# GLI SFINTERI ARTIFICIALI

*MANLIO SCHETTINI*

**ROMA**

**www.urologia-moderna.it**

# Incontinenza post-RRP : cosa fare?

**Problemi Metodologici**

- **Tempo di valutazione**
- **Ginnastica pelvica**

# Incontinenza post-RRP : cosa fare?

## Valutazione Basale

- Pervietà uretrale
- Capacità vescicale

# Incontinenza post-RRP : cosa fare?

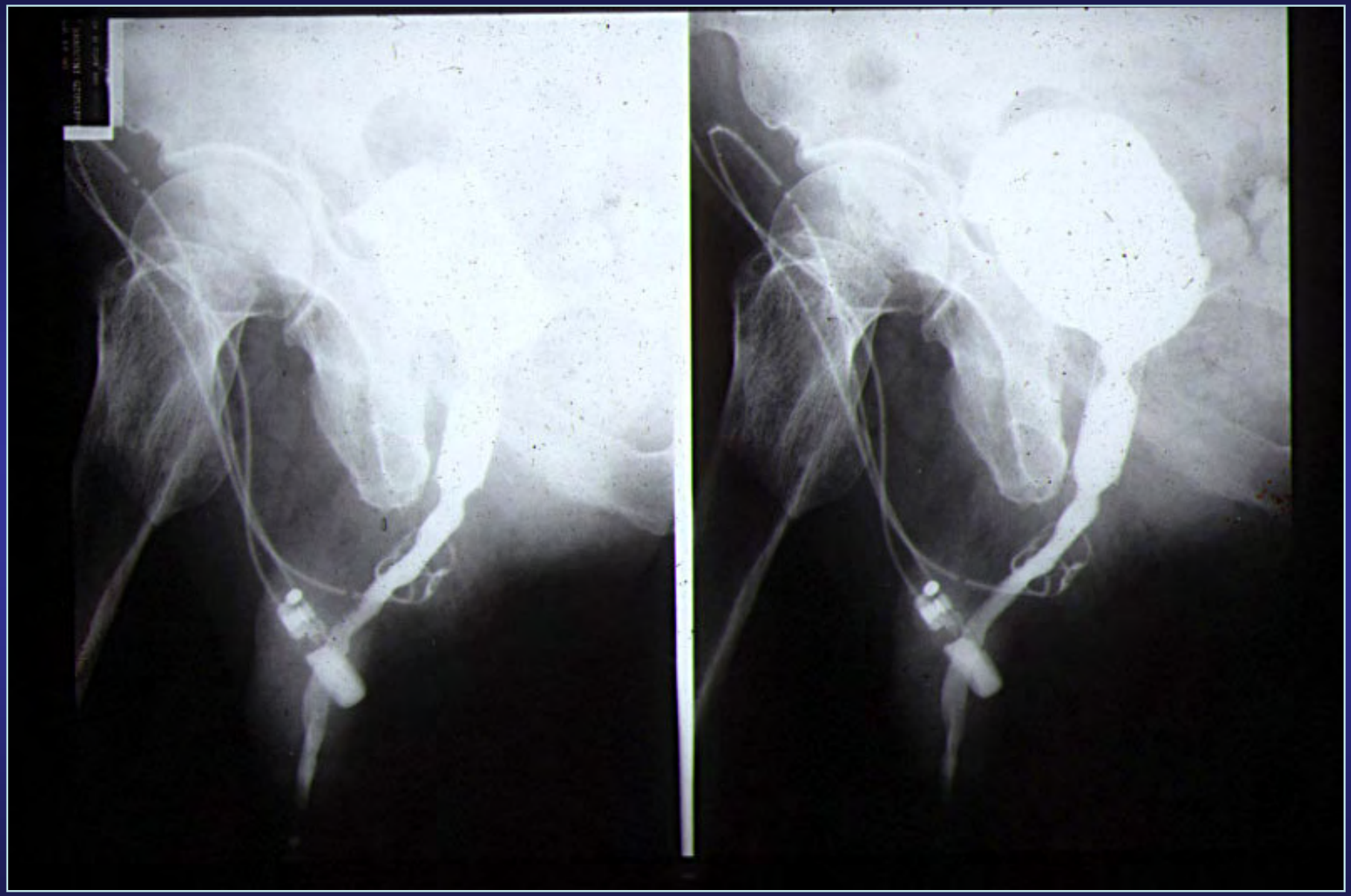
**Presenza di stenosi anastomotica**

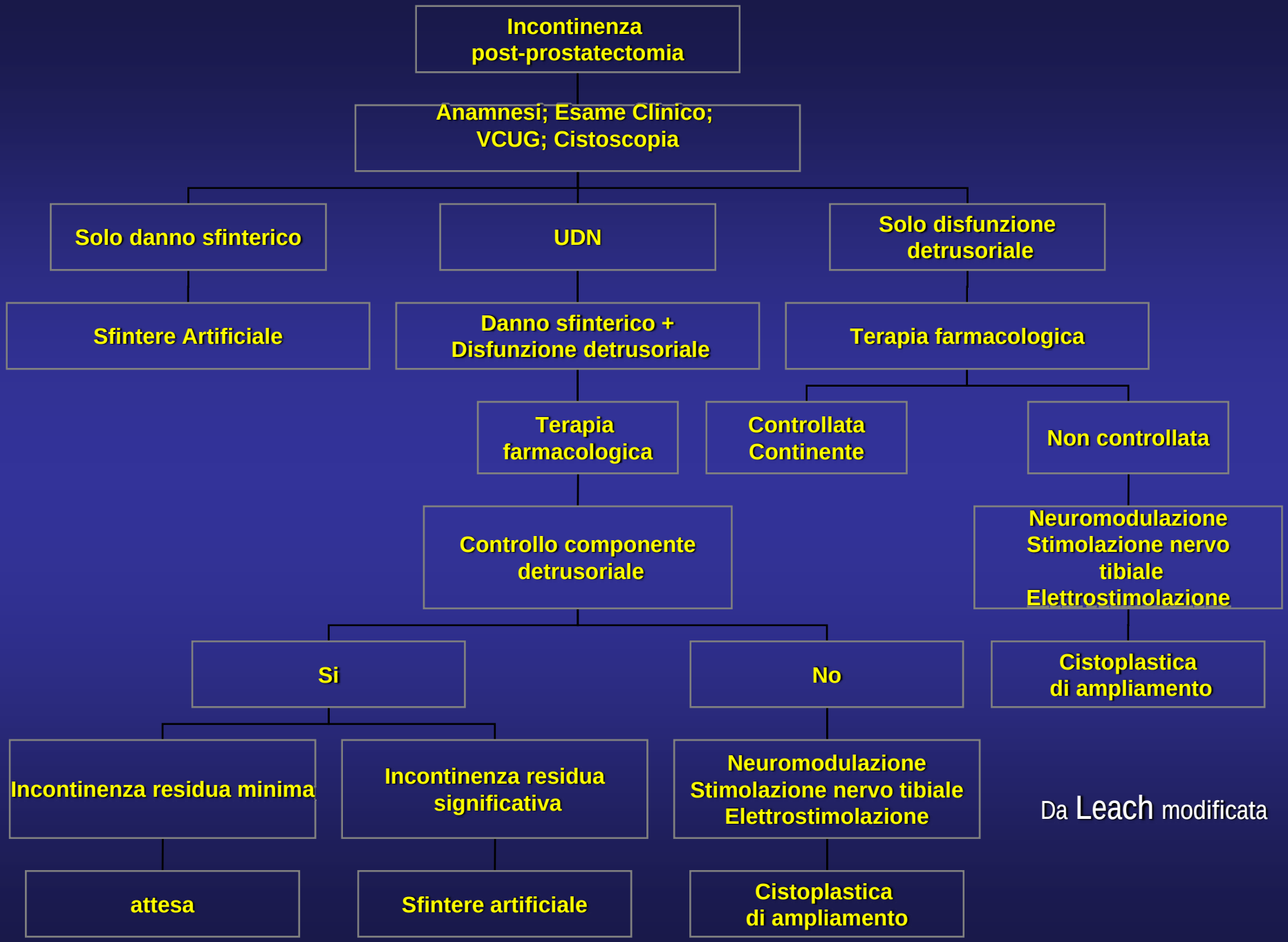
- **Trattare prima**
- **Congruo periodo di attesa**

JOURNAL OF ENDOUROLOGY
Volume 6, Number 5, 1992
Mary Ann Liebert, Inc., Publishers

# Treatment of Anastomotic Stricture and Incontinence after Radical Prostatectomy with Dilating Mesh Urolume and AMS-800 Artificial Sphincter

MANLIO SCHETTINI, M.D., and ANGELO ACCONCIA, M.D.






Da Leach modificata

# Solo danno sfinterico

## opzioni terapeutiche

- Attesa
- Duloxetina ( ?)
- Ginnastica pelvica
- Iniettabili
- Sling
- Sfintere artificiale

**TABLE III.** ***Injectable agents currently available or in development***

| Agent | Marketed Name | Industry Source |
|---|---|---|
| Bovine cross-linked collagen | Contigen | Bard, Covington, GA |
| Carbon beads | Durasphere | Advanced Uroscience, St. Paul, MN |
| Autologous fat | | |
| Human collagen | Urologen | Collagenesis |
| Autologous cartilage | | Reprogenesis, Boston, MA |
| Injectable suture material | Endomatrix | Bard, Covington, GA |
| Implantable microballoons | Urovive | American Medical Systems, Minneapolis, MN |
| Adjustable volume balloons | ACT | Uromedica, Minneapolis, MN |
| Hyaluronic acid and dextranomer microspheres | Deflux | Q-Med, Uppsala, Swedan |
| Cross-linked hyaluronic acid | Hylagel | Biomatrix, New York, NY |
| Calcium hydroxylapatite | Coaptite | Bioform, Franksville, WS |
| Silicone | Macroplastique | Uroplasty, Minneapolis, MN |
| Dimethyl sulfoxide and ethylene vinyl alcohol copolymer | Uryx | Genyx, San Diego, CA |
| Teflon | Urethrin | Mentor, Santa Barbara, CA |
| Protein/elastin admixture | Prolastin | Protein Polymers, San Diego, CA |
| Bovine elastin/collagen | Urolastin | Datascope, Mahwah, NJ |

