

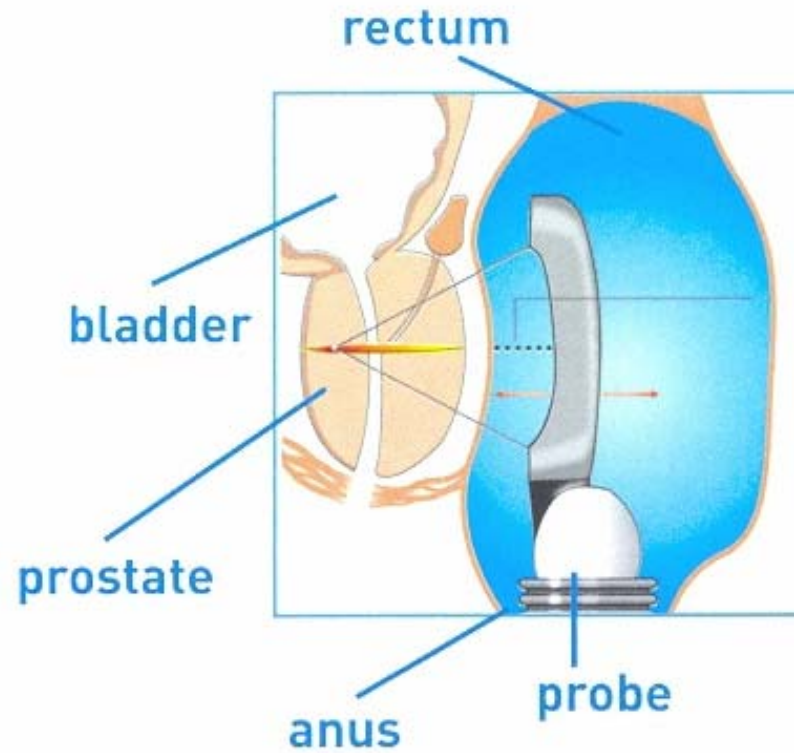
**ABLATHERM HIFU**  
**“THE CANADIAN**  
**EXPERIENCE”**

**WILLIAM L. OROVAN**  
**McMASTER UNIVERSITY**  
**MAPLE LEAF HIFU**

# **PROCEDURE**

- 1. Spinal Anaesthetic/IV Sedation**
- 2. Right Lateral Decubitus Position**
- 3. Transrectal Probe**
- 4. Catheter Intra/Post Op**
- 5. Ambulatory**

# I. PROCEDURE







# ABLATHERM HIFU: Position





⚠

Ablapar

POWER UP

# HIFU: Probe

- **Ablatherm®**
- **U/S 7.5 MHZ  
IMAGING**
- **U/S 3.0 MHZ FIRING**
- **Treatment port:**
  - **Power: 41.5 W**





# HIFU: Prostatic Image

The image shows a software interface for HIFU treatment planning. It features two main ultrasound views: a longitudinal view on the left and a transversal view on the right. Below the views are several control panels. The 'Mark' panel includes a 'Set lower limit position' button and a 'Lobe' dropdown menu set to 'Median lobe'. The 'Extension' panel displays dimensions: A.P. : 0 mm 34.66 mm, Width : 0 mm 32.34 mm, Length : 0 mm 24.95 mm, and Volume : 16.90 cc. The 'Treatment information' panel contains a table with columns for Block n°, Apert to L, Length, and Treated. A 'Volume prostatic' dialog box is open, showing 'Longueur : 25.55mm', 'Largeur : 34.65mm', 'Antéro-postérieur : 31.60mm', and a final 'Volume' of 14.12 cm<sup>3</sup>. The 'Copying / Temperature' panel shows 'Probe : 25.2°C' and 'Bath : 15.1°C'. The 'Settings' panel includes a 'Toggle contrast' button.

**Longitudinal localization**

**LONGITUDINAL VIEW**

**TRANSVERSAL VIEW**

9:25:31 7.5MHz  
6  
0

**Mark**

Set lower limit position

Lobe  
Median lobe

24.3 mm 4.9 mm

Number of blocks : 2  
Number of slices : 15

**Extension**

A.P. : 0 mm 34.66 mm  
Width : 0 mm 32.34 mm  
Length : 0 mm 24.95 mm  
Volume : 16.90 cc

**Treatment information**

Block n°	Apert to L	Length	Treated
1	0.0	0.0	
2	0.0	0.0	
3	0.0	0.0	
4	0.0	0.0	
5	0.0	0.0	

**Volume prostatic**

Longueur : 25.55mm  
Largeur : 34.65mm  
Antéro-postérieur : 31.60mm  
Volume : 14.12 cm<sup>3</sup>

**Copying / Temperature**

Probe : 25.2°C  
Bath : 15.1°C

Measure  
0.0 mm

**Settings**

Toggle contrast

Cancel

Prostatic volume

# HIFU: Treatment

Example: block 1

The screenshot displays the 'TRANSVERSAL LOCALIZATION : Level 1' window of a HIFU treatment system. The central ultrasound image shows a cross-section of the prostate with a blue wireframe treatment plan overlaid. The plan consists of a central vertical column of lines and two side columns of lines, all connected at the top. A pink curved line is visible at the bottom of the image. The top right of the image shows '9:25:33' and '7.5MHz'. The top left shows 'M1: 1.5', 'FR: 37', 'G: 75%', and 'Prs: 1'. The bottom left shows 'B-K Medical'. The bottom right of the image shows '6.' and '0.'. The right side of the window contains a 'Menu' section with buttons for 'Rectum', 'Prostate', 'Rectum Autodetection', 'Left Prostate', and 'Right Prostate'. Below these are navigation buttons '<<', 'Slices 6/8', and '>>'. The 'Treatment options' section includes 'Lesion Height' set to '19' and 'Safety distance' set to '3', with a 'Default' button. The 'Treatment informations' section shows 'Lesion/Slice : 20' and 'Block(s) : 2'. The bottom of the window features a 'Cooling / Temperature' section with 'Probe : 25.2°C' and 'Bath : 15.1°C', a 'Measure' button showing '0.0 mm', an 'AbView' button, a 'Settings' section with 'Video' and 'US Scanner' buttons, and a 'Cancel' button.

TRANSVERSAL LOCALIZATION : Level 1

9:25:33 7.5MHz

M1: 1.5  
FR: 37  
G: 75%  
Prs: 1

B-K Medical

6.

0.

