized representatives. BK Medical reserves the right to disclaim all responsibility, including but not limited to responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties. After service or repairs have been carried out, a qualified electrical engineer or hospital technician should verify the safety of all equipment.

Caring for the Transducer

The transducer may be damaged during use or processing, so it must be checked before use for cracks or irregularities in the surface. It should also be checked thoroughly once a month following the procedure in *Care, Cleaning & Safety*.

Cleaning and Disinfection

To ensure the best results when using BK Medical equipment, it is important to maintain a strict cleaning routine.

Full details of cleaning and disinfection procedures can be found in *Care, Cleaning & Safety* that accompanies this user guide. A list of disinfectants and disinfection methods that the transducer can withstand are listed in the Product Data sheet.

Sterile covers are available. See the Product Data sheet for more information.

WARNING

Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves. To avoid cross contamination, follow all infection control policies for personnel and equipment established for your office, department, or hospital.

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 144 of 309

Starting Imaging

All equipment must be cleaned and disinfected before use.

Connecting the Transducer

WARNING

Keep all plugs and sockets absolutely dry at all times.

The transducer is connected to the system using the array Transducer Socket on the system. To connect, the transducer plug's locking lever should first be in a horizontal position. Align the plug to the system socket and insert securely. Turn the locking lever clockwise to lock in place.

When connected, the transducer complies with Type BF requirements of EN60601-1 (IEC 60601-1).

Changing Frequency

The Multi-Frequency Imaging (MFI) facility enables you to select the imaging frequency. See the applicable system user guide for instructions. The selected frequency is displayed at the top of the screen.

Using a Transducer Cover

The transducer should be enclosed in a transducer cover or a standard condom. See the Product Data sheet for a list of available transducer covers.

WARNING

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), FDA is advising health-care professionals to identify their latex-sensitive patients and be prepared to treat allergic reactions promptly.

Apply sterile gel to the tip of the transducer or fill the cover with 1 to 2 ml of sterile water. This improves the screen images by preventing image artifacts caused by air bubbles.

Pull the transducer cover over the transducer.

Gel also creates a good acoustic contact between the skin and the transducer; therefore, apply a small amount to the outside of the cover prior to imaging. Re-apply the gel frequently to ensure good screen images.

WARNING

Use only water-soluble agents or gels. Petroleum or mineral oil-based materials may harm the cover materials.

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 145 of 309

WARNING

Do not use excessive force during insertion. Do not make excessive lateral movements during or after insertion. Risk of injury or tissue damage to the patient could occur under certain circumstances. A digital palpation of the rectum may need to be carried out by a clinician prior to insertion or use of the probe as a precautionary measure.

Using the Transducer Control Button

To change the imaging plane, press the button corresponding to that plane (see Figure 1). Pressing the button activates (starts) or freezes (stops) imaging in that plane. One button enables the sagittal or longitudinal array. A second button enables the transverse array. Each time a button is pressed, a beep is emitted.

Changing Orientation

To change the orientation of the image on the monitor, refer to the applicable system user guide for instructions.

Imaging with Type 8808e

Simultaneous Biplane Imaging

8808e can transmit transverse (T) and sagittal (S) images simultaneously. When you press the system's **Split** key, simultaneous imaging is automatically activated.

Transverse or Sagittal Imaging

Click **Simultan** to toggle simultaneous imaging on or off. When simultaneous imaging is off, you can change which plane is active and which is frozen by pressing the **Split** key or by placing the cursor on the image you want to be active and pressing the **Select** key.

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 146 of 309

Imaging Without Puncture or Biopsy

When 8808e is used for transrectal imaging without the puncture facilities, the dummy bracket UA1325 must be in place. This clicks into position on the transducer to cover the open channel (see Figure 3).

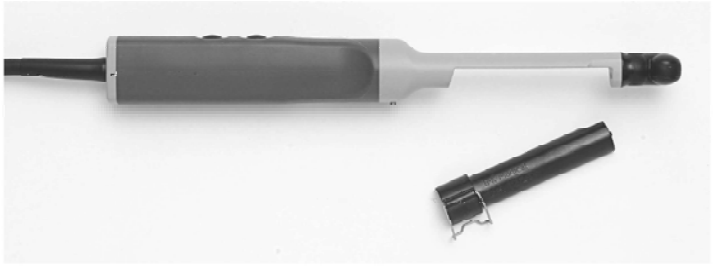


Figure 3. Type 8808e and the dummy channel bracket UA1325.

Note: *The dummy bracket must be removed before 8808e is prepared for disinfection. The bracket can be disinfected using the same methods as explained later under UA1326.*

Puncture and Biopsy Facilities

Transrectal and transperineal puncture and biopsy are possible with 8808e. The following pages illustrate the various transrectal and transperineal puncture accessories available and briefly describe usage and operating instructions. The transducer has an open channel into which the appropriate puncture accessories fit when the dummy channel bracket (UA1325) has been removed (see Figure 3).

⚠ **WARNING**

It is essential for the patient's safety that only the correct puncture attachments, as described in this guide, are used. Never use unauthorized combinations of transducers and puncture attachments or other manufacturers' puncture attachments.

For Transrectal Puncture

With 8808e, you can perform transrectal puncture and biopsy by imaging in simultaneous biplane (imaging in both the transverse and sagittal planes).

The biopsy guide is available in both a non-sterile reusable version (light green) and a sterile-packed single-use version (dark green).

Non-sterile biopsy guides (light green)

The dummy channel bracket UA1325 and the reusable biopsy guide (UA1326) are non-sterile when supplied and must be disinfected by immersion in a suitable solution and autoclaved. The dummy channel bracket and reusable biopsy guide may be damaged during use or processing, so they must be checked before use for cracks or irregularities in the surface. They should also be checked thoroughly once a month following the procedure in *Care, Cleaning & Safety.*

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Advance Medical Designs v. Corbin Clinical Resources, PGR2023-00041
Page 147 of 309