# Male Incontinence treatment

- Dynamic sphincter
- Soft Compression
- Fixed Compression

# Dynamic Sphincter

- Low pressure flow
- Adequate occlusion pressure
- Self restoring pressure

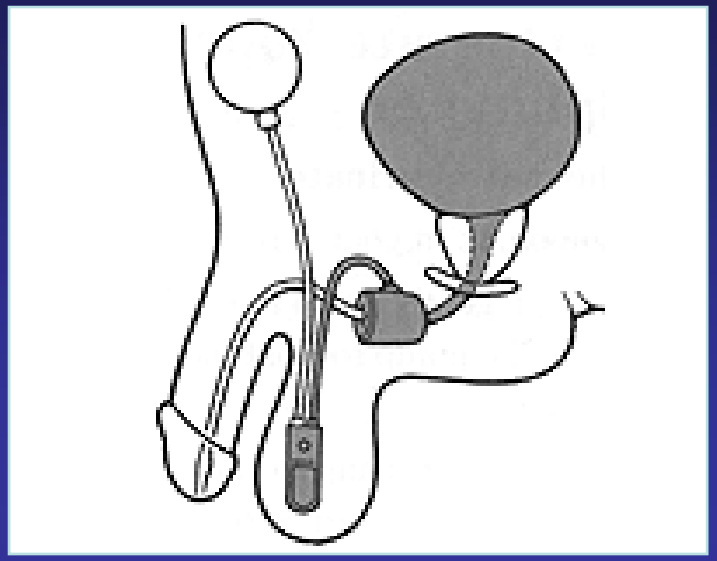
ICS-SINUG-SIUD-WORKSHOP
ROTTERDAM 2007

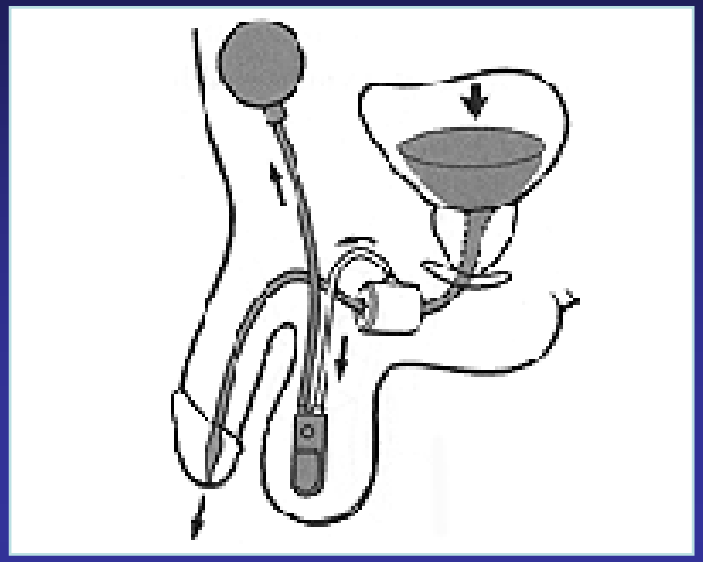
# Dynamic Sphincter

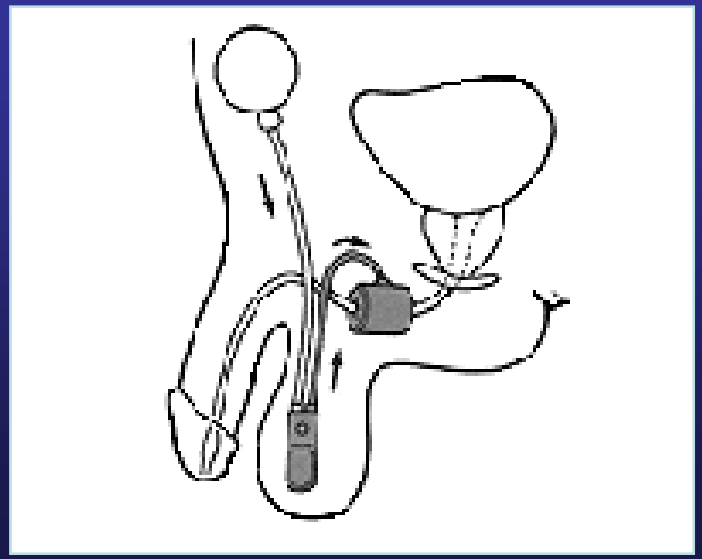
- AMS 800
- “Mundy” AUS

# ICS-SINUG-SIUD-WORKSHOP
## ROTTERDAM 2007

# ICS-SINUG-SIUD-WORKSHOP
## ROTTERDAM 2007







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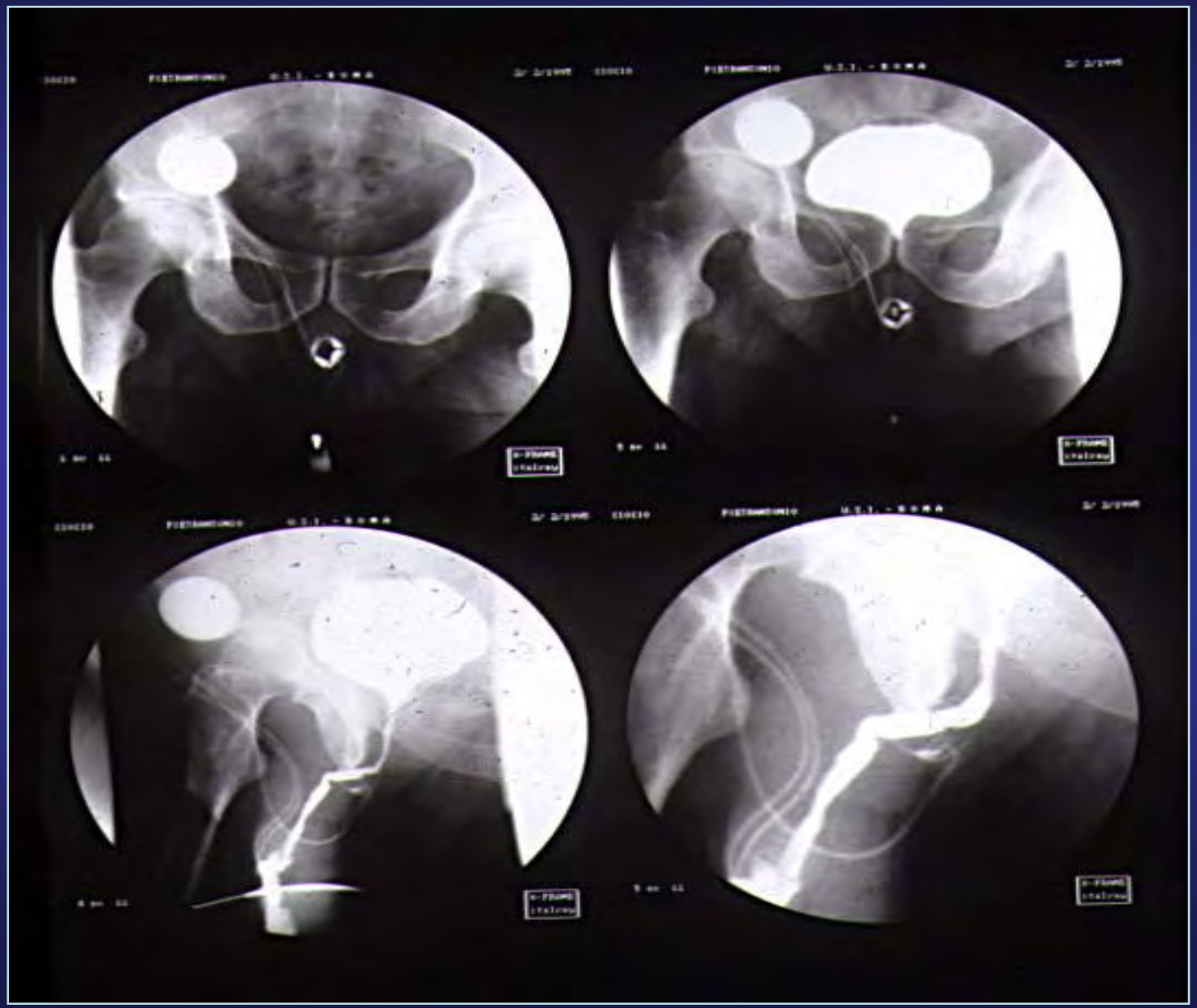

# ICS-SINUG-SIUD-WORKSHOP
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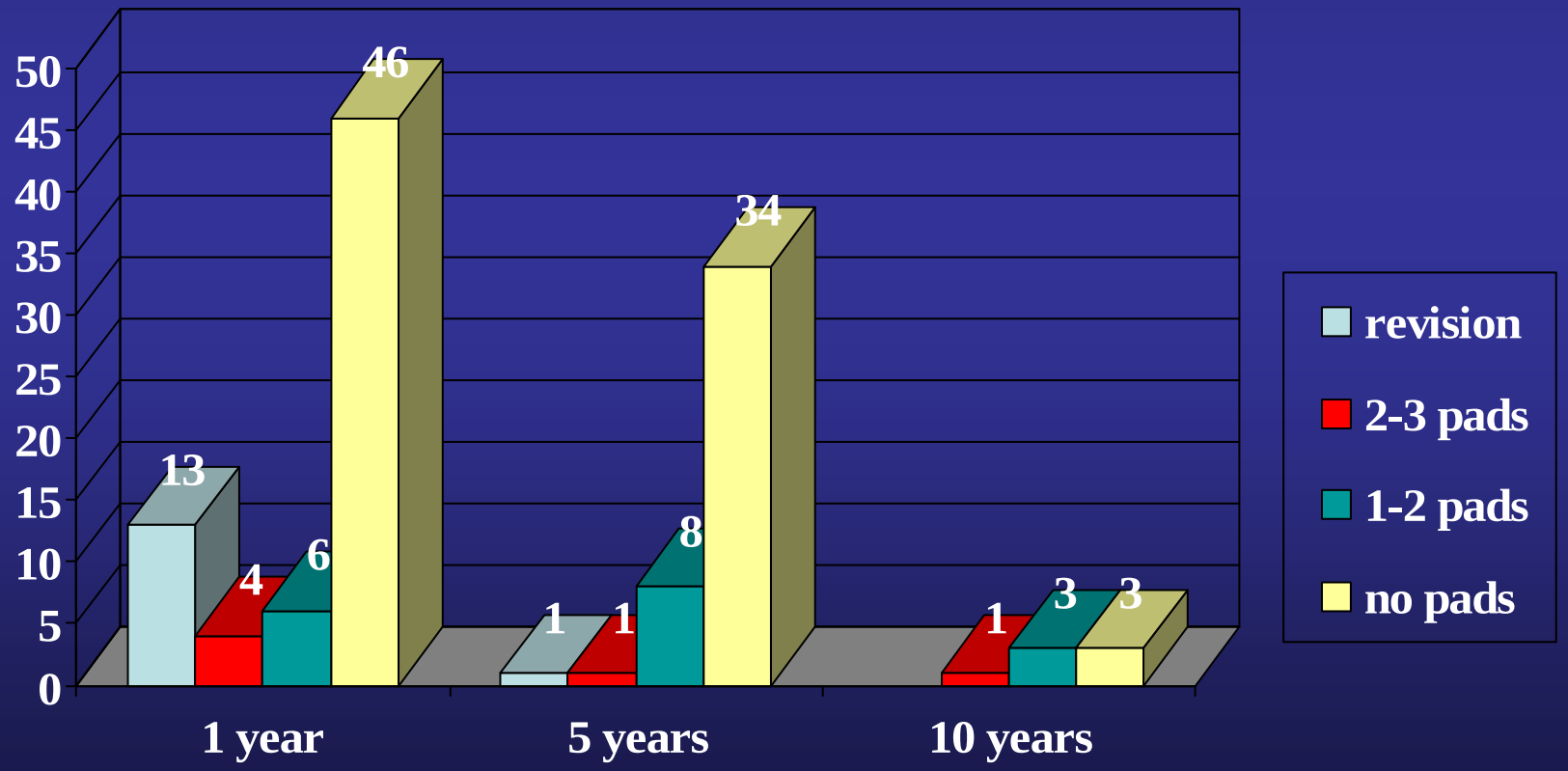
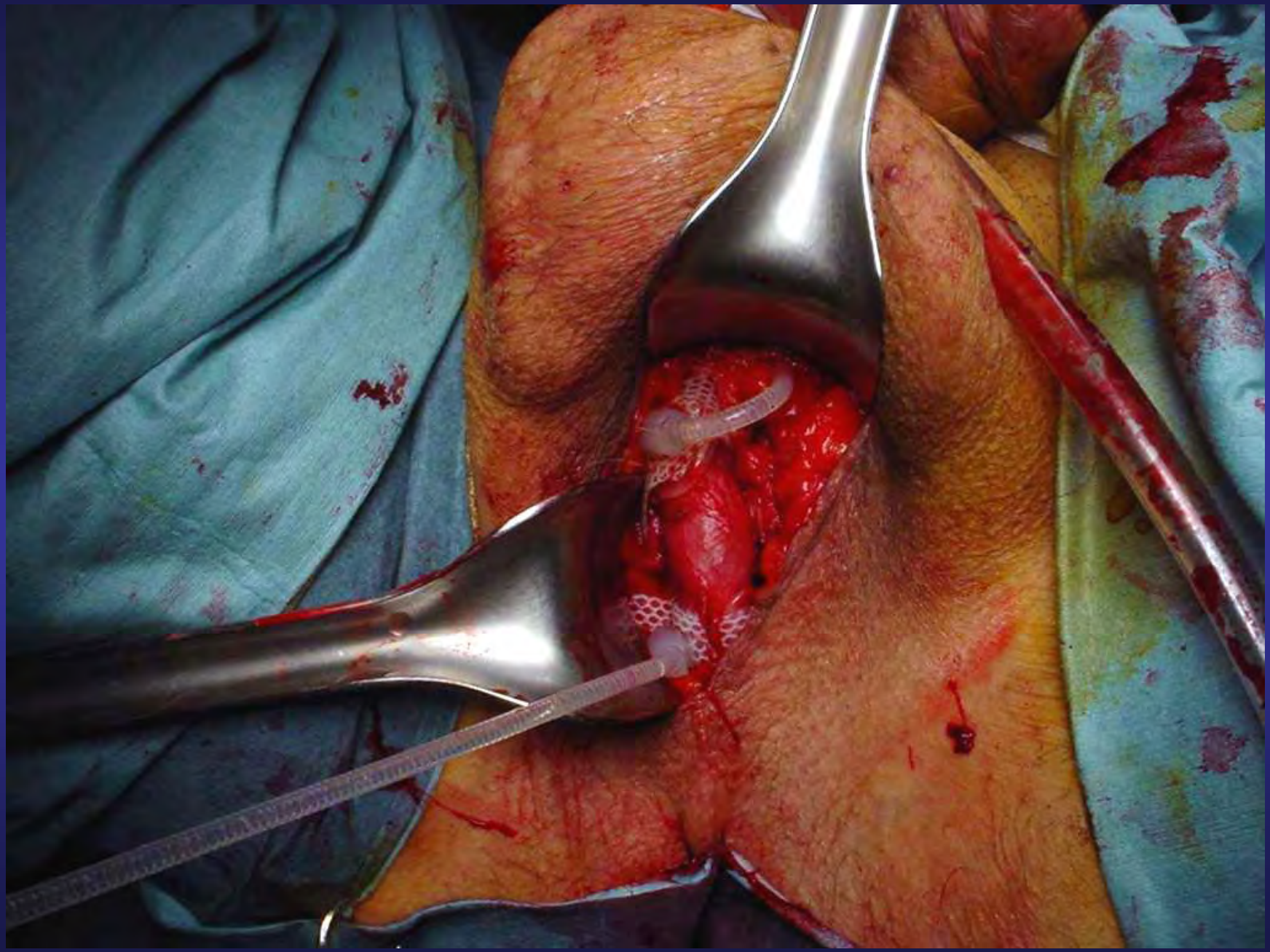
# CONTINENCE STATUS
# Ten-year follow-up





# ICS-SINUG-SIUD-WORKSHOP
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*Printed in U.S.A.*

# SUCCESS OF DE NOVO REIMPLANTATION OF THE ARTIFICIAL GENITOURINARY SPHINCTER

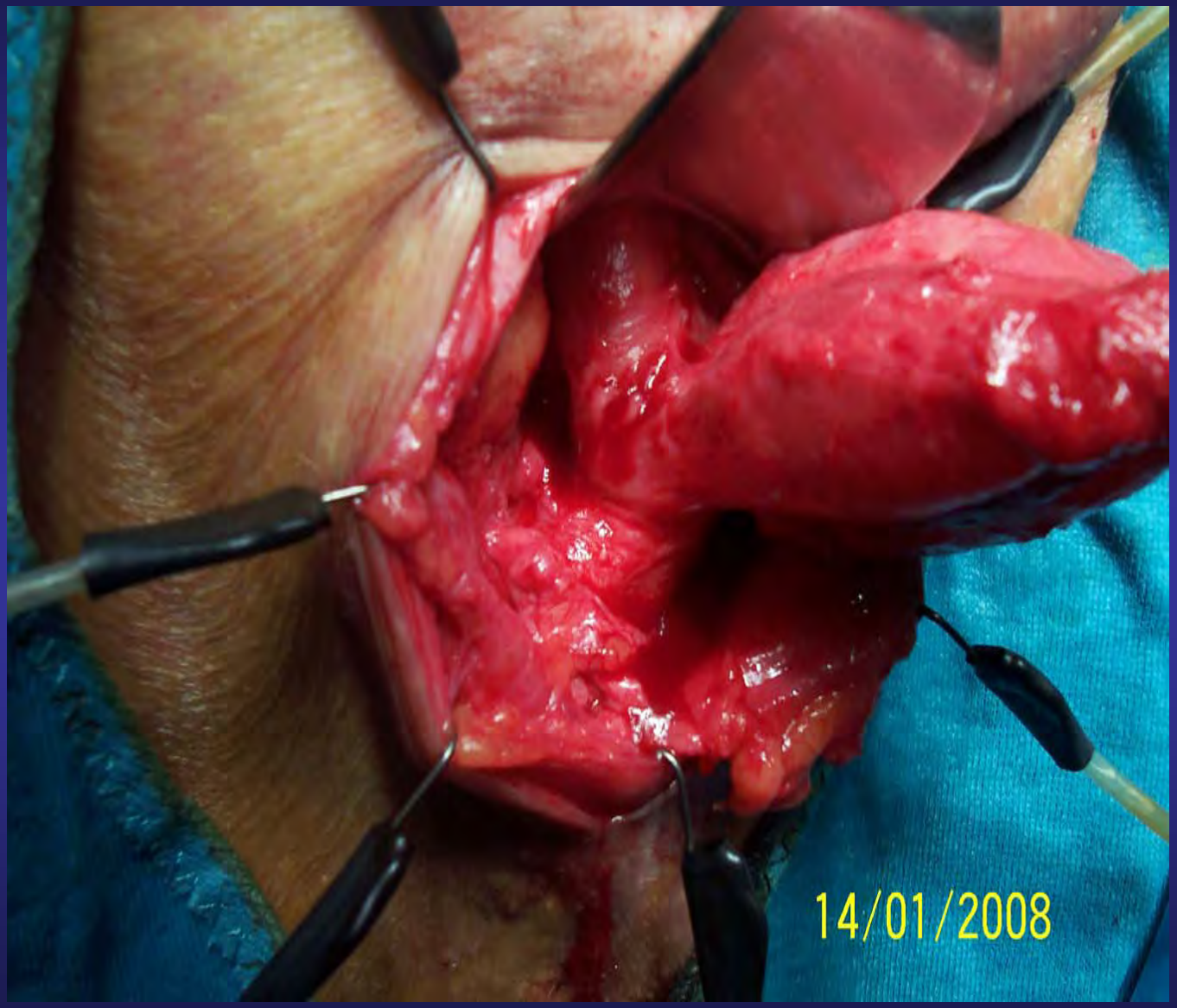
IGOR FRANK, DANIEL S. ELLIOTT AND DAVID M. BARRETT



*Recently reported complication and continence rates of primary implantation of the artificial genitourinary sphincter*

| References | No. Pts. | % Reoperation | % Infection | % Cuff Erosion | % Tissue Atrophy | % Continence |
|---|---|---|---|---|---|---|
| Schettini et al[5] | 52 | 28.6 | 9.6 | 3.8 | 0 | 92 |
| Marks and Light[6] | 37 | 24 | 5.4 | 8 | 3 | 94 |
| Fishman et al[7] | 148 | 17 | 7 | 2 | 7.4 | 90 |
| Malloy et al[3] | 42 | 19 | 10 | 10 | 9.5 | 76 |
| Light and Reynolds[8] | 126 | 27 | 7 | 0 | 19 | 95 |
| Montague[9] | 166 | 19.3 | 1.2 | 6 | 6.6 | 75 |
| Liebovich and Barrett[2] | 458 | 23.1 | 1.7 | 4.6 | 8.5 | 88 |
| Elliott and Barrett[10] | 184 (narrow backing cuff only) | 17 | Less than 1 | 6.5 | 1 | Not available |
| Current study | 23 | 12.9 | 0 | 8.7 | 4.3 | 95.8 |