Menu

Rectum

Prostate

Rectum Autodetection

Left Prostate

Right Prostate

<< Slices 6/8 >>

Treatment options

Lesion Height : 19

Safety distance : 3

Default

Treatment informations

Lesion/Slice : 20

Block(s) : 2

Cooling / Temperature

Probe : 25.2°C

Bath : 15.1°C

Measure

0.0 mm

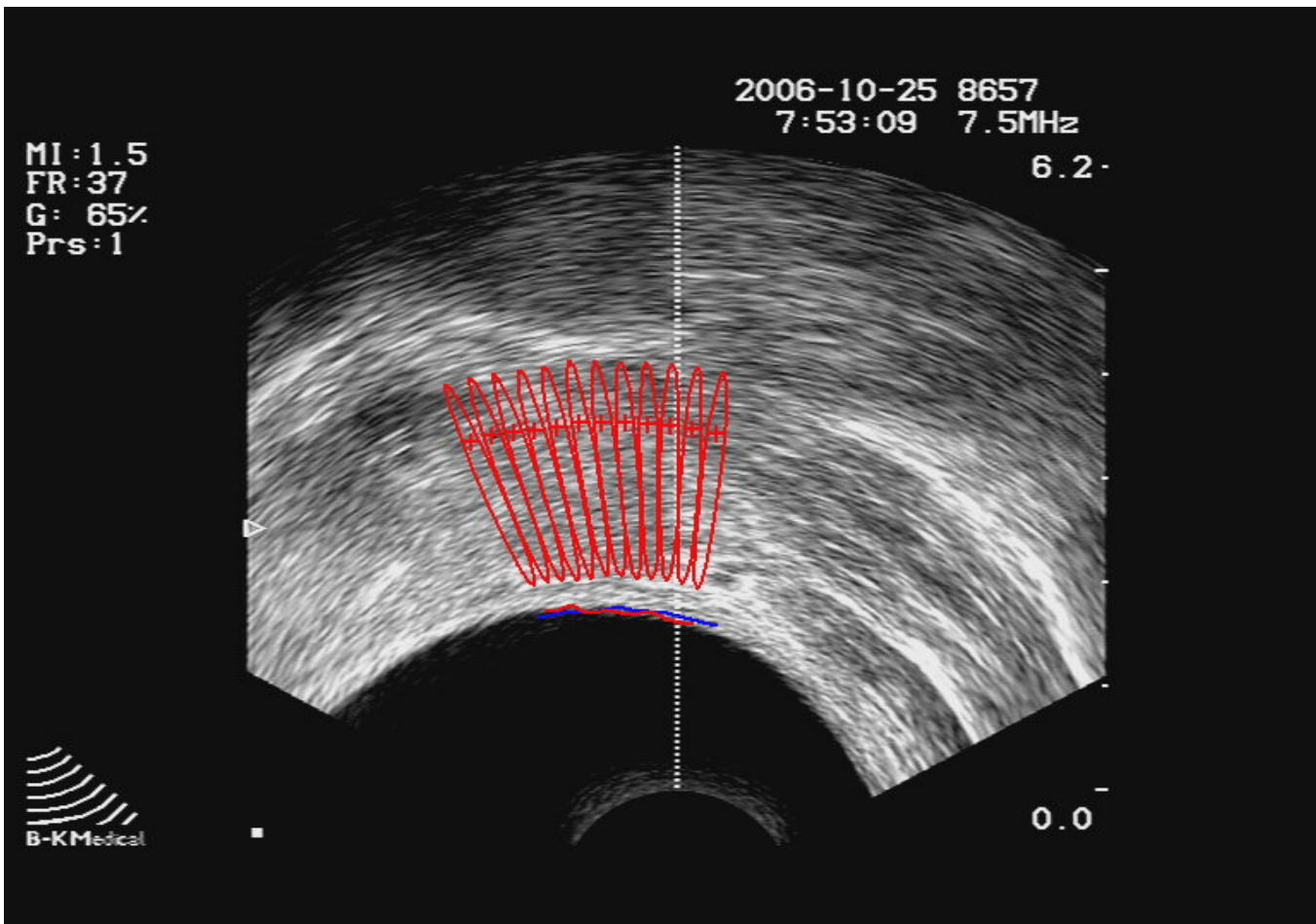
AbView

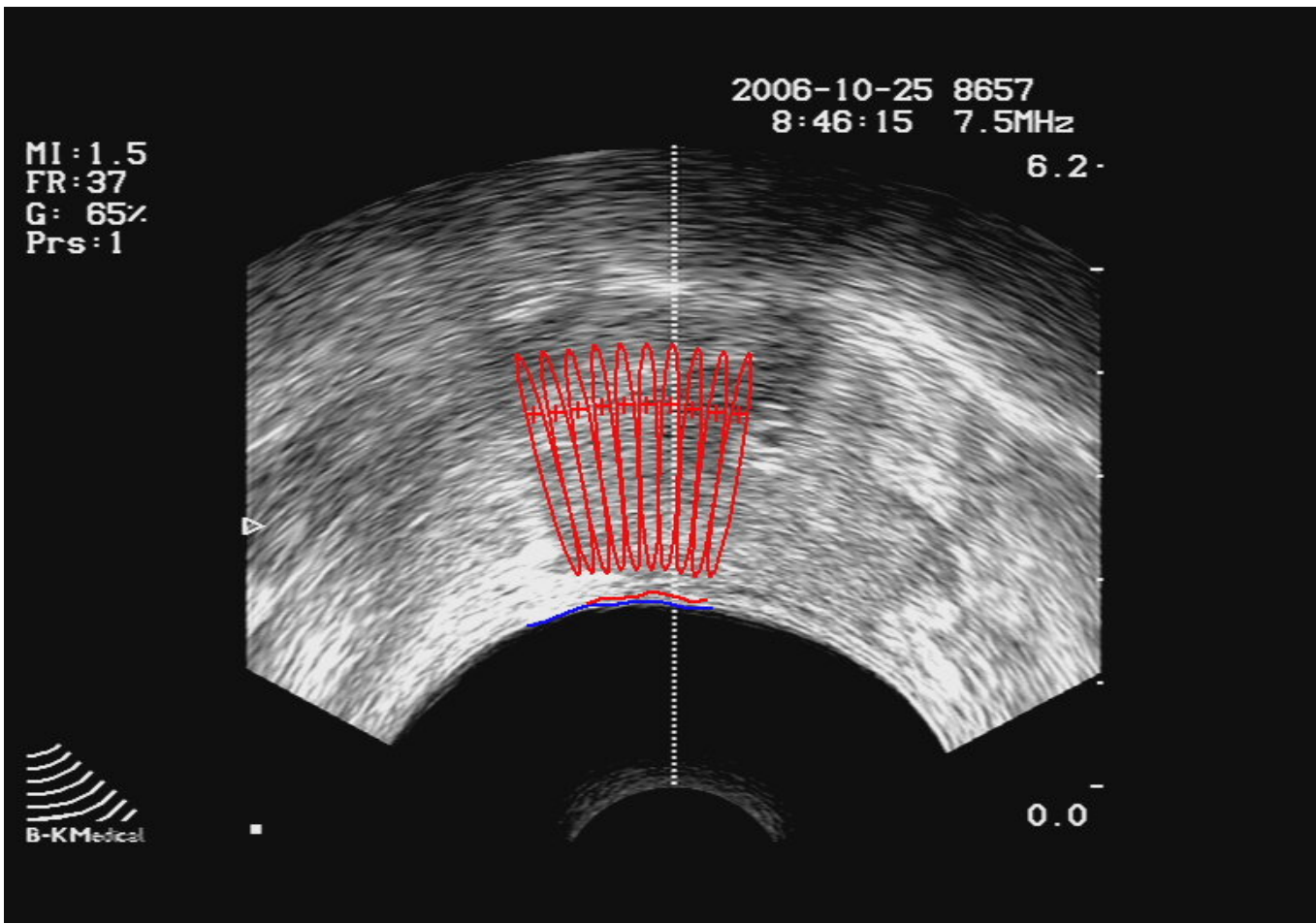
Settings

Video

US Scanner

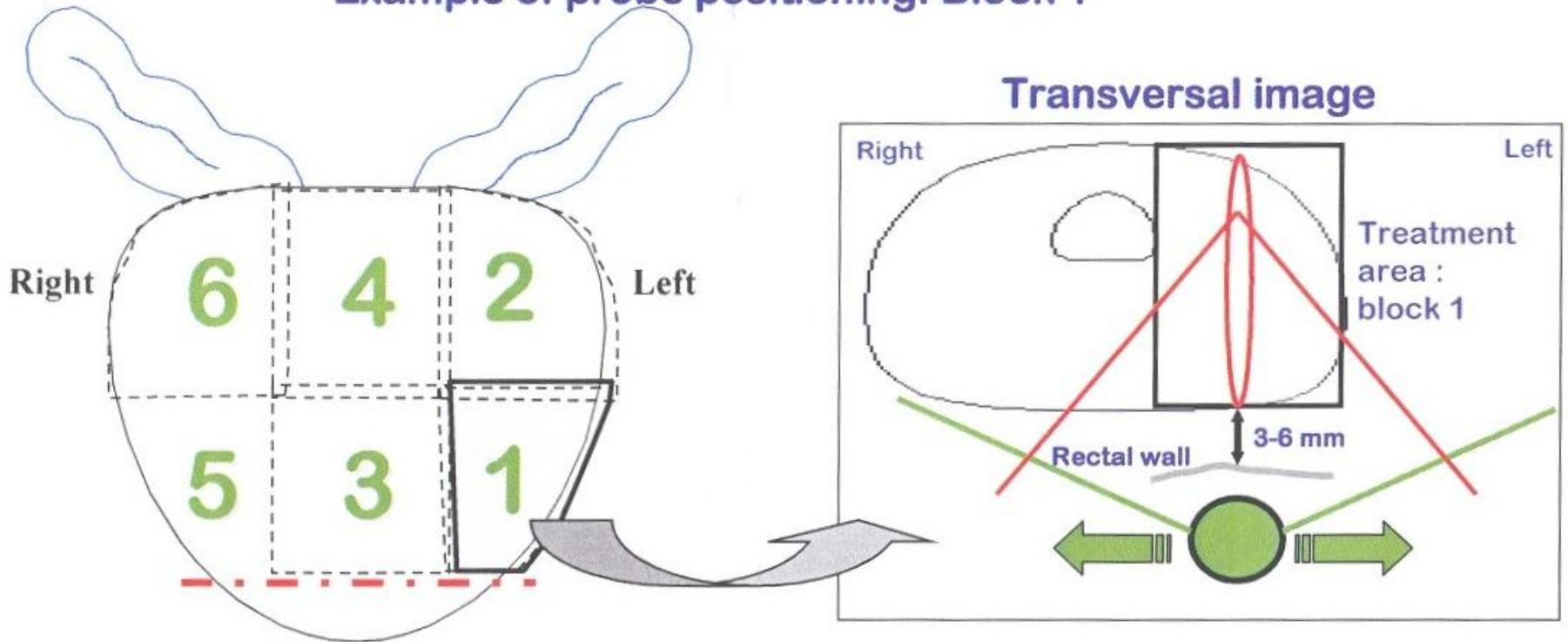
Cancel





# PROBE POSITIONING

Example of probe positioning: Block 1



# **PUBLISHED DATA:**

**ABLATHERM: BLANA**

**146 PATIENTS    22 MONTHS MEDIAN F/U**

**ASTRO Criteria            84% Success**

**(Other publications – Chaussy, Gelet,  
Thurhoff, Poissonier)**

**UROLOGY 2004 Feb 63(2) 297-300**

# **EUROPEAN 8 YEAR RESULTS**

## **BLANA ET AL EUROPEAN UROLOGY**

■ **140 PATIENTS**