14/01/2008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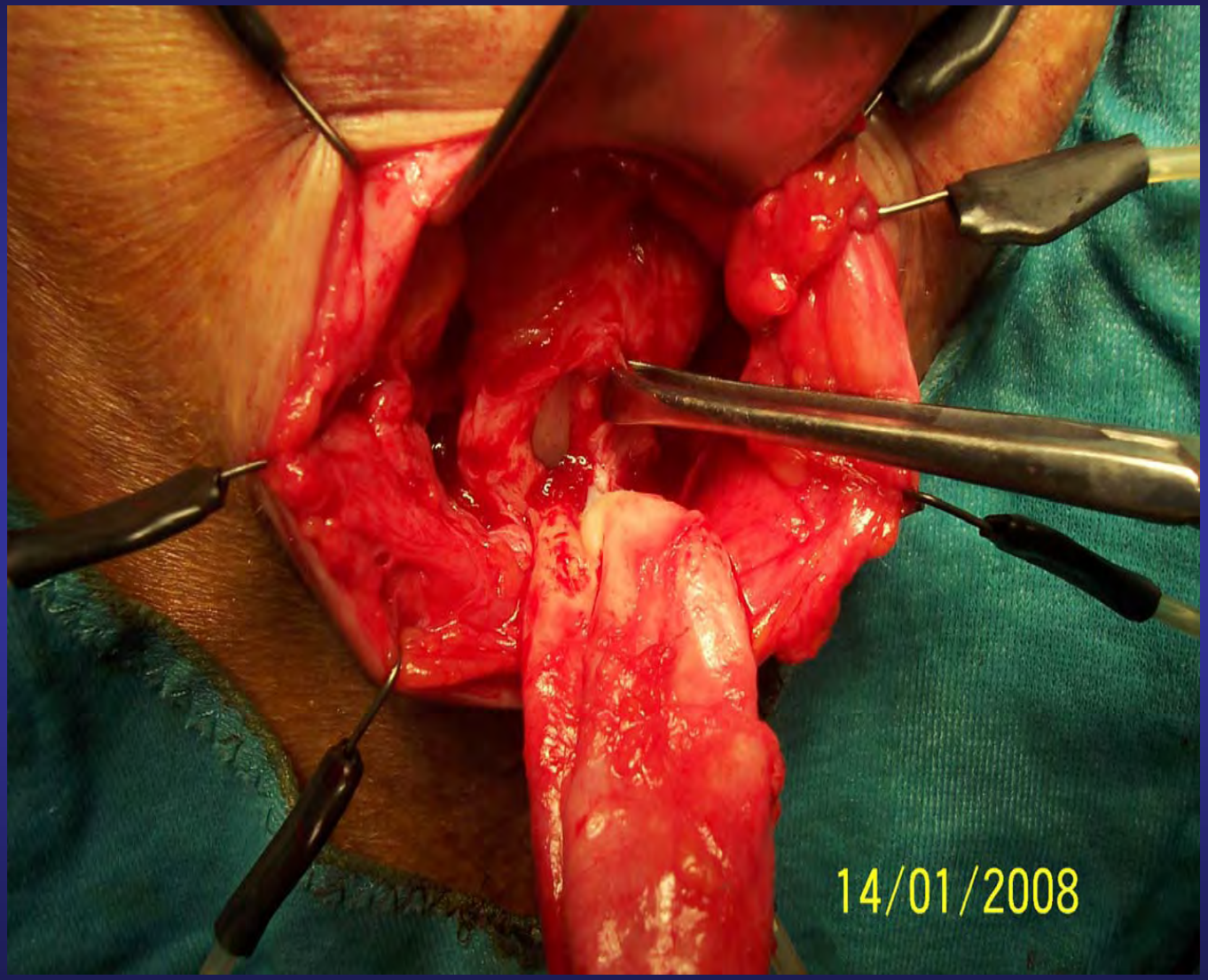
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# ARTIFICIAL SPHINCTER AMS 800

- 30-year experience
- Efficient but expensive
- Invasive implant technique
- High complication rate
- High revision rate
- Poor long term continence

# “Mundy “ Sphincter

- Self-sealing port for in situ pressure adjustment
- Stress relief balloon to increase occlusion pressure
- One-piece assembly
- Improved cuff design

# ICS-SINUG-SIUD-WORKSHOP
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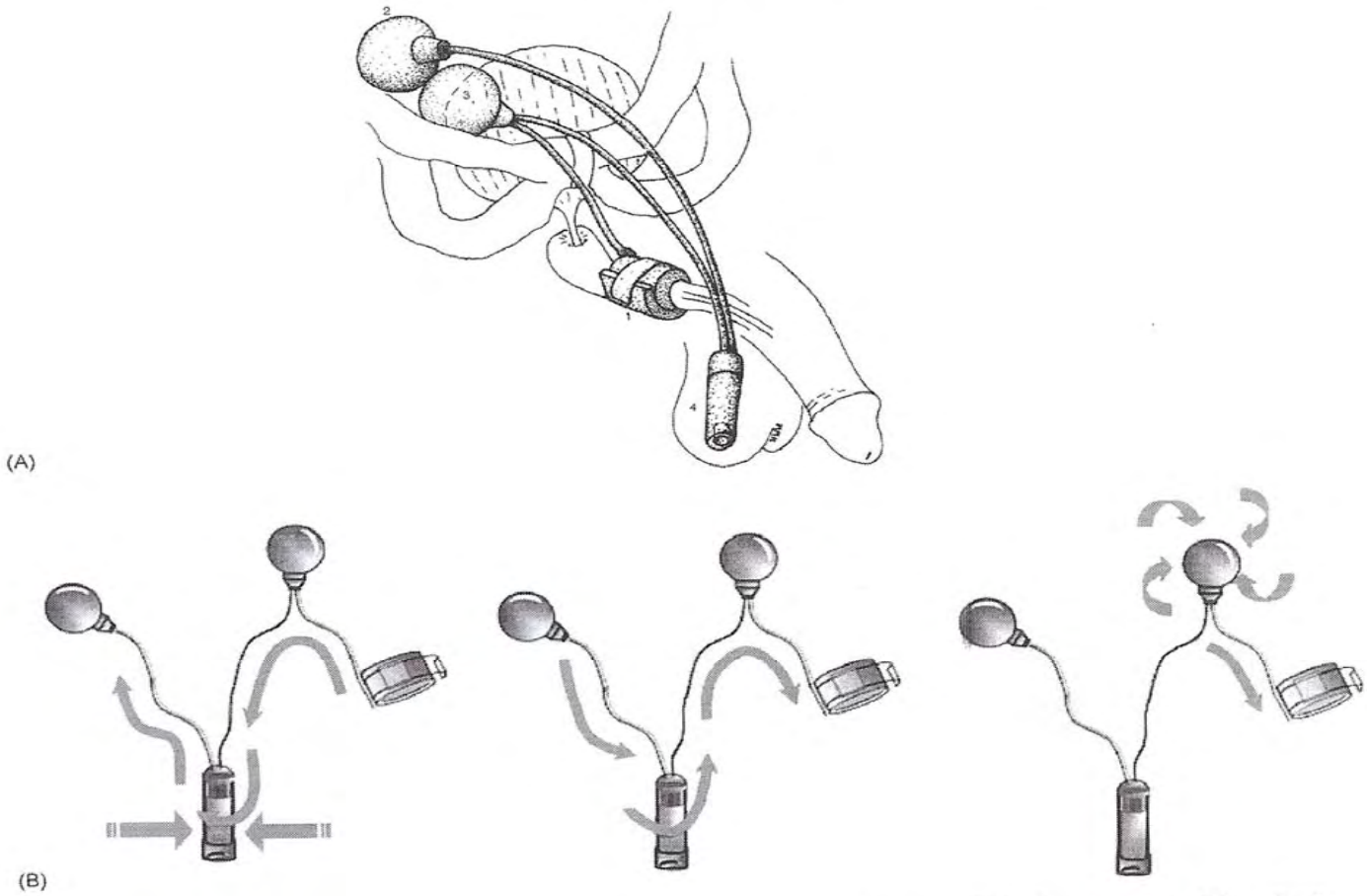


Fig. 1 – (A) The new artificial urinary sphincter with conditional occlusion showing individual components: (1) urethral occlusion cuff, (2) pressure-regulating balloon, (3) stress relief balloon, (4) pump and valve assembly unit with self-sealing port for pressurisation. (B) Operation of the new AUS: (1) The urethral occlusion cuff is deflated by squeezing the pump unit located in the scrotum, fluid is transferred to the pressure-regulating balloon and the patient can void through the empty cuff. (2) The cuff re-inflates through a slow return valve; rapid re-inflation can be achieved by squeezing the top of the pump unit. The cuff exerts sufficient pressure to maintain continence without compromising the urethral tissues. (3) During periods of raised intra-abdominal pressure, the fluid from the stress relief balloon is transferred to the cuff to provide additional pressure to maintain continence.

# Soft Compression

- Fixed pressure
- Normal flow
- Modifiable pressure

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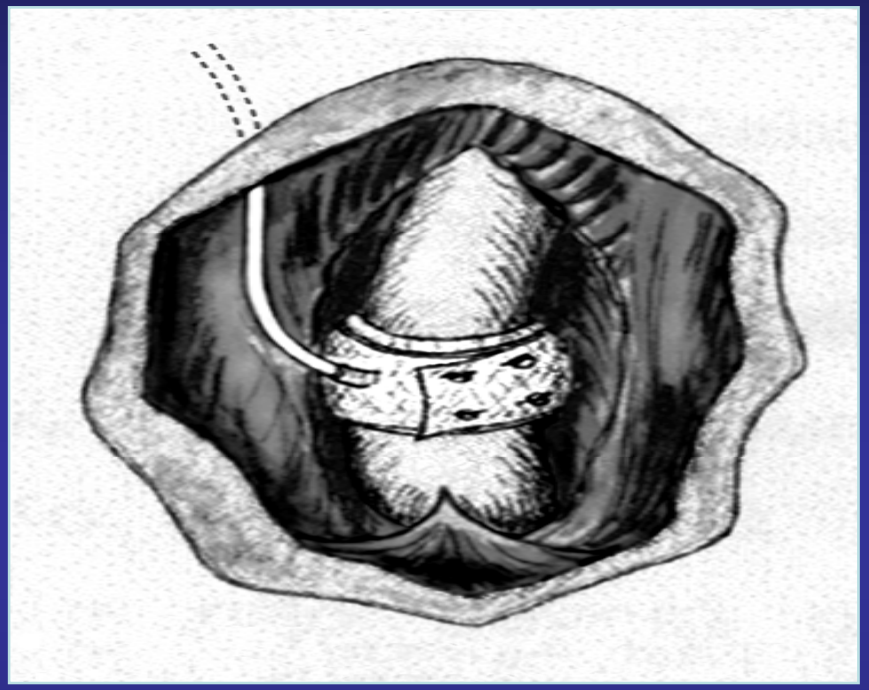
# Soft Compression

- Urethral costrictor
- Pro ACT

# “ SILIMED” peri-urethral constrictor

# PRESSURE REGULATING RESERVOIR

# CUFF



| Size | Perimeter | Max Volume |
|---|---|---|
| 1° | 5.5-6.0cm | 3.5 ml |
| 2° | 6.5-7cm | 4.0 ml |
| 3° | 7.5-8cm | 4.5 ml |

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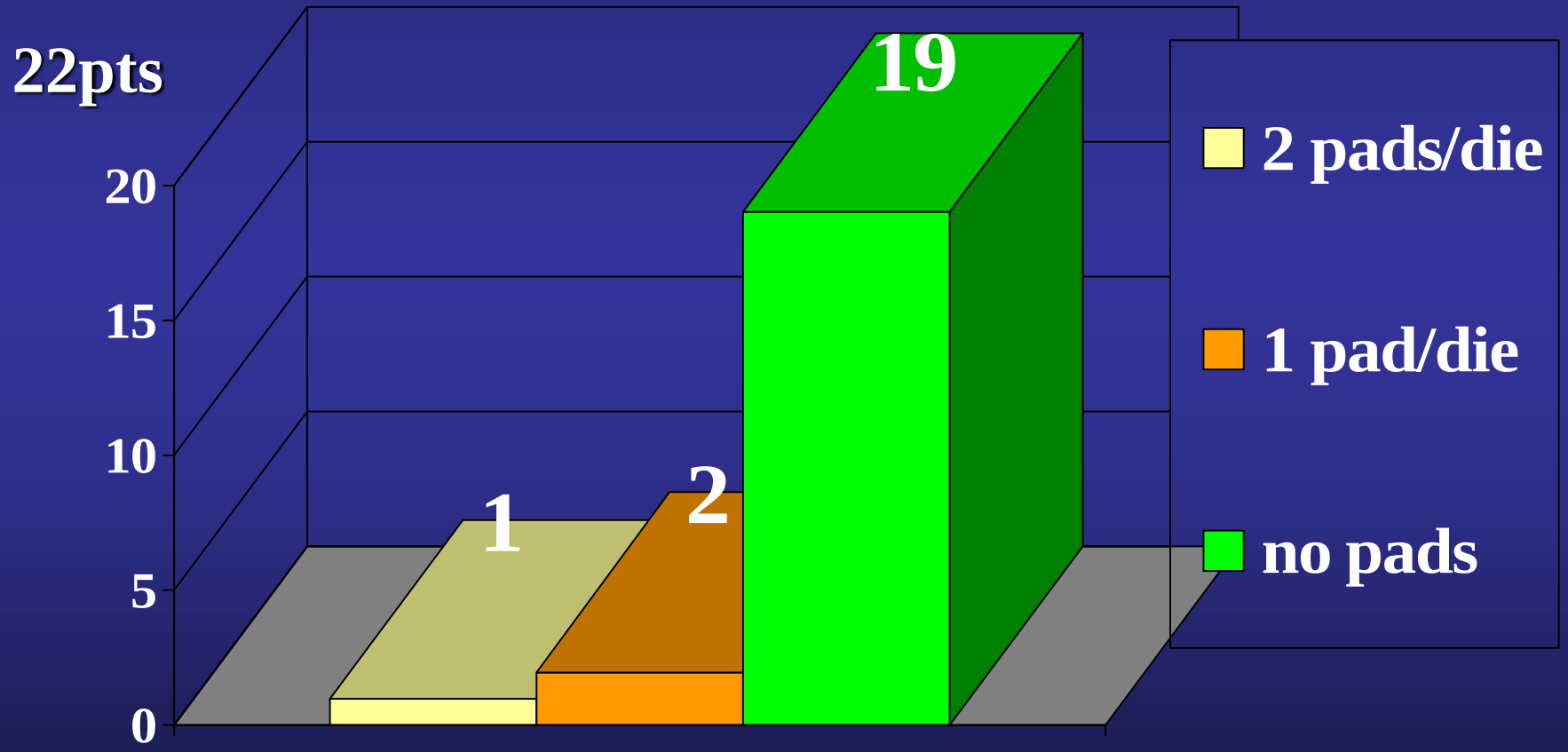
# " SILIMED" PERI-URETHRAL CONSTRICTOR

- SOFT URETHRAL COMPRESSION
- IMPROVE URETHRAL RESISTENCE
- HIGH PRESSURE FLOW
- MODIFIABLE PRESSURE

# “ SILIMED” PERI-URETHRAL CONSTRICTOR

# RESULTS

## 1 year continence status




Guaglianone & Gallucci 2007
Unpublished data


03/03/2008

# Pro-ACT

- Inflatable silicone balloon
- Titanium port for adjustments
- 12 & 14cm lengths
- Radiopaque marker at tip

# Pro-ACT *Implant tools*

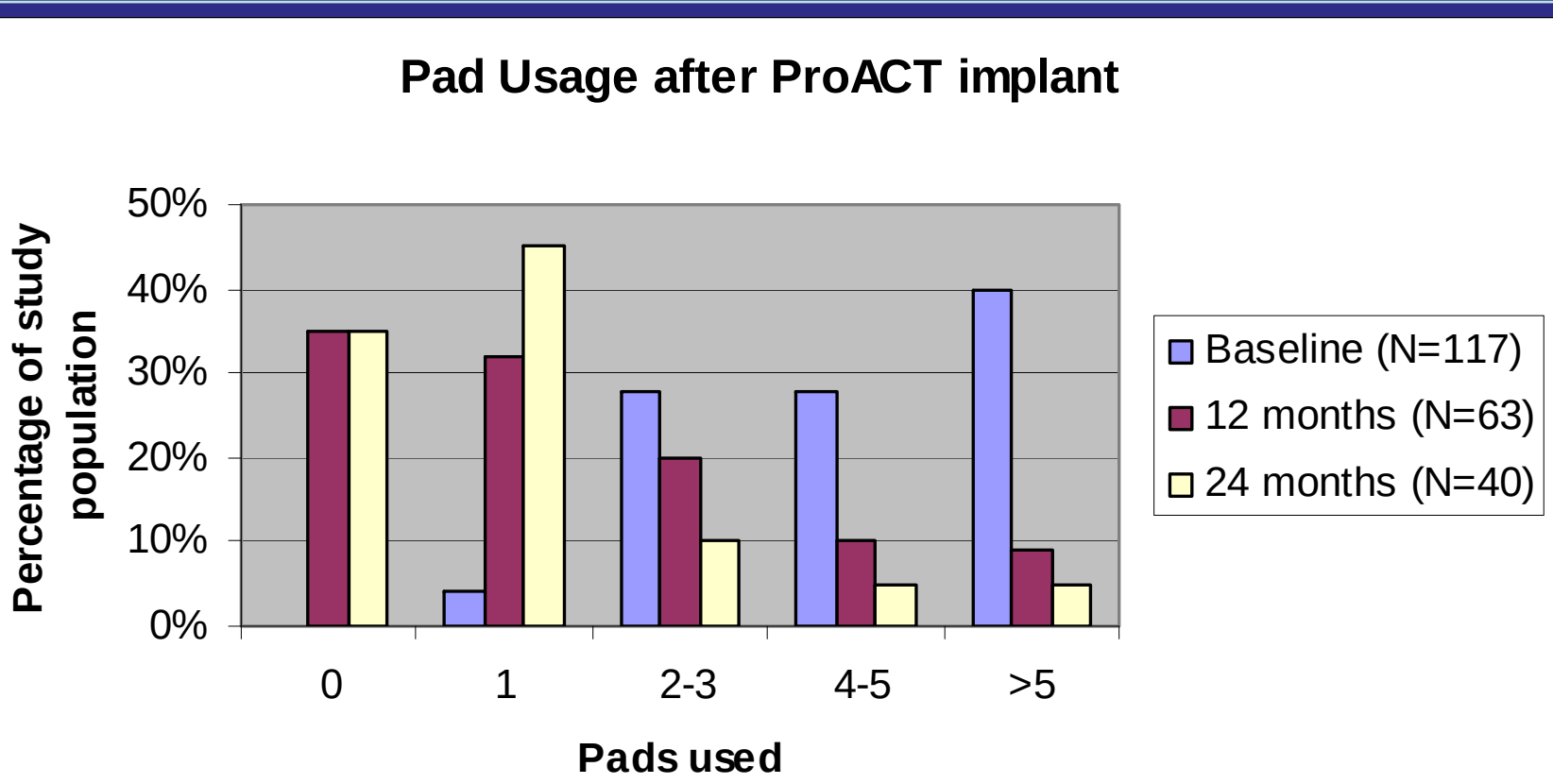
- U-channel sheath for trocars and balloons insertion
- Trocars for blunt and/or sharp tissue dissection
- Expanding device for dissection at location of the balloon

# Mechanism of Action

- Coaptation of urethra
- Demonstrated on reverse urethrogram

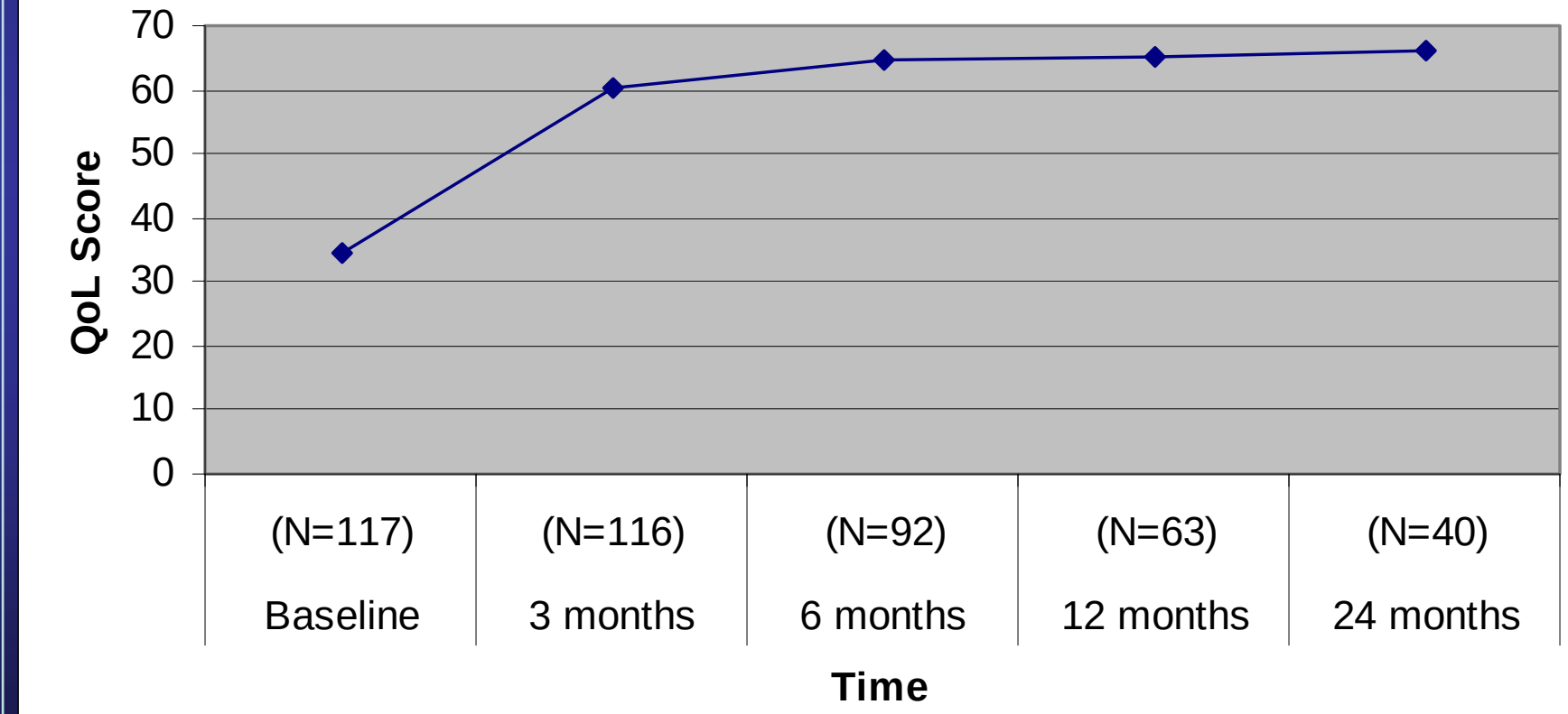
# Pad usage after ProACT™ Implant

Reported in: "treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy by Huebner and Schlarp in BJUI, September 2005



# Improvement in QoL after ProACT™ Implant

Reported in: "treatment of incontinence after prostatectomy using a new minimally invasive device: adjustable continence therapy by Huebner and Schlarp in BJUI, September 2005



# ProACT vs. AUS

- Good clinical efficacy
- Minimally invasive
- Easily reversible
- Shorter Procedure time
- More economical
- Long term data not yet available
- Passive system, no patient involvement
- Moderate infection and adverse event rates

- Good clinical efficacy
- Invasive
- Not easily reversible
- Longer procedure time
- Higher cost
- Long term data available .
- Active system, dependent on patient operation
- Higher infection and adverse event rates

# Fixed compression

- Sling
- Remix
- Argus
- In-Vance
- Advance

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# Male Sling

| | | | |
|---|---|---|---|
| • Jorion | 1997 | 30 pts | m.recti fascia |
| • Schaeffer | 1998 | 64 pts | polyethylene |
| • Madjar | 2001 | 16 pts | Straight-in |
| • Comiter | 2002 | 21 pts | In Vance |
| • Dikranian | 2004 | 36 pts | Various |
| • Castle | 2005 | 42 pts | In Vance |

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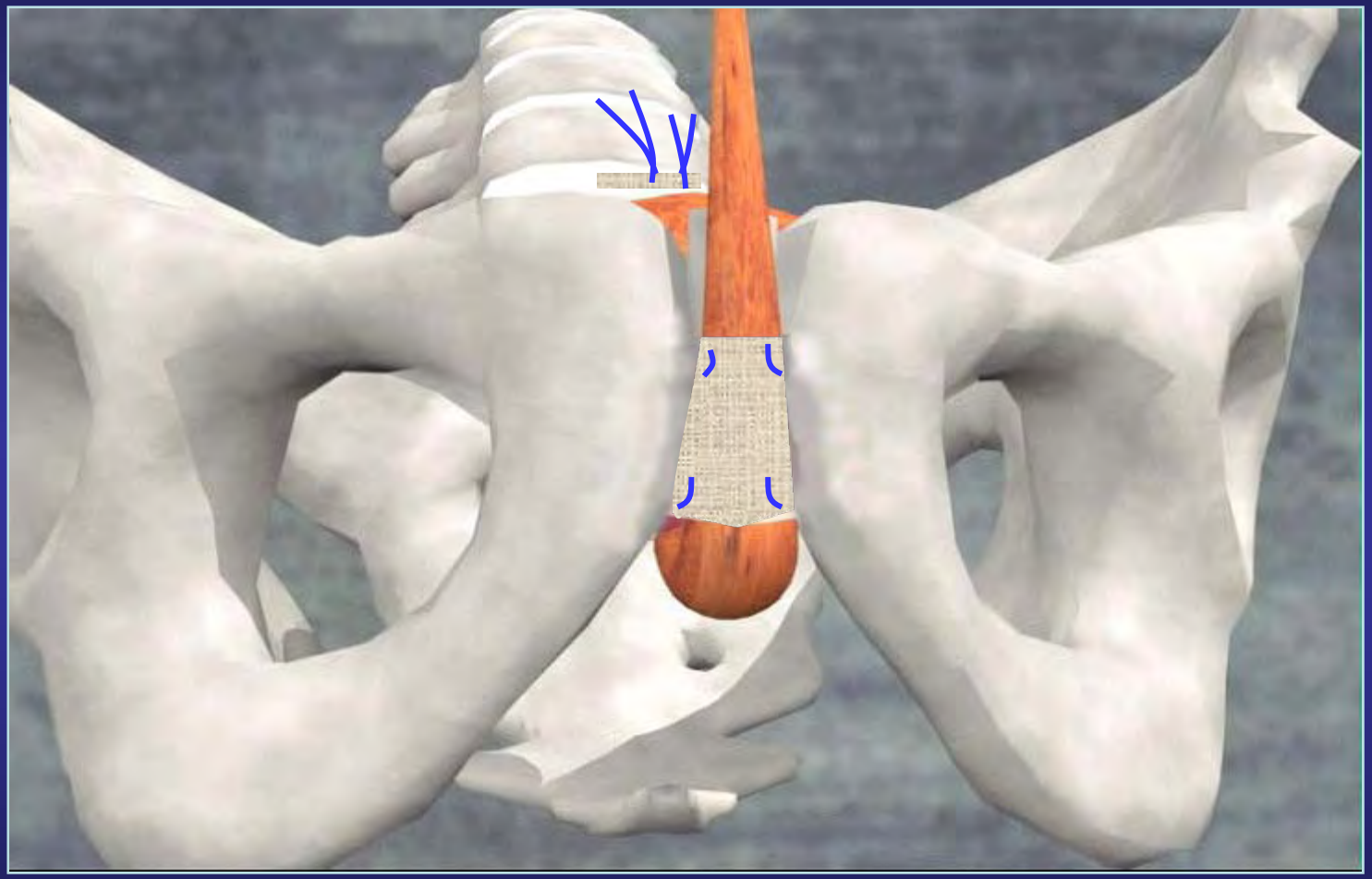
# SURGICAL PROCEDURES

## Type of sling

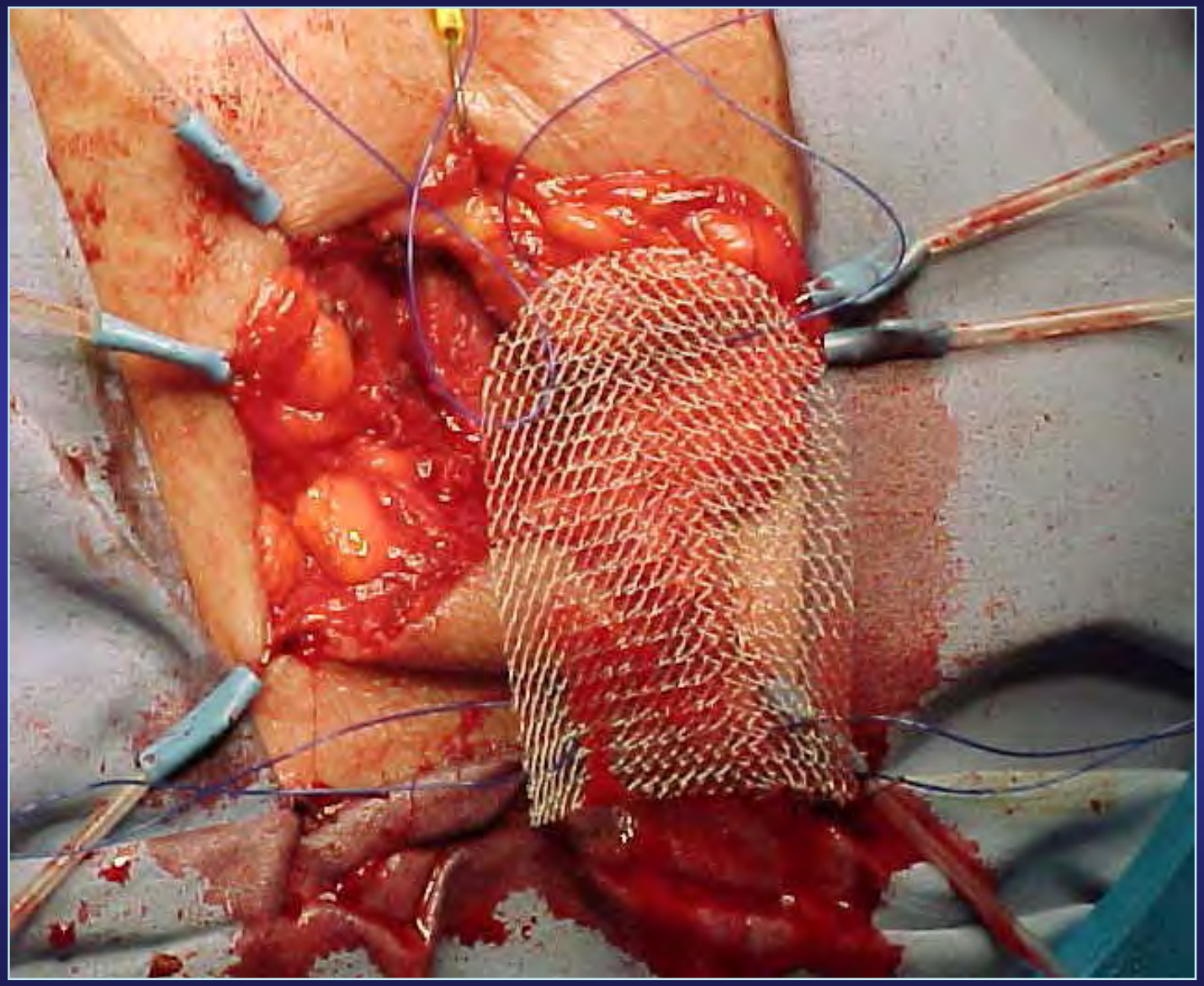
- Autologous sling
- Eterologous sling
- Synthetic sling