■ **MEAN FOLLOW UP 6.4 YEARS**

■ **BOCHEMICAL FAILURE FREE SURVIVAL:**

**60 MONTHS - 77%**

**84 MONTHS - 69%**

**UROLOGY 2008 Dec : 72(6) 329-333**

# MAPLE LEAF RESULTS

- SINGLE TREATMENT
- NO PRIOR TURP
- VOL < 40 cc
- AMBULATORY
- SPINAL ANAESTHETIC/IV SEDATION
- URETHRAL CATHETER



# **INCLUSION CRITERIA**

<b>■ TOTAL PATIENTS TREATED</b>	<b>507</b>
<b>■ HIGH RISK GROUP/PRIOR Rx</b>	<b>144</b>
<b>■ &lt; 6 MONTH F/U OR &lt; 2 DATA POINTS</b>	<b>131</b>
<b>■ ANALYZED COHORT</b>	<b>232</b>

# PATIENT CHARACTERISTICS

■ PATIENT AGE MEAN 61 (45-82)

■ PRE Rx PSA 6.6 ug/L

■ Bx # / Bx +ve 8 / 3

■ PROSTATE VOL (CALC) 25.2 cc

# RISK CATEGORY

■ **LOW** 97

■ **INTERMEDIATE** 134

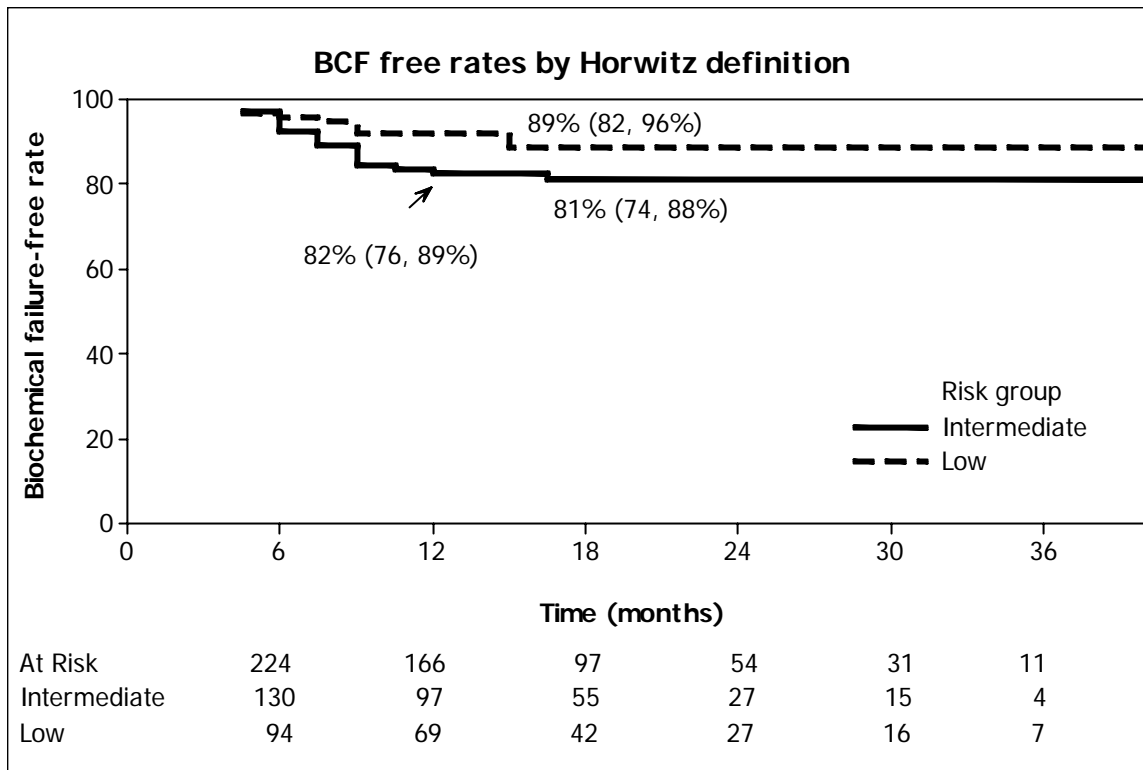
# TREATMENT DATA

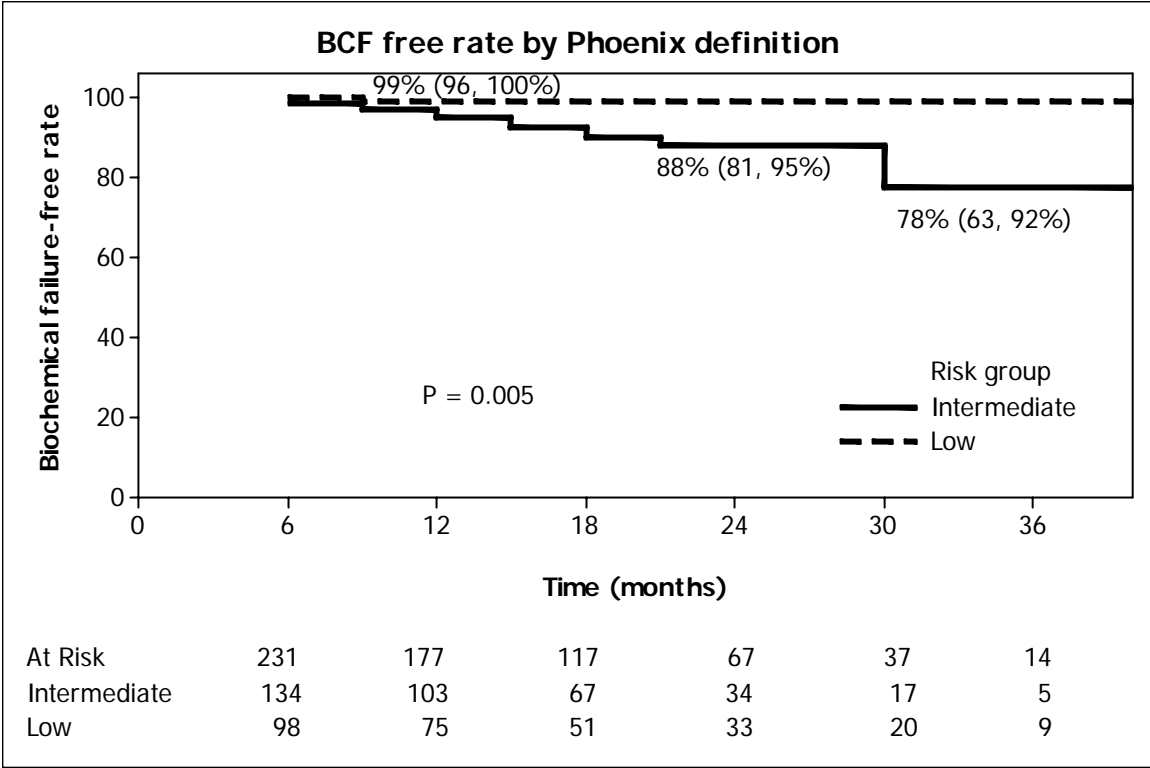
■ Rx TIME      122 minutes (85-142)