# perineal / suprapubic approach



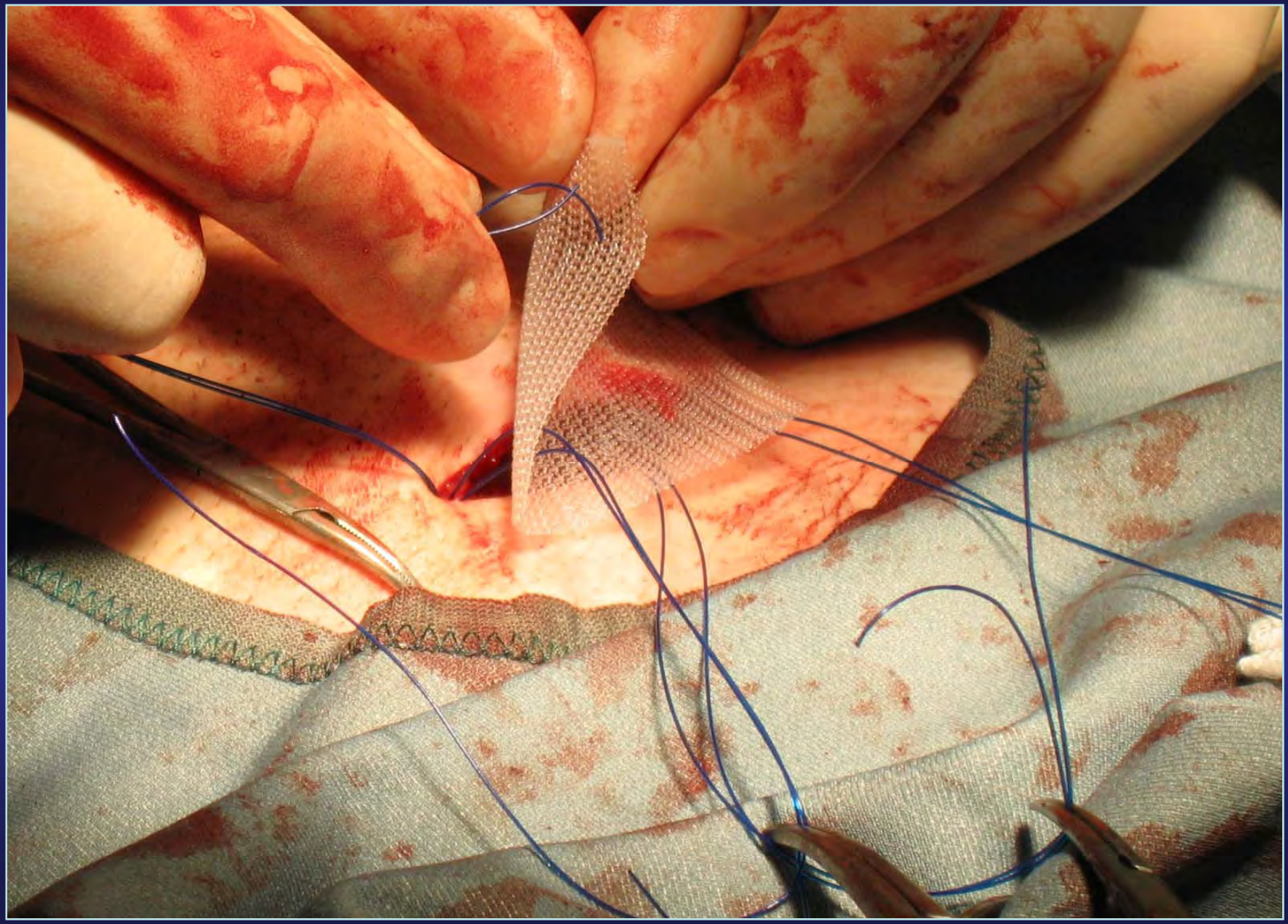
READJUSTABLE SLING

# perineal / suprapubic approach

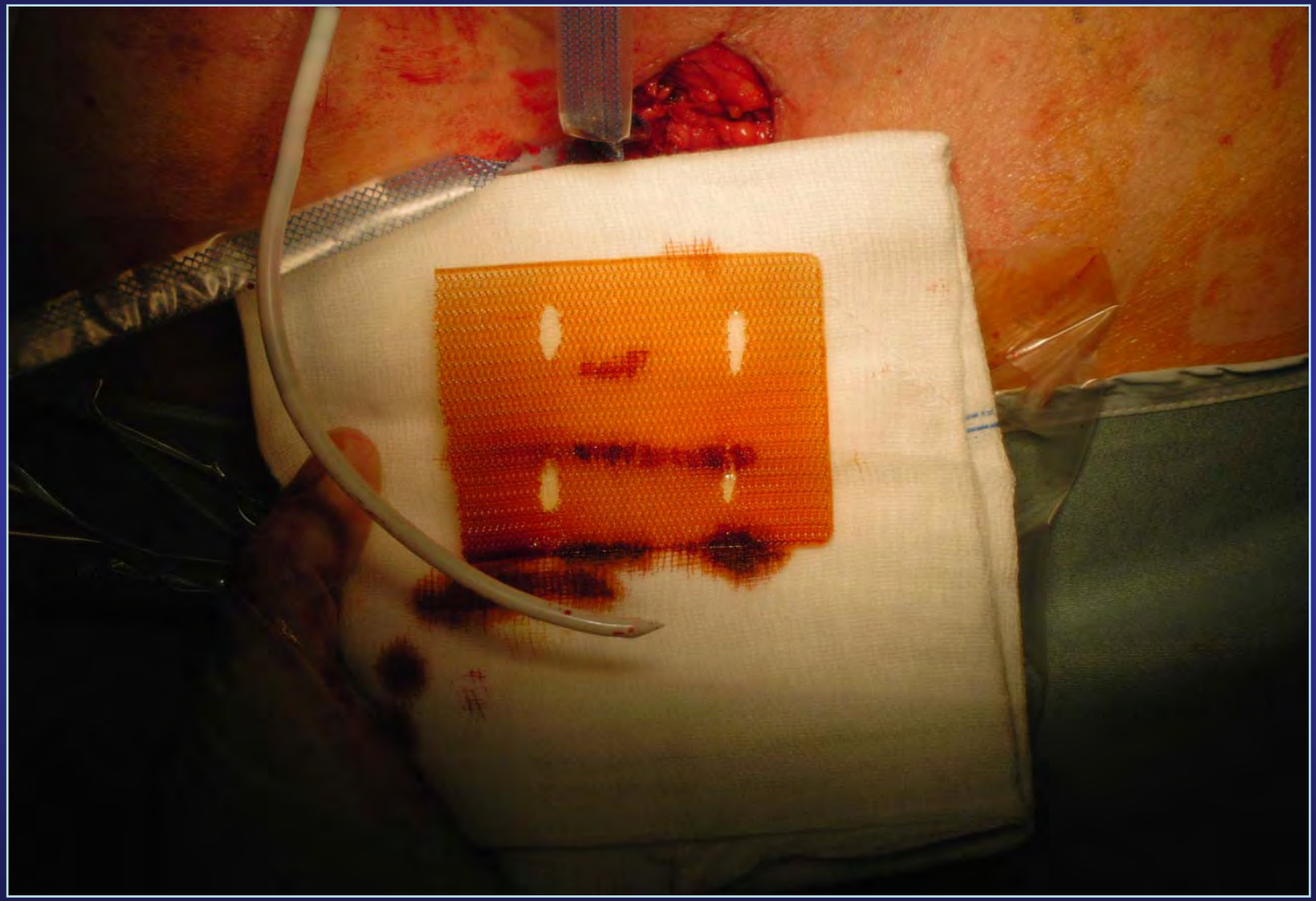


***A 4 x 5 cm Prolene mesh is tailored and four 1#0 Prolene sutures are fixed to its four angles***

# perineal / suprapubic  approach

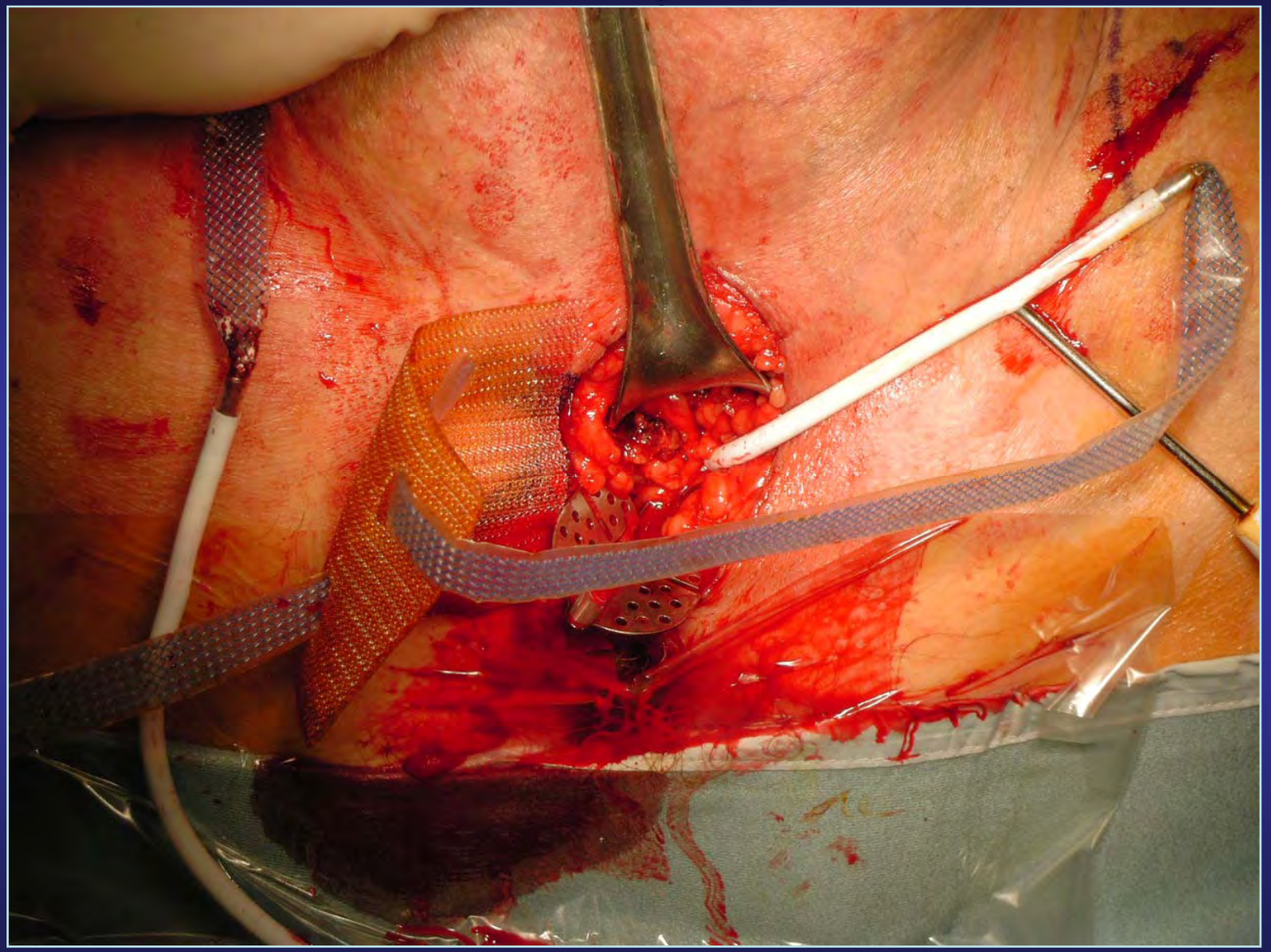


# transobturatory approach



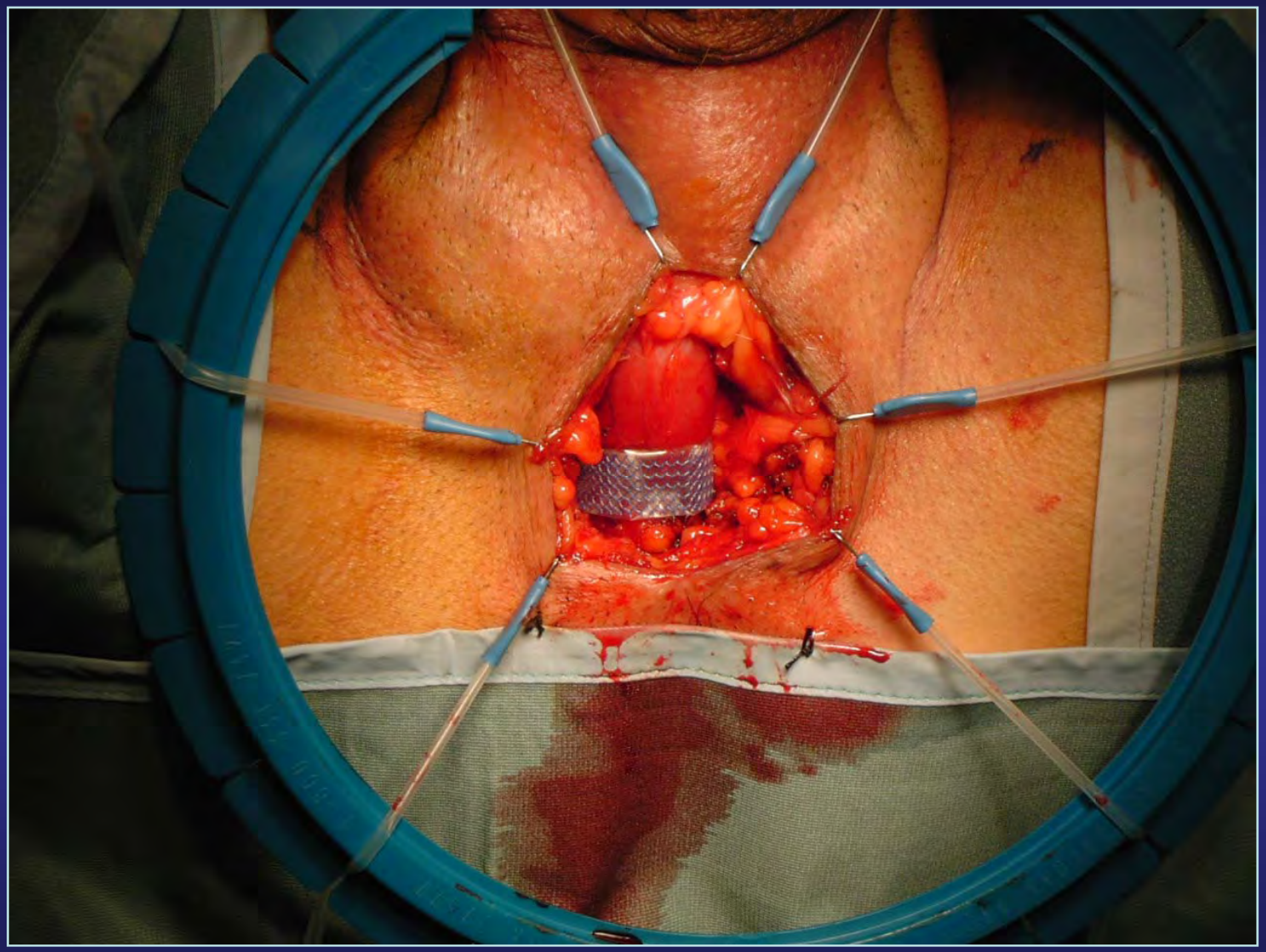
Tailoring of the  Mesh

# transobturatory approach



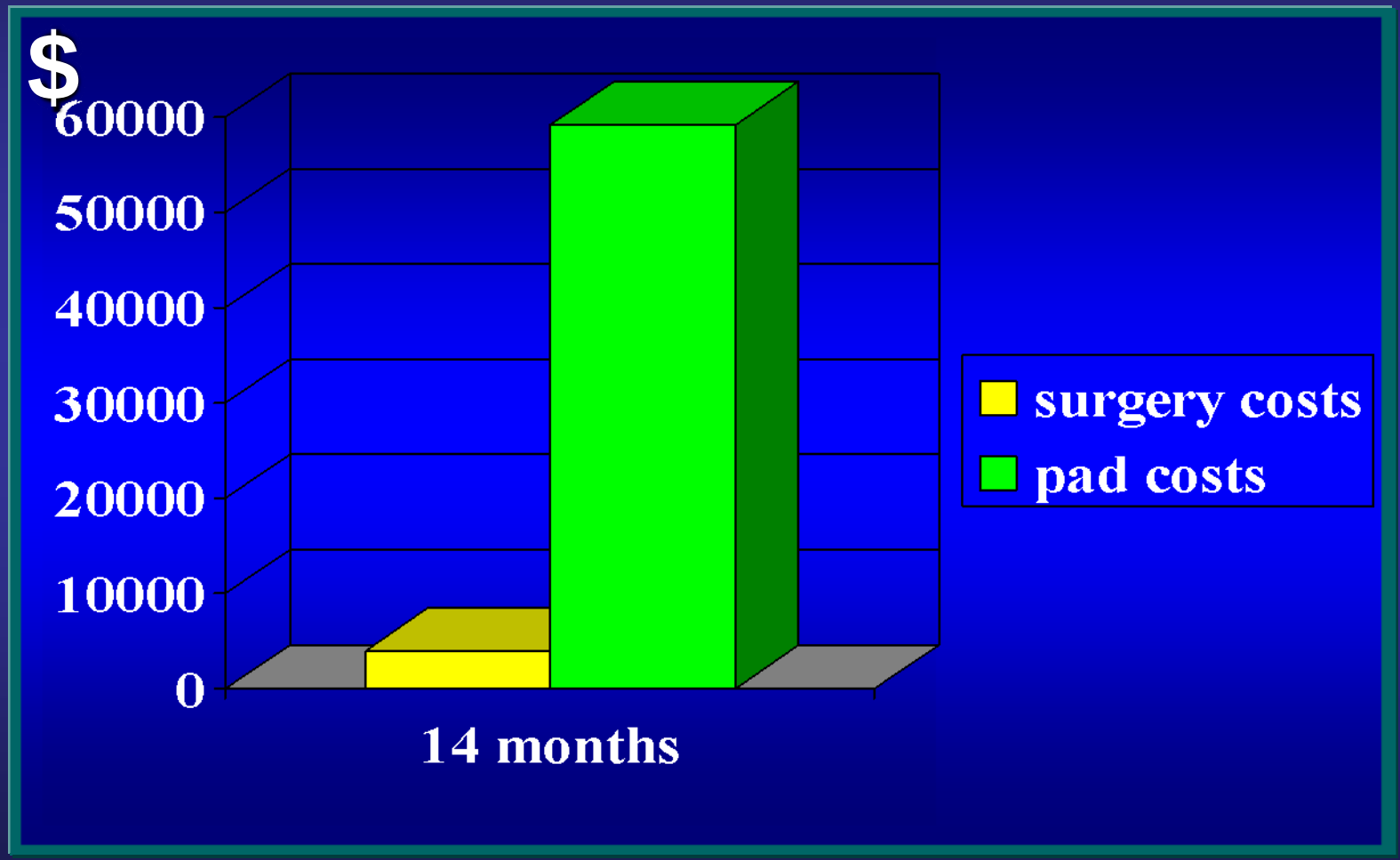
Needle is passed through the holes of the mesh

# transobturatory approach



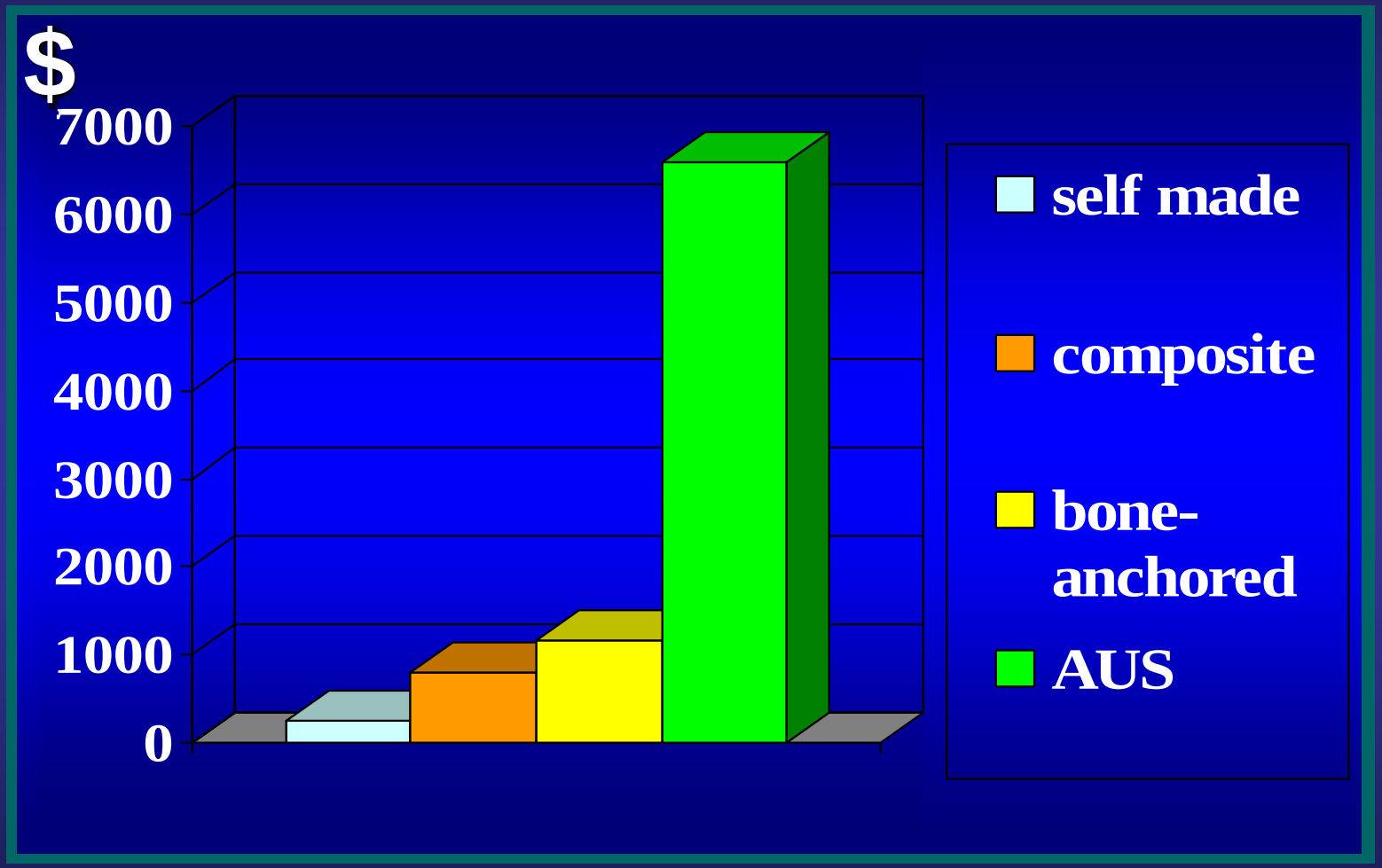
**Single Tape has been insufficient in our experience**