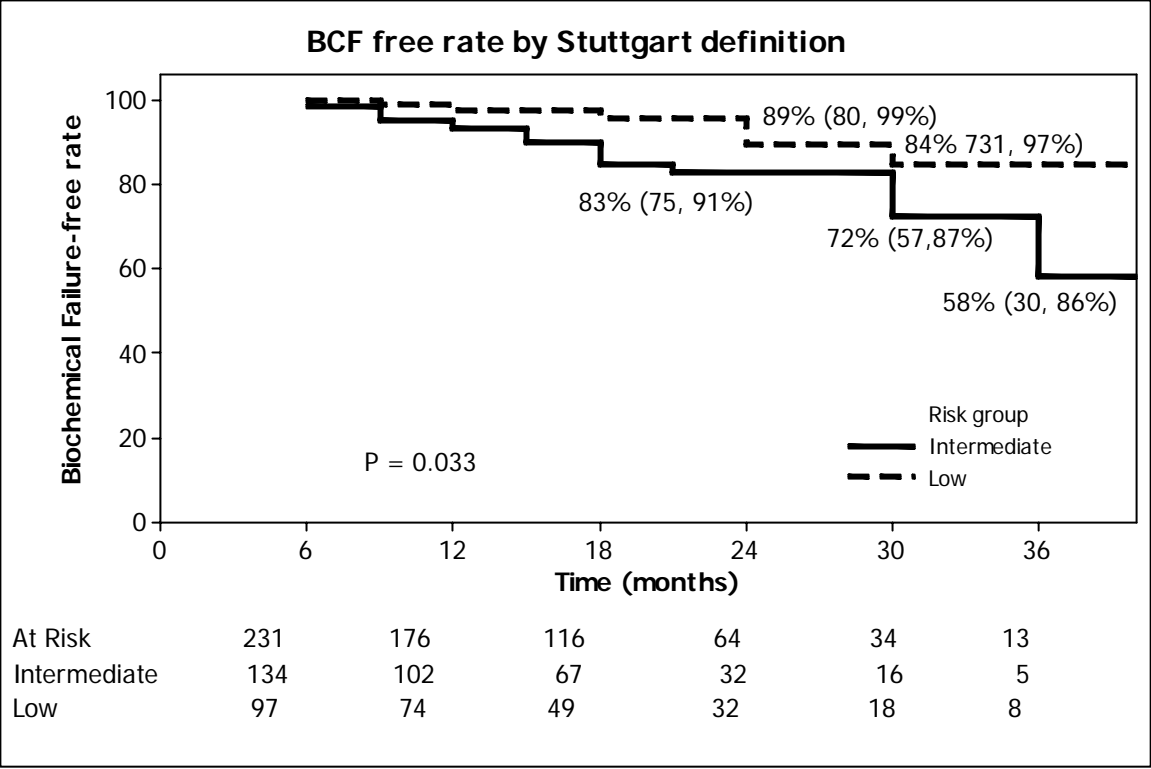
■ Rx "LESIONS"      532  $\pm$  88.0

■ VOL Rx/VOL CALC      1.4

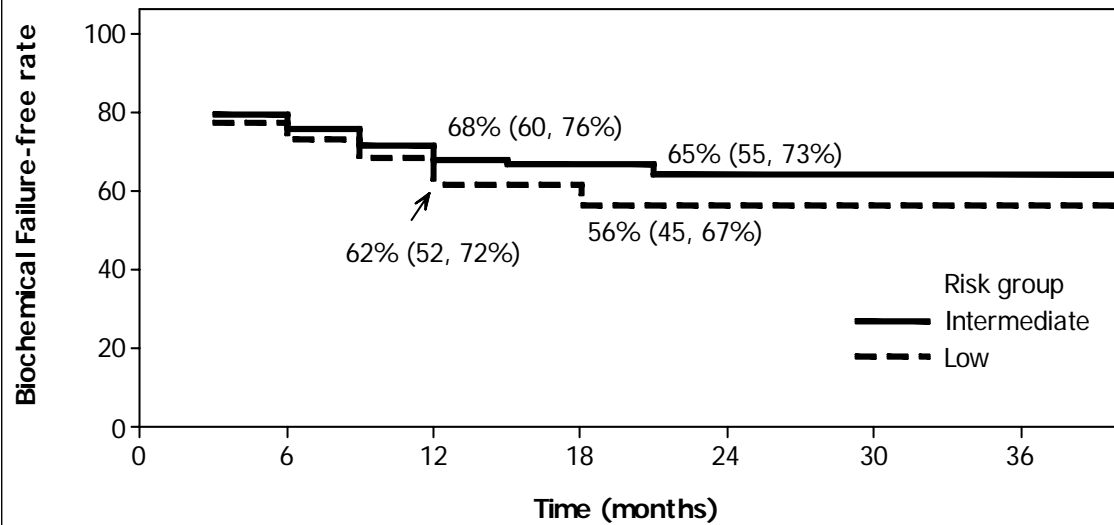
■ AVERAGE POWER      41.4 WATTS







### BCF free rates using Stephenson definiiton



At Risk	182	125	76	41	24	9
Intermediate	107	72	43	21	11	3
Low	75	53	33	20	13	6



# COMPLICATIONS

**PROLONGED CATHETER DEPENDENCE 25%**  
**(>2 WEEKS)**

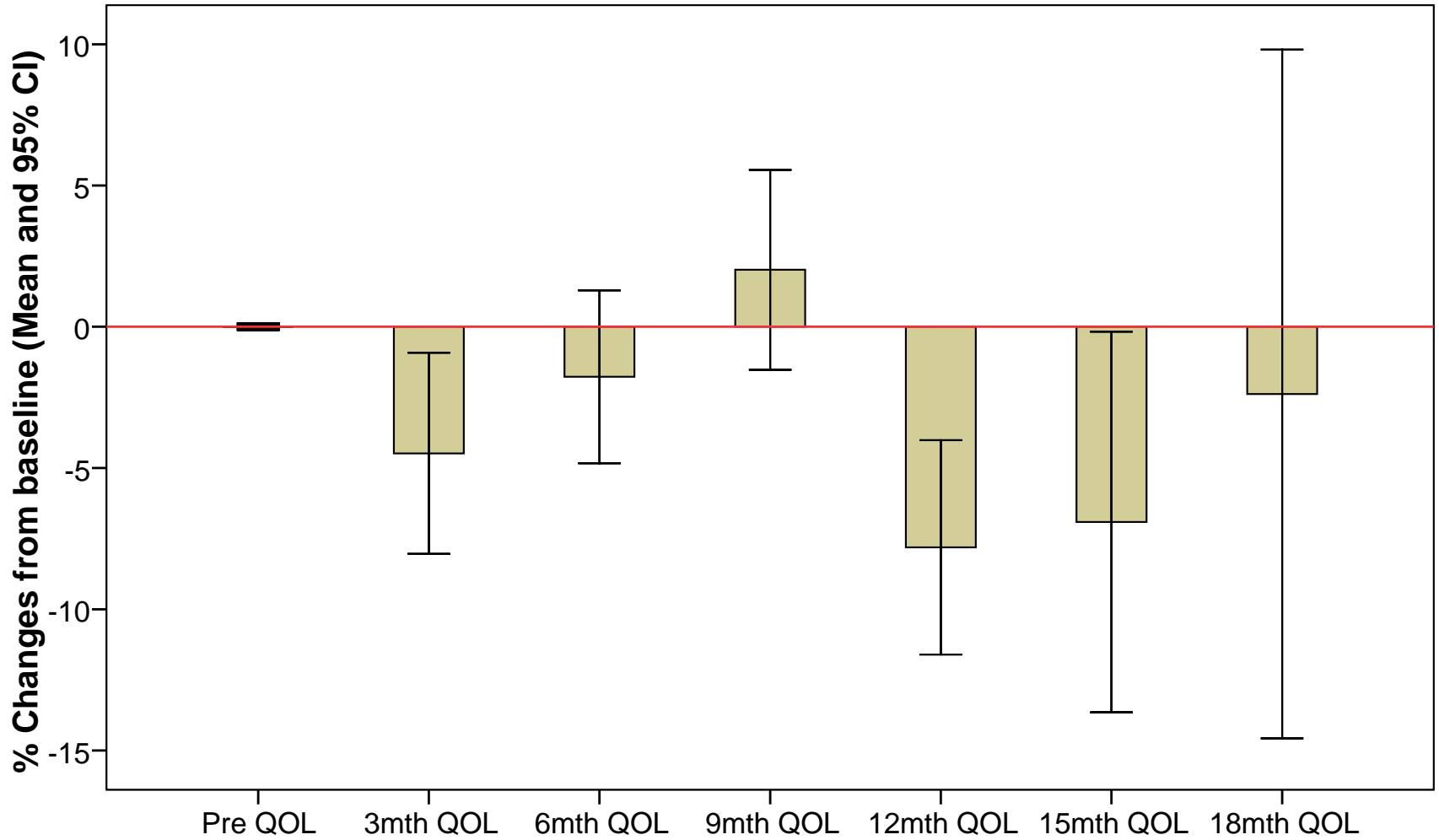
**STRICTURE 11%**  
**(DILATATION/TVU)**