# COSTS



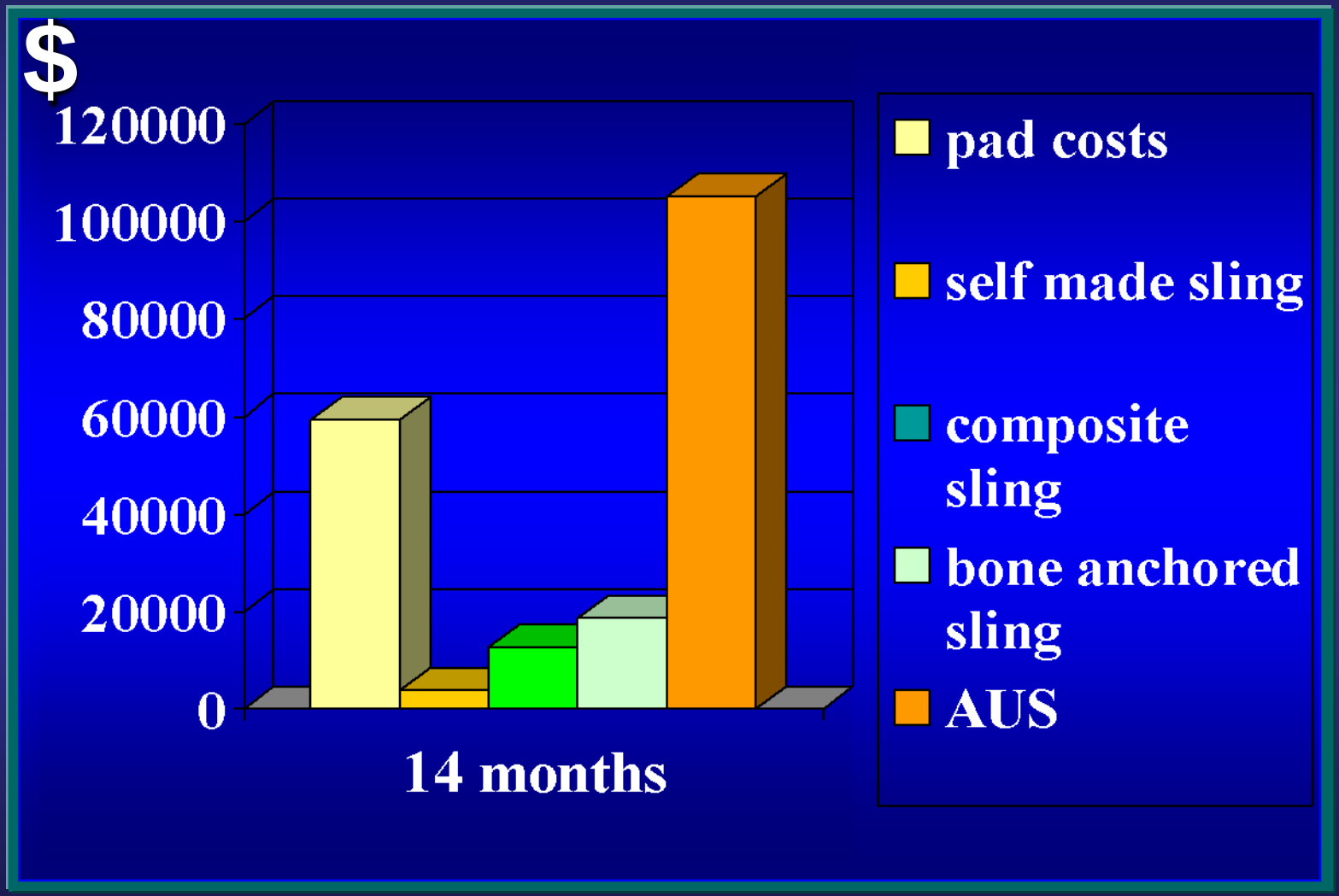

Migliari 2006

# COSTS




Migliari 2006

# COSTS




Migliari 2006

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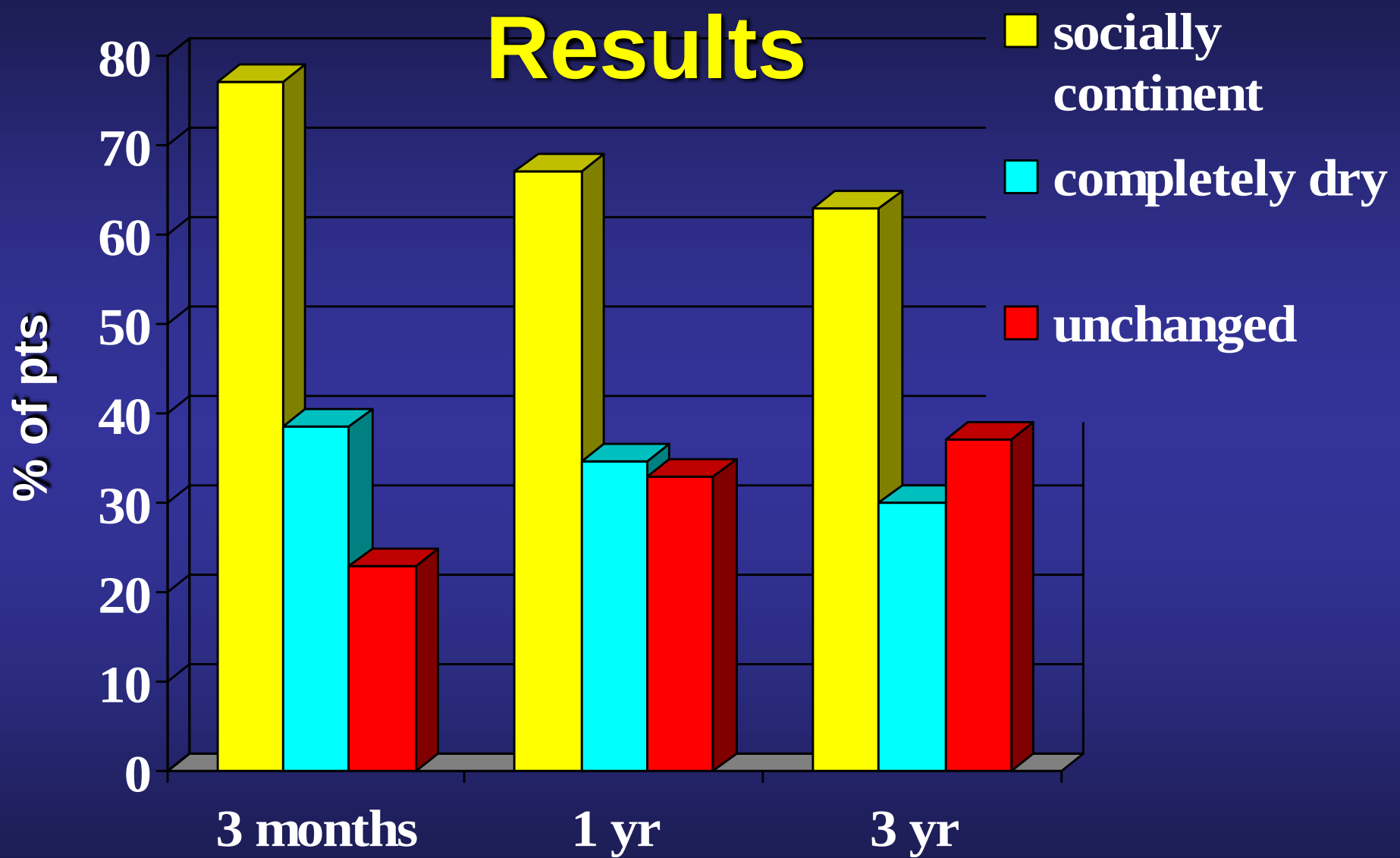
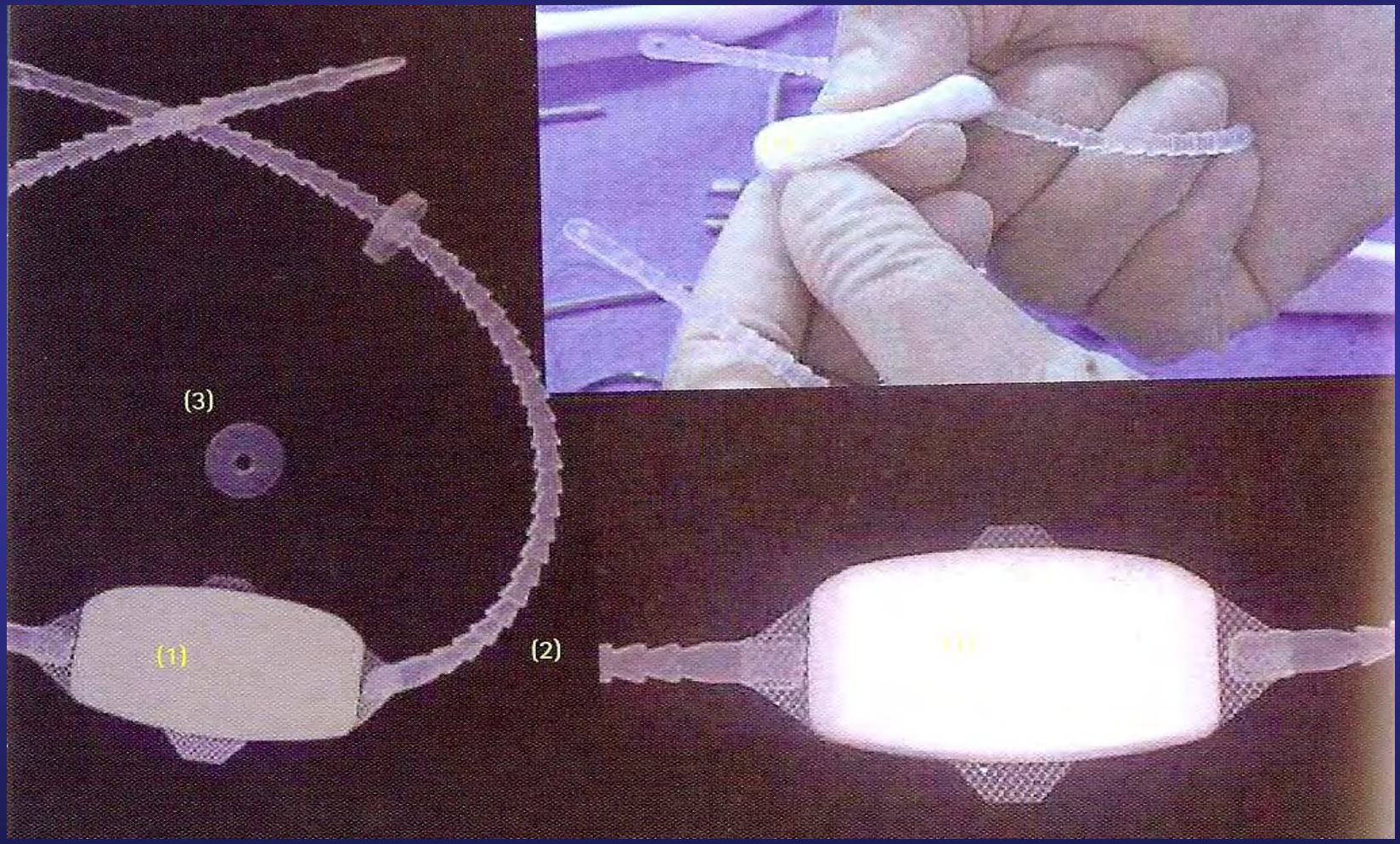



*Clinical success was defined as completely dry (wearing no pad) or socially continent (1 pad /day)*

Migliari 2006

# “ARGUS “ SLING



# An adjustable male sling for treating urinary incontinence after prostatectomy: a phase III multicentre trial

SALOMON V. ROMANO, SERGIO E. METREBIAN*, FERNANDO VAZ†, VALTER MULLER†, CARLOS A. D'ANCONA†, EUGENIO A. COSTA DE SOUZA¶ and FABIO NAKAMURA§

*Urology Departments, Hospital Durand, Buenos Aires, and *Hospital Privado, Cordoba, Argentina, †Hospital Dos Servidores Do Estado, Rio De Janeiro, †Universidad De Unicamp, Campinas, ¶Fundaçao Felice Rosso, Belo Horizonte, and §Centro Medico Ultralitho, Florianopolis, Brazil*


ARGUS SLING

# Argus
# Particolarità tecniche

- Cuscinetto di silicone che rende più morbida la compressione sull'uretra;

- Sistema di anelli tensivanti che rendono possibile la modifica della tensione dello sling.

# Argus
# Esperienza clinica

- Romano, l'ideatore della protesi, in 48 pazienti di uno studio multicentrico ha verificato un 73% di successo con un follow-up medio di 7.5 mesi e bassa incidenza di complicanze.

Romano ; 2006

# Sling “Remix”

## Readjustable mechanical external device

- Concepito inizialmente per l’incontinenza urinaria femminile
- Regolatore di tensione impiantato nel sottocutaneo retropubico
- Due fili di prolene
- Mesh impiantata  sull’uretra bulbare.

# Remix
## Funzionamento

- Attraverso  il regolatore di tensione è possibile variare la pressione della mesh sull’uretra stessa , e questa modifica è realizzabile anche a distanza attraverso un manipolatore esterno.

# TRATTAMENTO DELL'INCONTINENZA URINARIA MASCHILE DA DANNO SFINTERICO con MESH IN-VANCE ™

## MATERIALI e METODI

- -2 pz erano stati sottoposti a Prostatectomia radicale retropubica
- -2 pz erano stati sottoposti ad Adenomectomia trans-vescicale
- -4 pz erano stati sottoposti a TURP
- -2 pz già portatori di sfintere artificiale AMS 800 espiantato

**10 pz.**

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# compressive mesh
# IN-VANCE ™



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# TRATTAMENTO DELL'INCONTINENZA URINARIA MASCHILE DA DANNO SFINTERICO con MESH IN-VANCE ™

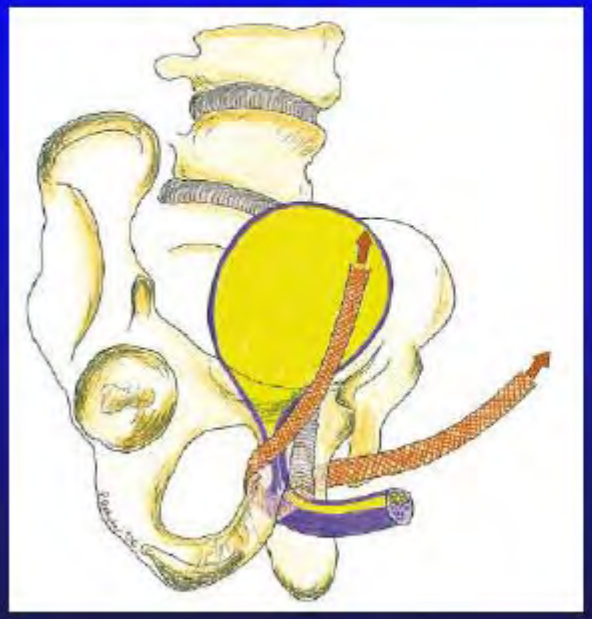
## RISULTATI

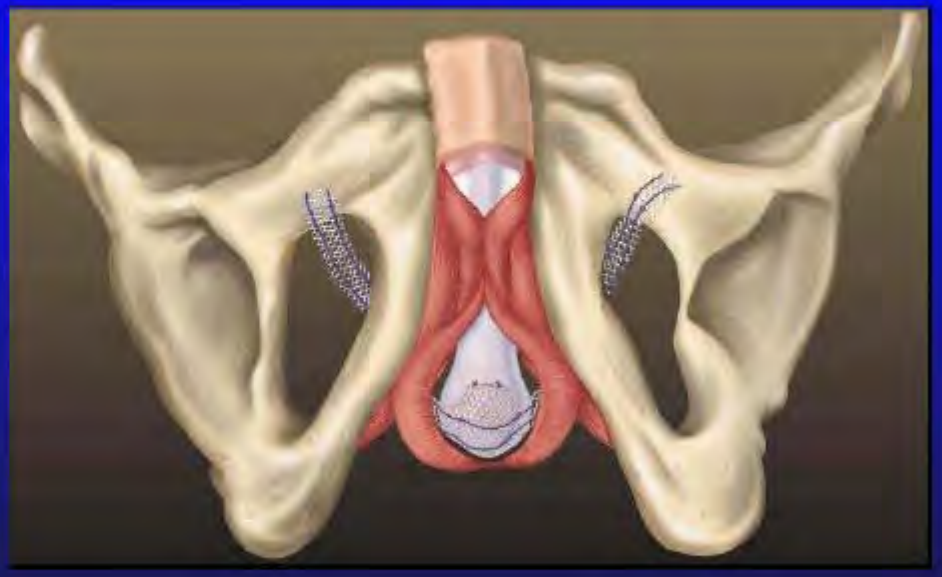
- Il follow up medio è stato 7 mesi.
- Non ci sono state complicanze intra peri operatorie.
- 1 Ascesso perineale a 10 mesi
- La durata media dell'intervento è stata di 35 minuti (20-70).


Skettini 2007

# SLING TRANS-OTTURATORIO ADVANCE

Modalità di azione: riposizionare prossimalmente l'uretra bulbare innalzando il centro tendineo e ottimizzando quindi la funzione sfinteriale.

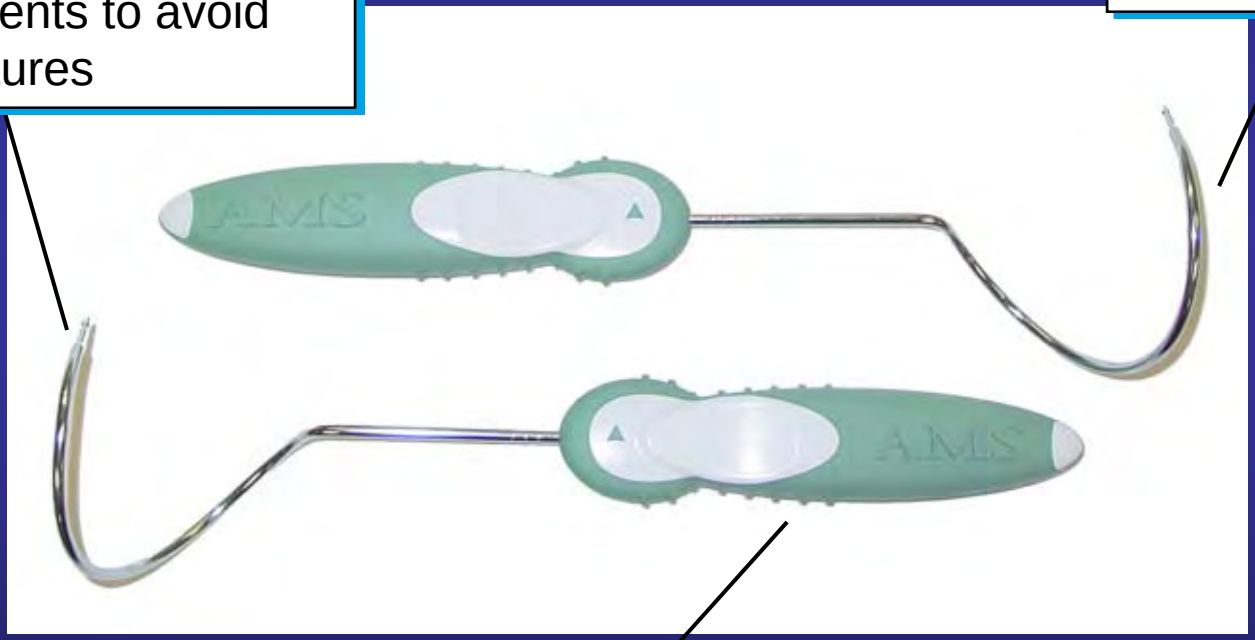




# Instrument Features

Needle tip angle optimized for male patients to avoid critical structures

Helix diameter optimized for male pelvis



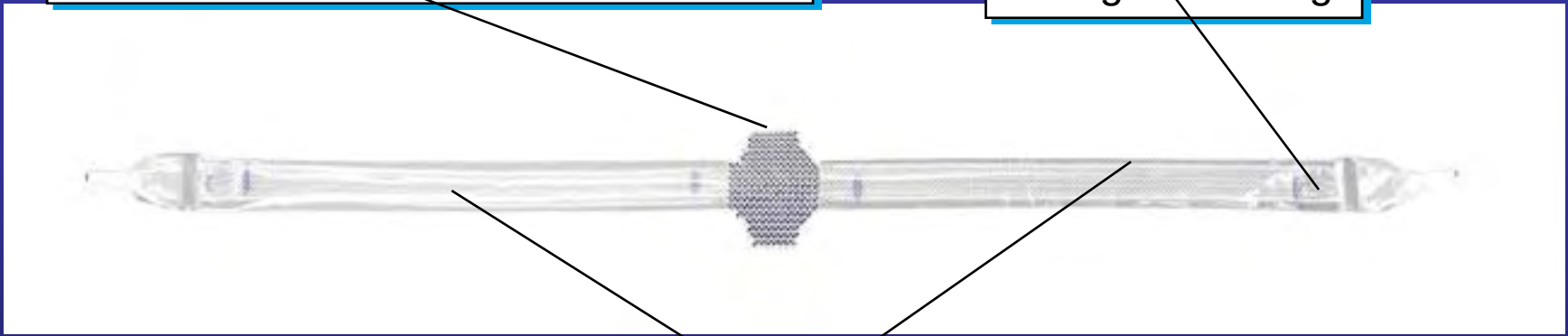

Handle orientated to allow high force generation and maximum torque

# Sling Features

**Polypropylene mesh optimized for significant tension and high short-term tissue retention and stability**

Broad center allows fixation to corpus spongiosum and support of the bulbar urethra and perineal body