**URETHRA/RECTAL FISTULA < 0.4%**

# QOL (110)

PRE QOL	3/12	6/12	9/12	12/12	15/12
93.1	90.7	92.1	95.2	85.9	87.1

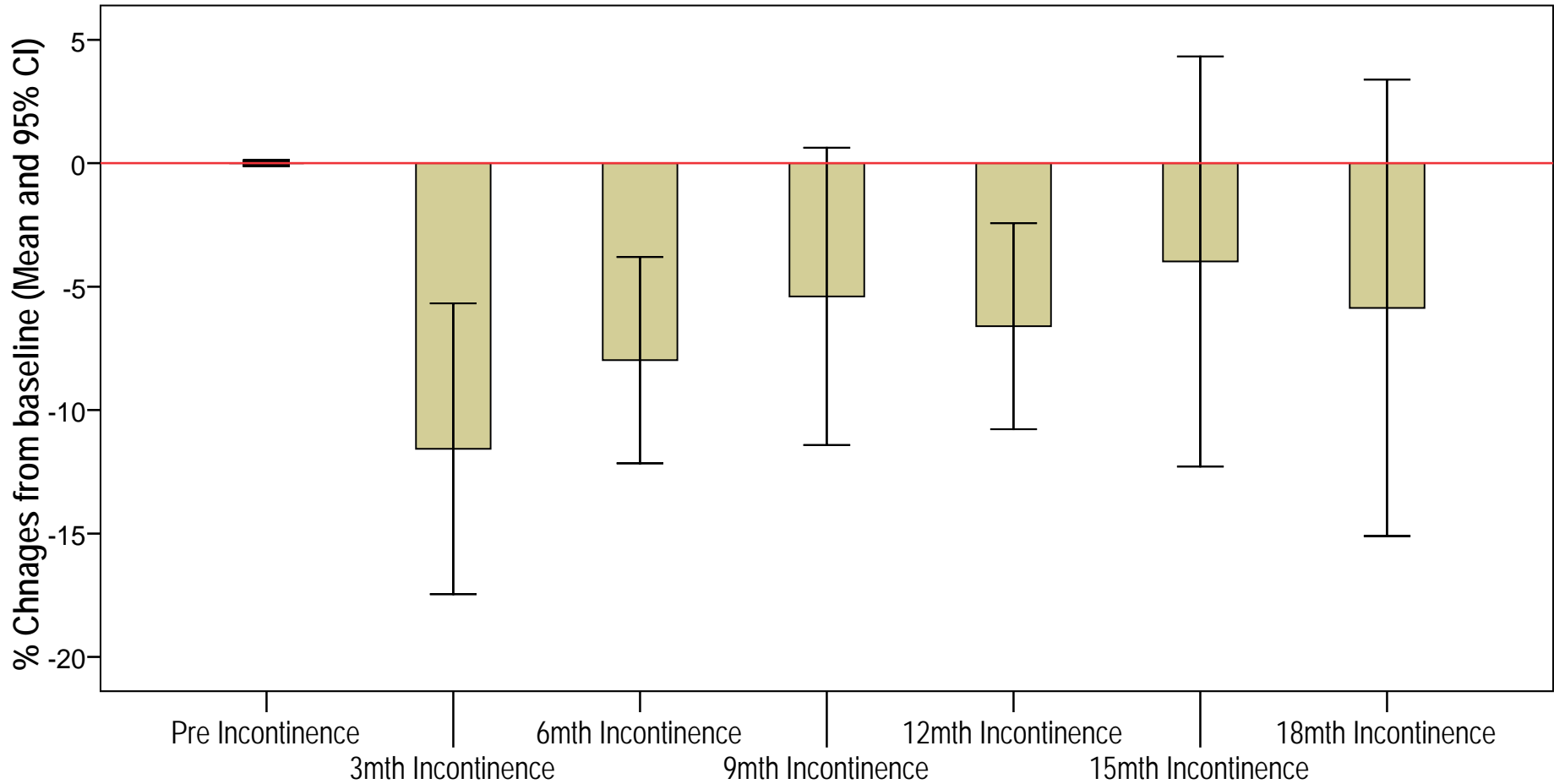
# Mean % changes from pre-op QoL



# **INCONTINENCE (110)**

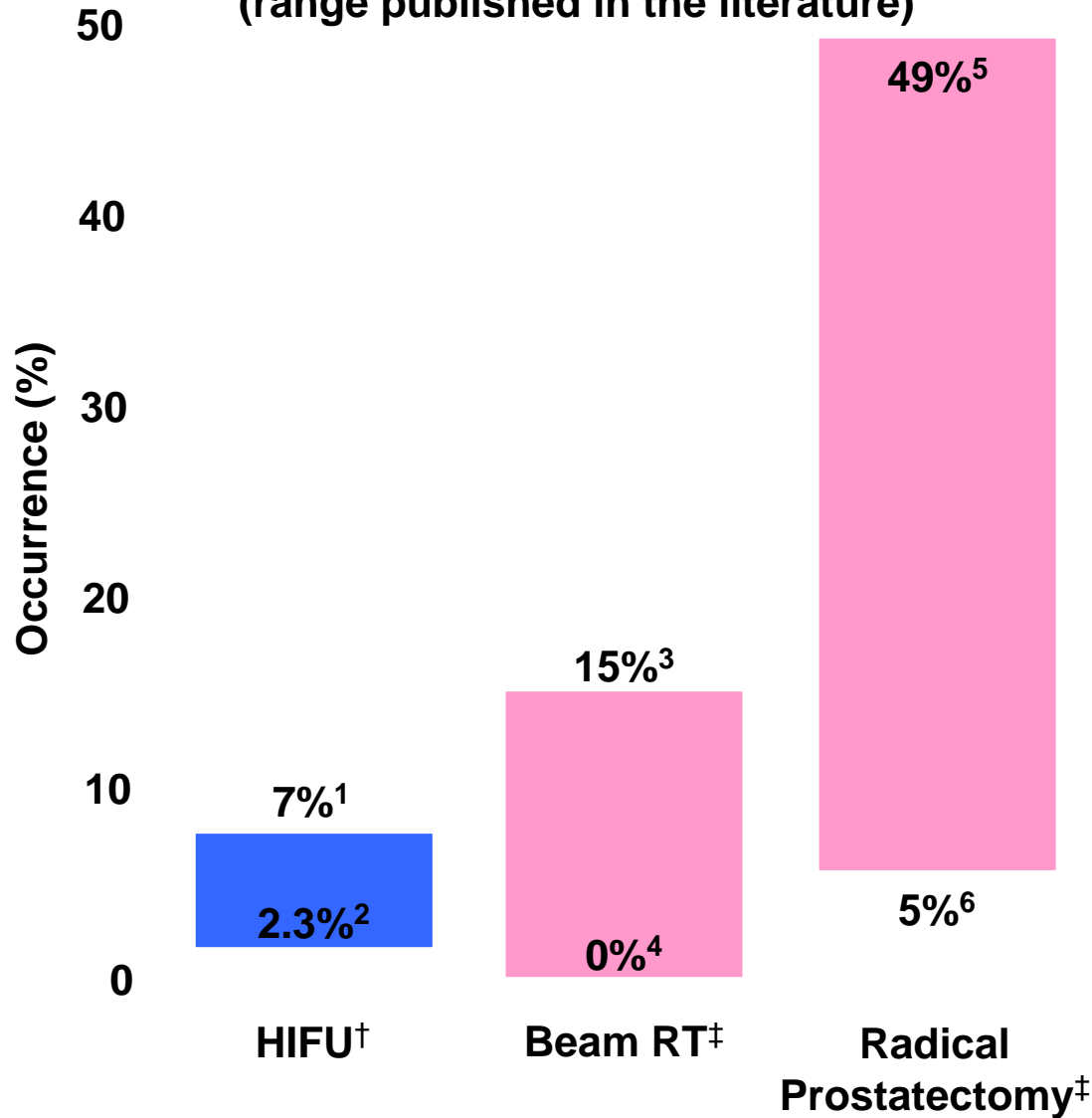
<b>PRE INCONTINENCE</b>	<b>3/12</b>	<b>6/12</b>	<b>9/12</b>	<b>12/12</b>	<b>15/12</b>
<b>106</b>	<b>94.5</b>	<b>94.5</b>	<b>100.2</b>	<b>96.6</b>	<b>92.4</b>

# Mean % changes from pre-op incontinence



# Incontinence

(range published in the literature)

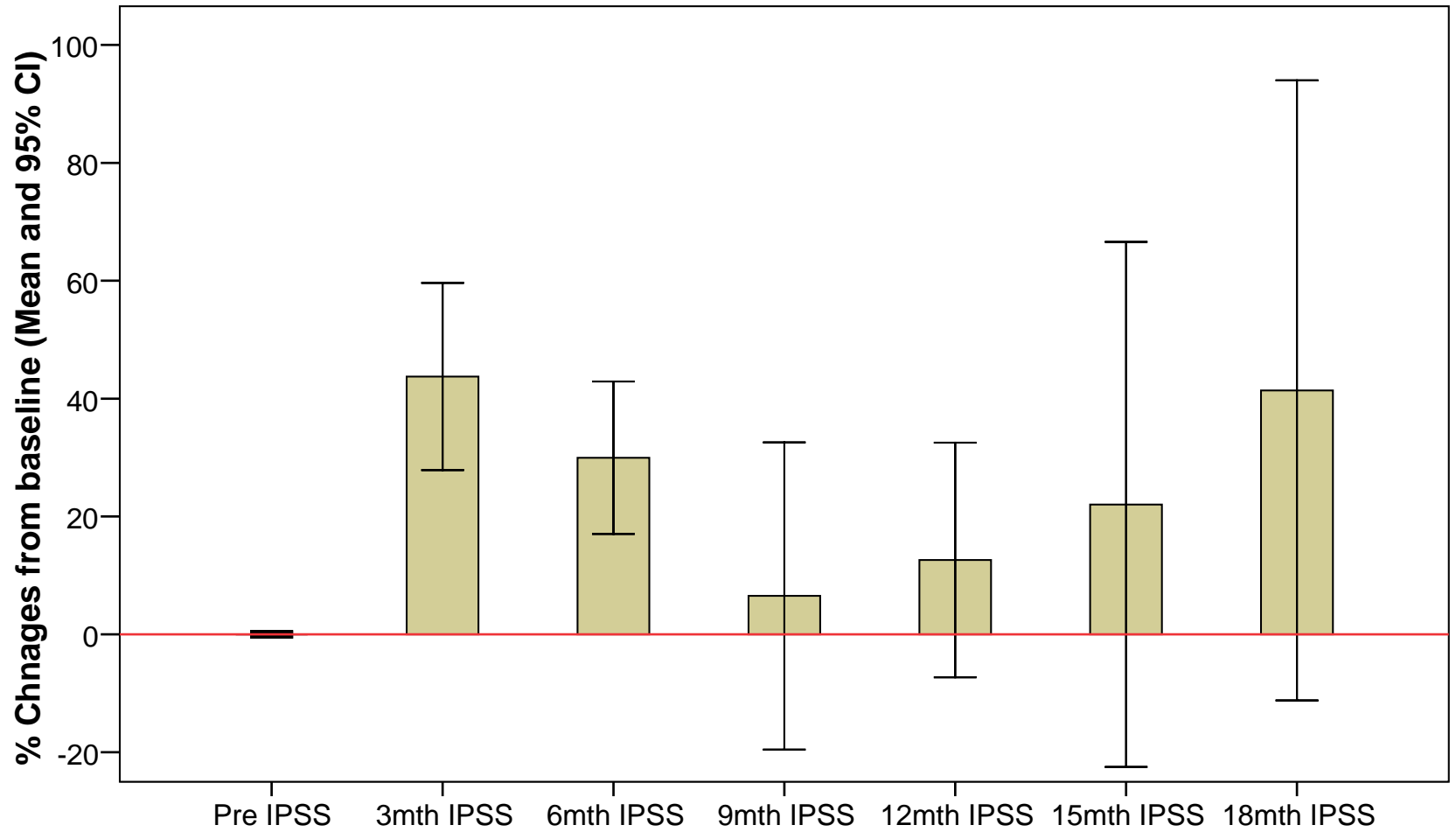


<sup>†</sup>excluding grade I, <sup>‡</sup>pad rate. 1. Ficarra et al, BJU Int. 2006 Dec;98(6):1193-8. 2. Chaussy and Thuroff Curr Urol Rep. 2003;4(3):248-52. 3. Zelefsky et al, Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6; 4. Brabbins et al, Int J Radiat Oncol Biol Phys. 2005 Feb 1;61(2):400-8. 5. Steineck et al, N Engl J Med. 2002 Sep 12;347(11):790-6; 6. Abou-Elela et al, Eur J Surg Oncol. 2007; 33:96-101

# IPSS (40)

<b>PRE Rx</b>	<b>3/12</b>	<b>6/12</b>	<b>9/12</b>	<b>12/12</b>	<b>15/12</b>
<b>8.2</b>	<b>12.3</b>	<b>12.7</b>	<b>8.4</b>	<b>12.8</b>	<b>12.1</b>

# Mean % changes from pre-op IPSS





# IIEF (75)

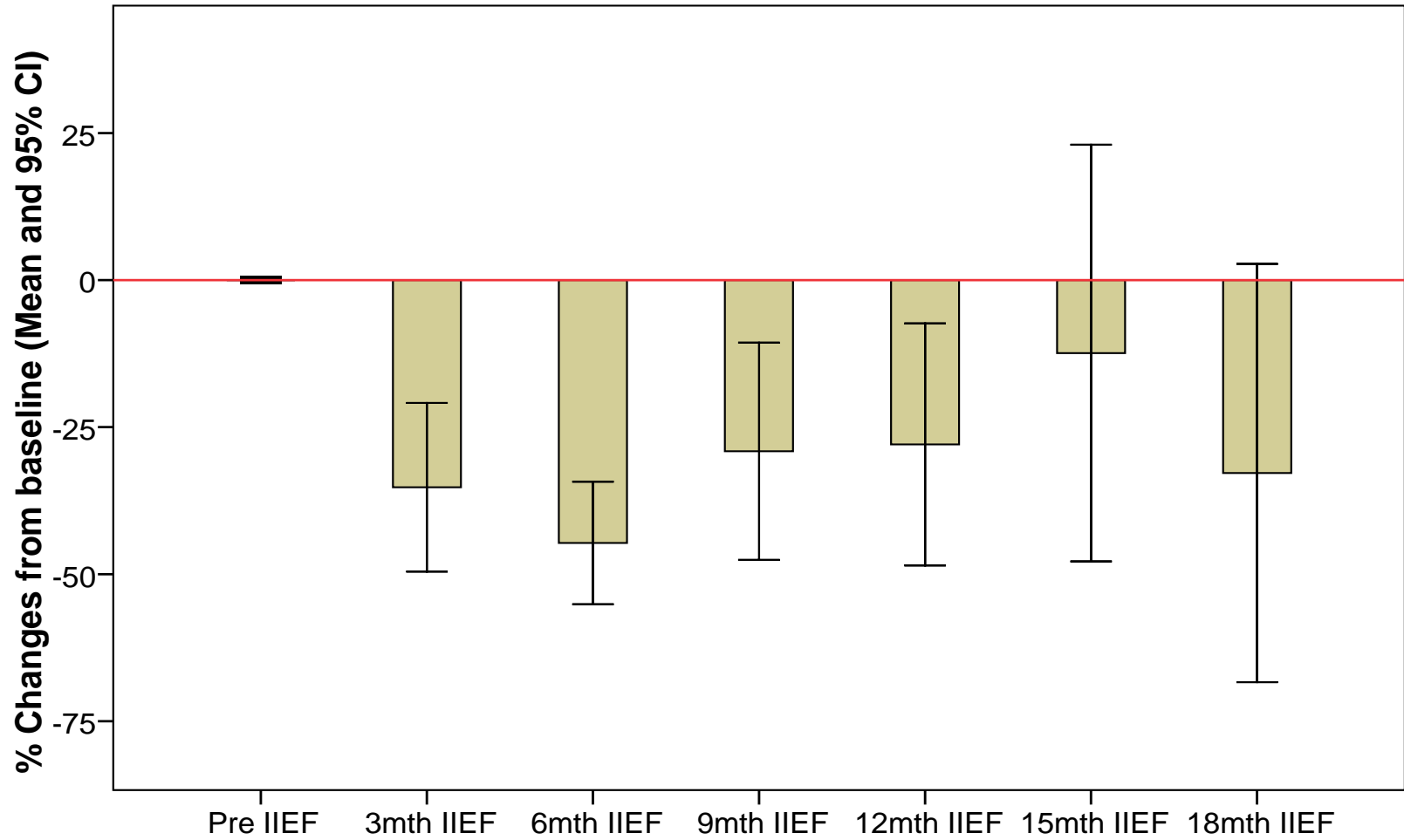
**(NO NERVE SPARING) N<sub>1</sub> = 58**