Reinforced mesh ends for strength during tensioning

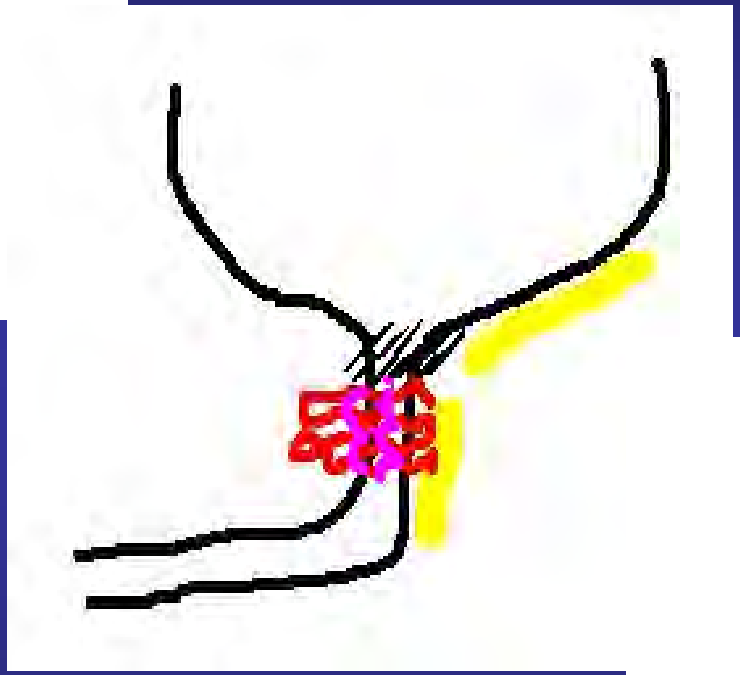


Two long-lasting absorbable sutures with multiple knots and strengthened heat-sealed mesh edges enhance short term stability in tissue and sling strength

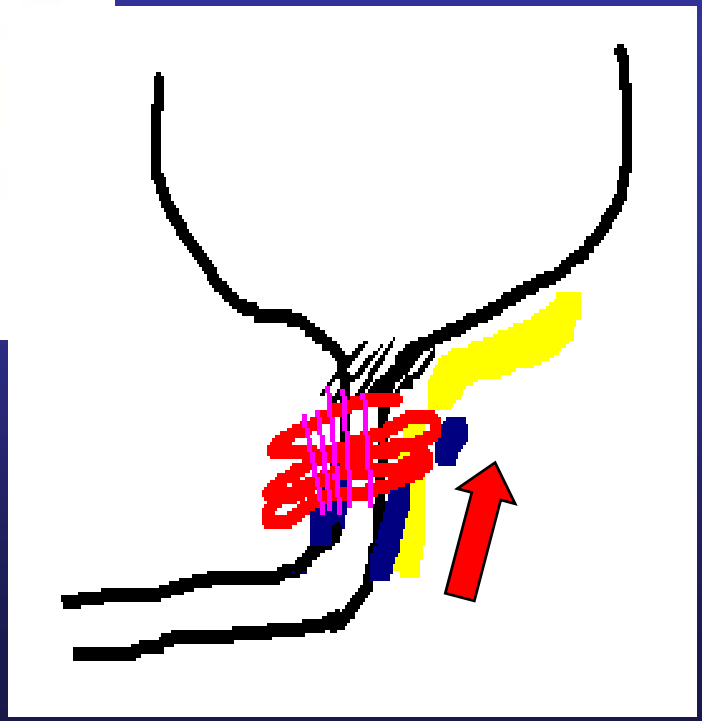
# Prolasso maschile

## Incontinenza dopo prostatectomia radicale

**Reason for incontinence is dorsal sphincteric laxity**



**Supporting sphincteric support structures leads to regaining of continence**



Christian Gozzi

# Impianto Advance™

*Christian Gozzi*

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology


Incontinence

## Transobturator Sling Suspension for Male Urinary Incontinence Including Post-Radical Prostatectomy

*Peter Rehder*, Christian Gozzi*

In the clinical series, the mean urethral closure pressure improved from 13.2 to 86.4 cmH2O following placement of the TOT.
The membranous urethral length increased from a mean of 3 to 17.2 mm following tensioning of the tape.
No significant differences in Qmax pre- and postoperatively were observed.
Incontinence cure rate (no pad usage) was 40% and improved rate (1–2 pads per day) was 30%.

# AdVance™ Innsbruck results:

- 30 patients Implanted
- 16 mild to moderate , 14 severe
- 27 post RP (3 RT, 3 failed SC, 2 AUS)
  3 post TURP

- Median follow-up 8 months (range 2-12)
- Mean pad usage decreased from 5.2 to 0.4
- 97% cured or improved
  - 23 cured (no pads)
  - 6 improved (1-2 pads)
- 1 showed no improvement

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ICS-SINUG-SIUD-WORKSHOP

ROTTERDAM 2007

# Male Incontinence treatment

## The future

# STAMINAL CELLS

# Autologous myoblasts and fibroblasts for female stress incontinence: a 1-year follow-up in 123 patients

**Michael Mitterberger, Rainer Marksteiner*, Eva Margreiter*, Germar M. Pinggera, Daniela Colleselli, Ferdinand Frauscher†, HannoUlmer‡, Martin Fussenegger¶, Georg Bartsch and Hannes Strasser**

*Departments of Urology, *Biochemical Pharmacology, †Radiology II and ‡Medical Statistics, Informatics and Health Economy, University of Innsbruck, and ¶Department of Otolaryngology, Sisters of Charity Hospital, Wels, Austria*

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Type of Study – Therapy (case series)
Level of Evidence 4

## OBJECTIVE

To assess the efficacy and safety of the application of autologous myoblasts and fibroblasts for treating female stress urinary incontinence (SUI) after a follow-up of ≥1 year.

## PATIENTS AND METHODS

In all, 123 women with SUI (aged 36–84 years) were treated with transurethral ultrasonography-guided injections with autologous myoblasts and fibroblasts obtained from skeletal muscle biopsies. The fibroblasts were suspended in a small amount of collagen as carrier material and injected into the urethral submucosa, while the myoblasts were implanted into the rhabdosphincter. All patients were evaluated before and 12 months after the injection using the Incontinence and Quality of Life Instrument (I-QOL) scores, urodynamic variables, and morphology and function of the urethra and rhabdosphincter.

## RESULTS

At 1 year after implanting the cells, 94 of the 119 women (79%) were completely continent, 16 (13%) had a substantial improvement and nine (8%) a slight improvement. Four patients were lost to follow-up.The incontinence and I-QOL scores, and the thickness, contractility and electromyographic activity of the rhabdosphincter were significantly improved after treatment.

## CONCLUSIONS

These results show the efficacy and safety of transferring autologous myoblasts and fibroblasts in the treatment of female SUI, after a follow-up of 1 year.

## KEYWORDS

autologous myoblasts, fibroblasts, endoscopic injection, stress urinary incontinence, rhabdosphincter

*TABLE 1 The characteristics of the 119 patients treated with autologous cells at baseline and the 1-year follow-up. The statistical differences between before and after treatment were assessed using the Wilcoxon test. The incontinence score and IQOL score are shown as the median (range), and all numeric variables as the mean (SD)*

| Variable | Before | After (1 year) | P |
|---|---|---|---|
| Incontinence score | 6 (5–6) | 0 (0–4) | 0.001 |
| IQOL score | 51 (27–70) | 108 (29–110) | 0.001 |
| Thickness of urethra, mm | 3.5 (0.8) | 4.9 (0.9) | 0.001 |
| Thickness of rhabdosphincter, mm | 2.1 (0.3) | 3.4 (0.4) | 0.001 |
| Contractility of rhabdosphincter | 0.65 (0.3) | 1.39 (0.3) | 0.001 |
| Maximum: | | | |
| residual urine, mL | 49.2 (131.7) | 12.5 (67.8) | 0.001 |
| urinary flow rate, mL/s | 21.6 (9.1) | 25.2 (8.1) | 0.001 |
| detrusor pressure during flow, $cmH_2O$ | 36.6 (25.7) | 31.2 (16.7) | 0.001 |
| bladder capacity (ml) | 425.9 (129.6) | 450.5 (118.0) | 0.570 |
| closure pressure at rest, $cmH_2O$ | 28.8 (12.3) | 40.5 (15.8) | 0.001 |
| closure pressure during voluntary contraction of rhabdosphincter, $cmH_2O$ | 51.8 (35.8) | 78.1 (56.2) | 0.001 |
| Periurethral EMG, µV | | | |
| at rest | 34.0 (11.0) | 45.1 (15.0) | 0.001 |
| during voluntary contraction of rhabdosphincter | 43.1 (11.8) | 55.4 (15.3) | 0.001 |

# Myoblast and Fibroblast Therapy for Post-Prostatectomy Urinary Incontinence: 1-Year Followup of 63 Patients

**Michael Mitterberger,* Rainer Marksteiner,† Eva Margreiter,† Germar M. Pinggera, Ferdinand Frauscher, Hanno Ulmer, Martin Fussenegger,‡ Georg Bartsch and Hannes Strasser†**

*From the Departments of Urology (MM, GMP, GB, HS), Biochemical Pharmacology (RM, EM), Radiology II (FF), and Medical Statistics, Informatics and Health Economics (HU), Innsbruck Medical University, Innsbruck, and Department of Otolaryngology, Sisters of Charity Hospital, Wels (MF), Austria*

**Purpose:** We assessed the efficacy and safety of the application of autologous fibroblasts and myoblasts for treatment in post-prostatectomy urinary incontinence after a minimal followup of 1 year.

**Materials and Methods:** Sixty-three patients with stress urinary incontinence after radical prostatectomy were treated with transurethral ultrasound guided injections of autologous fibroblasts and myoblasts obtained from skeletal muscle biopsies. All subjects were evaluated preoperatively and 12 months postoperatively in terms of incontinence and Quality of Life Instrument scores, urodynamic parameters, and morphology and function of the urethra and rhabdosphincter.

**Results:** Of the 63 patients 41 were continent 12 months after implantation of cells, 17 showed improvement and 5 did not show any improvement. Incontinence and Quality of Life Instrument scores as well as thickness and contractility of the rhabdosphincter were significantly improved postoperatively.

**Conclusions:** The use of myoblast and fibroblast therapy represents a minimally invasive, safe and effective treatment for post-prostatectomy incontinence after a followup of 1 year.

*Key Words: myoblasts; fibroblasts; endoscopy; urinary incontinence, stress*

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*Characteristics of patients treated with autologous myoblasts and fibroblasts*

| | Preop | Postop Followup (1 yr) | p Value (Wilcoxon test) |
|---|---|---|---|
| Mean pt age ± SD | 68 ± 6.4 | | |
| Median incontinence score (range) | 6 (5–6) | 1 (0–5) | <0.001 |
| Median quality of life instrument score (range) | 52 (31–69) | 101 (59–110) | <0.001 |
| Mean mm urethra thickness | 3.5 ± 0.7 | 5 ± 1 | <0.001 |
| Mean mm rhabdosphincter thickness ± SD | 2.2 ± 0.4 | 3.3 ± 0.4 | <0.001 |
| Mean contractility of rhabdosphincter ± SD | 0.7 ± 0.3 | 1.2 ± 0.3 | <0.001 |
| Mean ml max residual urine ± SD | 49.5 ± 130.0 | 12.5 ± 67.0 | <0.001 |
| Mean ml/sec max urinary flow ± SD | 16.6 ± 6.7 | 18.3 ± 5.9 | <0.001 |
| Mean ml max bladder capacity ± SD | 420.0 ± 125 | 446.5 ± 128.0 | <0.570 |
| Mean cm $H_2O$ max detrusor pressure ± SD | 64.4 ± 11 | 56 ± 14.2 | <0.001 |
| Mean cm $H_2O$ max urethral closure pressure at rest ± SD | 42.9 ± 16 | 62.8 ± 11 | <0.001 |
| Mean cm $H_2O$ max urethral closure pressure at contraction ± SD | 95.6 ± 18.6 | 112.7 ± 8.5 | <0.001 |
| Mean cm $H_2O$ Valsalva leak point pressure ± SD | 46.3 ± 17.1 | 68.2 ± 24.3 | <0.001 |

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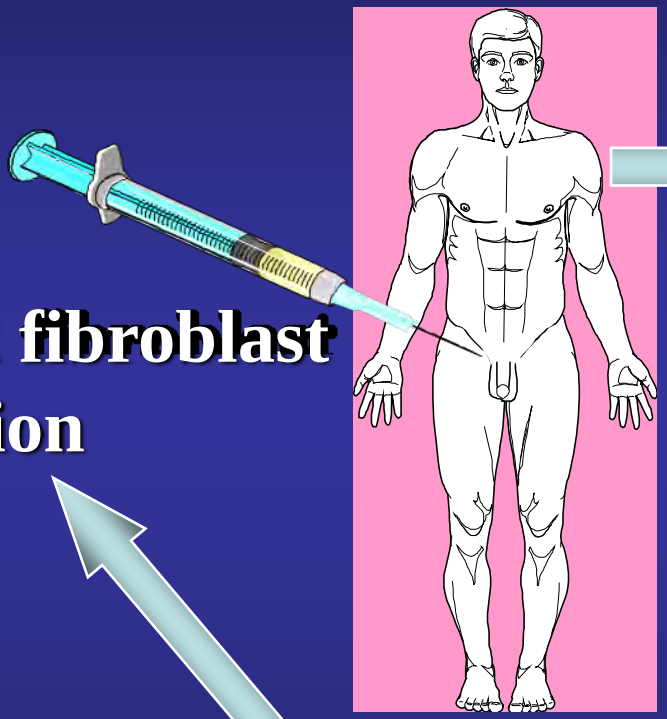
## ULTRASOUND GUIDED INJECTION OF STAMINAL CELLS IN URINARY INCONTINENCE TREATMENT



Myoblast and fibroblast injection

Muscle biopsy

Myoblast and fibroblast colture

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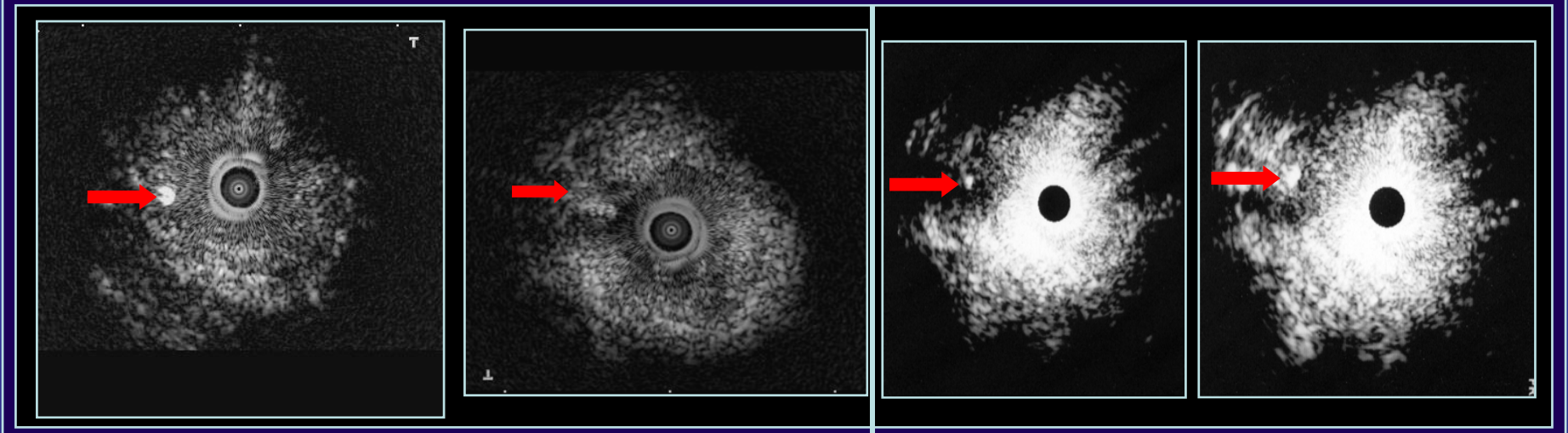
SUBMUCOSA

RHABDMYOSPHINCTER



SUBMUCOSA

RHABDOMYOSPHINCTER

**LOW DOSES (50-100 µl)**

# The future

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