	Pre	3/12	6/12	9/12	12/12
<b>MEAN 1</b>	<b>49.9</b>	<b>25.1</b>	<b>24.4</b>	<b>29.6</b>	<b>29.4</b>

**(NERVE SPARING) N<sub>2</sub> = 44**

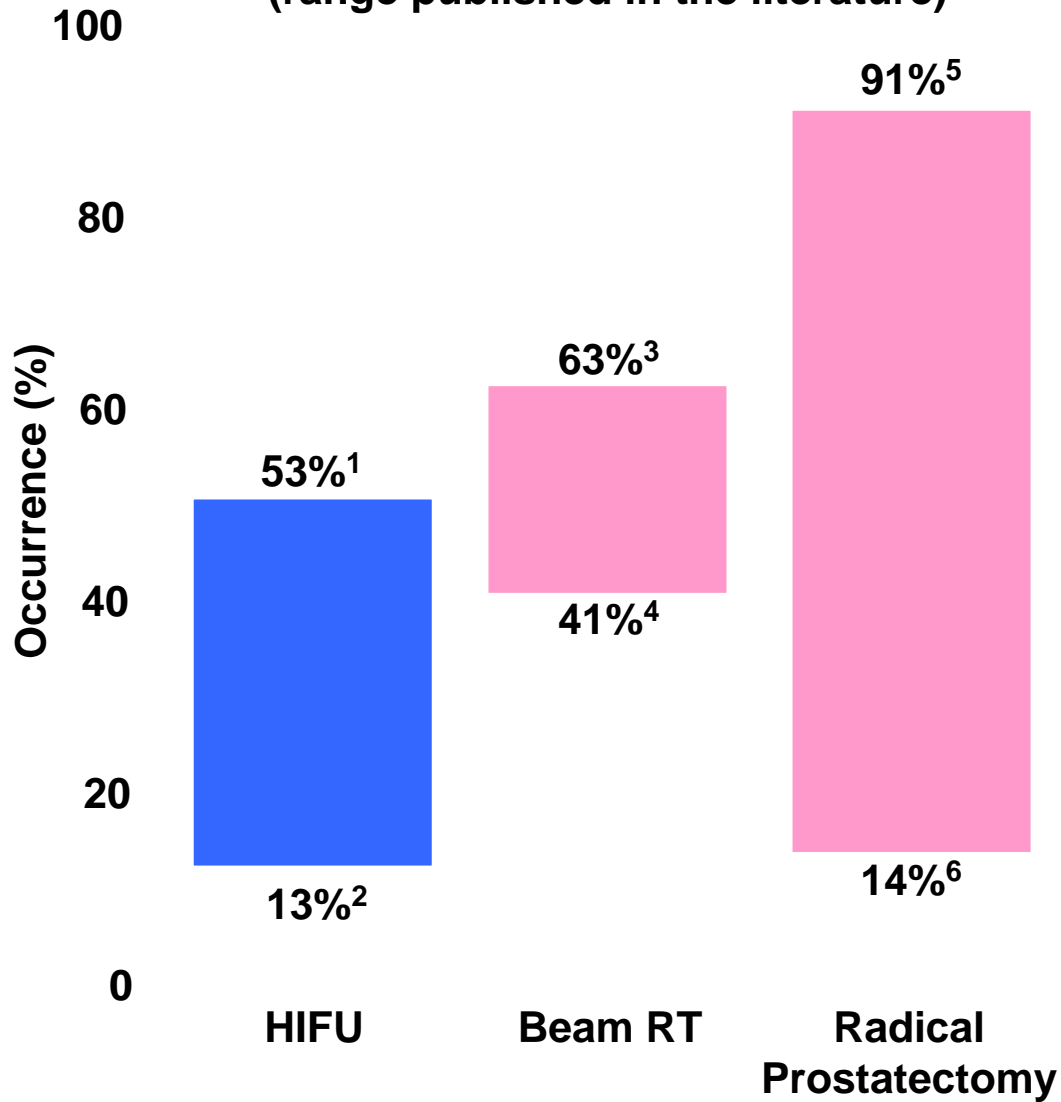
	Pre	3/12	6/12	9/12	12/12
<b>MEAN 2</b>	<b>64.9</b>	<b>39.4</b>	<b>27.5</b>	<b>74.0</b>	<b>37.6</b>

# Mean % changes from pre-op IIEF



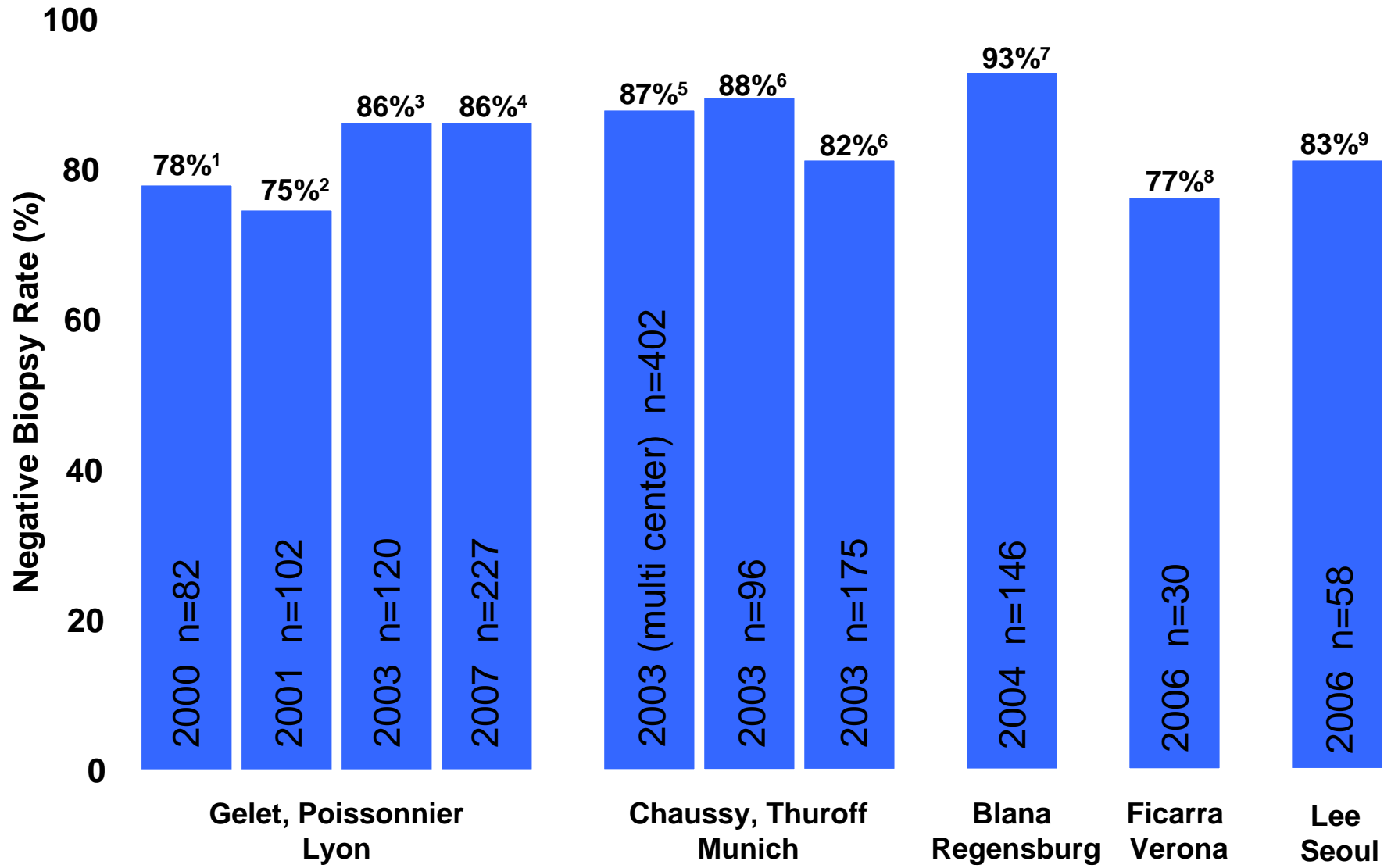
# Impotence

(range published in the literature)



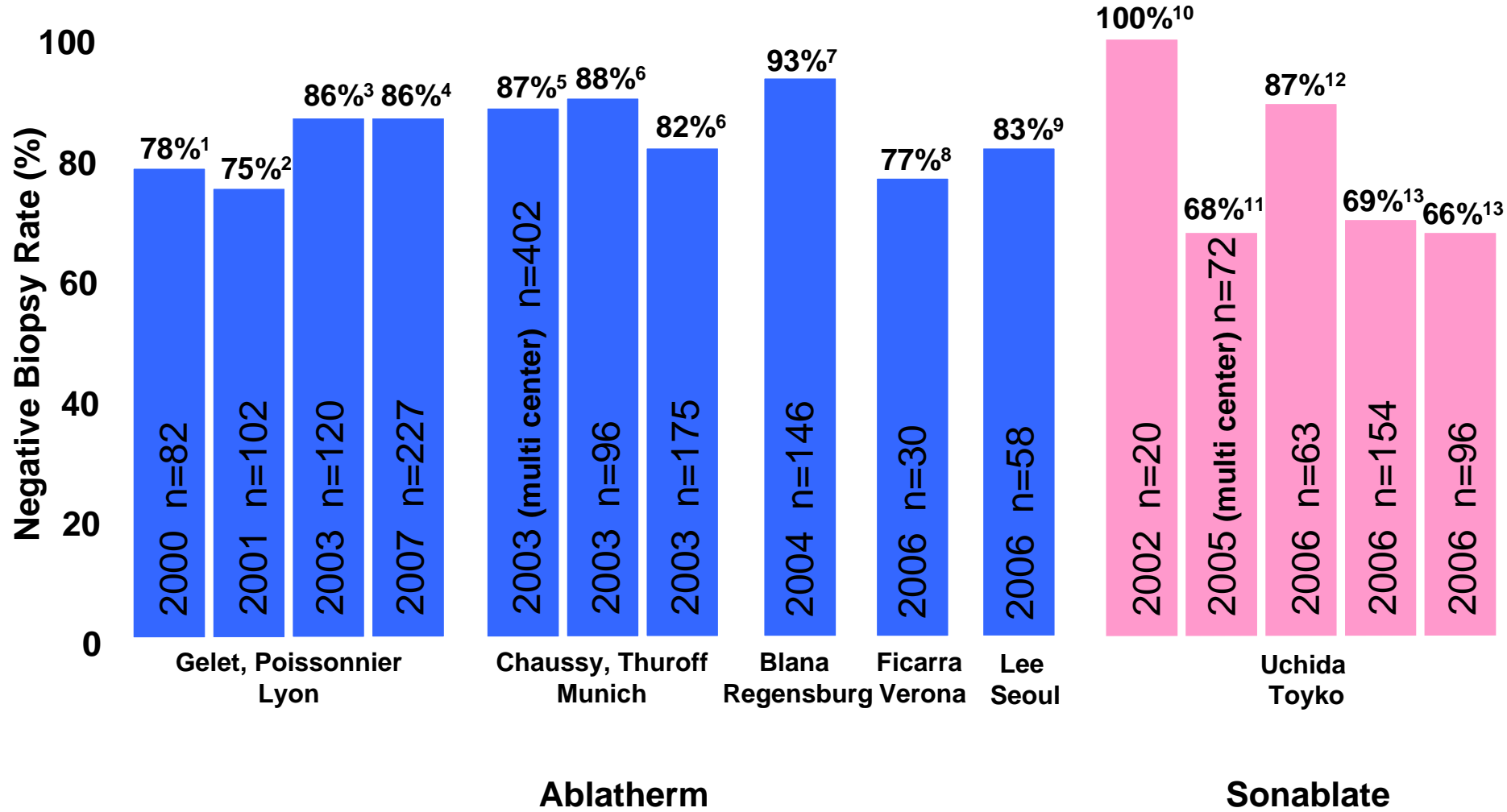
1. Blana et al Urology. 2004 Feb;63(2):297-300. 2. Thuroff et al. J Endourol. 2003 Oct;17(8):673-7. 3. Potosky et al, J Natl Cancer Inst. 2000 Oct 4;92(19):1582-92; 4. Matalinska et al, J Clin Oncol. 2001 Mar 15;19(6):1619-28; 5. Matalinska et al, J Clin Oncol. 2001 Mar 15;19(6):1619-28; 6. Walsh et al, J Urol. 2000 Jun;163(6):1802-7.

# Negative Biopsy Rate



1. Gelet et al, J Endourol. 2000;14(6):519-28; 2. Gelet et al, Eur Urol. 2001;40(2):124-9; 3. Poissonnier et al Prog Urol. 2003;13(1):60-72; 4. Poissonnier et al Eur Urol. 2007;51(2):381-7; 5. Thuroff et al J Endourol. 2003;17(8):673-7; 6. Chaussy et al Curr Urol Rep. 2003;4(3):248-52; 7. Urology. 2004;63(2):297-300; 8. Ficarra et al BJU Int. 2006;98(6):1193-8; 9. Prostate Cancer Prostatic Dis. 2006;9(4):439-43.

# Negative Biopsy Rate



1. Gelet et al, J Endourol. 2000;14(6):519-28; 2. Gelet et al, Eur Urol. 2001;40(2):124-9; 3. Poissonnier et al Prog Urol. 2003;13(1):60-72; 4. Poissonnier et al Eur Urol. 2007;51(2):381-7; 5. Thuroff et al J Endourol. 2003;17(8):673-7; 6. Chaussy et al Curr Urol Rep. 2003;4(3):248-52; 7. Urology. 2004;63(2):297-300; 8. Ficarra et al BJU Int. 2006;98(6):1193-8; 9. Prostate Cancer Prostatic Dis. 2006;9(4):439-43; 10. Uchida et al Urology. 2002 Mar;59(3):394-8; 11. Uchida et al Hinyokika Kyo. 2005 Oct;51(10):651-8; 12. Uchida et al Int J Urol. 2006 Mar;13(3):228-33; 13. Uchida et al BJU Int. 2006 Oct;98(4):770-2.

# FDA TRIAL (ENLIGHT)

- T-1 or T-2
- $\geq$  50 Years
- Gleason score 3+3
- Prostate volume  $\leq$  40 cc
- AP Diameter  $\leq$  25 mm

# **FDA TRIAL LOCATIONS (HIFU)**

**University of Colorado Hospital and Health Science Center  
Aurora, Colorado**

**Florida Foundation for Healthcare Research Inc  
Ocala, Florida**

**Hackensack University Medical Center  
Hackensack, New Jersey**

**Memorial Sloan-Kettering Institute  
New York, New York**

**Duke University Medical Center  
Durham North Carolina**

# **FDA TRIAL LOCATIONS (HIFU)**

**Thomas Jefferson University  
Philadelphia, Pennsylvania**

**Vanderbilt University Medical Center  
Nashville, Tennessee**

**Urology Associates Of North Texas  
Arlington, Texas**

**The University of Texas M.D. Anderson Cancer  
Center  
Houston, Texas**



# **FDA TRIAL LOCATIONS (HIFU)**

**Virginia Urology Center  
Richmond, Virginia**

**Medical College of Wisconsin, Inc  
Milwaukee, Wisconsin**

**Maple Leaf HIFU  
Hamilton, Ontario, Canada**

# **CONCLUSIONS:**

- **ABLATHERM HIFU IS A SAFE AND EFFECTIVE TREATMENT FOR LOCALIZED PROSTATE CA**
- **MORE STUDY WITH LONGER FOLLOW UP NEEDED**