

An update on male slings

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Facts

Post-RP stress urinary incontinence (SUI)

- affects 2% to 45% of the patients, depending on the definition used
- alters the QoL and is a frustrating condition for both the patient and the physician
- is treated initially conservatively using physiotherapy and surgically when conservative treatments fail

Historical background

Brantley F. Scott
Baylor College of Medicine,
Houston, Texas 1973

Artificial urinary sphincter

Historical background

Urethra compression devices:
- dynamic: AUS
- fixed or adjustable: slings

1970 1973 > 1990

Kaufman prostheses Scott's internal artificial sphincter Sling procedures

Historical background

Anthony J. Schaeffer
Northwestern University Medical
School, Chicago, Illinois, 1998

Male bulbo-urethral sling:

- retropubic passage
- 3 bolsters of vascular graft material (PTFE)

- 64 patients mainly severe SUI
- median followup of 18 months
- 56% cured (75% after retightening procedure in a quarter of the patients)
- lower rate of success in irradiated patients
- revision, erosion and infection rates were 27%, 6%, and 3% /
- lower results after radiation therapy
- J Urol 159:1510-15, 1998

Historical background

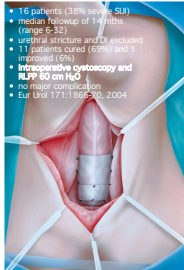
- 9 patients mainly severe SUI
- mean followup of 14 months (range 12-20)
- retightening under local possible
- 5 patients cured, 2 improved, 2 unchanged
- no mesh removal
- Eur Urol 43:152-7, 2003

R. Migliari & M. De Angelis
Arezzo, Italy, 2003

Male bulbo-urethral sling:

- retropubic passage
- 5 x 4 cm polypropylene mesh

Historical background

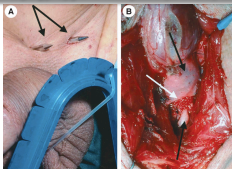


- 16 patients (38% severe SUI)
- median follow-up of 14 months (range 5-32)
- urethral stricture and/or excluded
- 13 patients cured (80%); need improved (6%)
- retroperitoneal cystoscopy and RLEP 80 cm H₂O
- no major complications
- Eur Urol 17(1):89P-90, 2004


Hubert John
University of Zürich, Zürich, Switzerland, 2004

Composite suspension:

- porcine dermal collagen patch (Pelvicol®)
- & polypropylene retropubic (Uretex®) sling



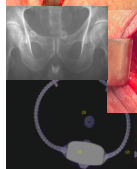
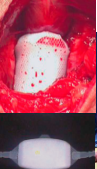

Historical background



Salomon V. Romano & colleagues
Buenos Aires, Argentina 2005

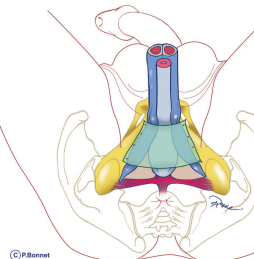
'Readjustable' retropubic sling

- silicone foam pad + silicone columns + silicone washers for adjustment

Argus® (Promedon SA)

Historical background




Shahar Madjar & coll.
Haifa, Israël, 2001

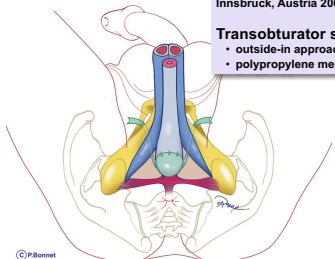
Craig V. Comiter
Tucson, Arizona, USA, 2002

Perineal bone-anchored sling:

- screws pre-attached with polypropylene sutures
- trapezoid mesh of synthetic material or cadaveric fascia
- indicated only in mild to moderate SUI patients




Historical background



Peter Rehder & Christian Gozzi
Innsbruck, Austria 2007

Transobturator sling:

- outside-in approach
- polypropylene mesh with 2 arms



Why transobturator bulbourethral slings for the treatment of post-RP SUI?

Transobturator male slings are conceptually attractive since:

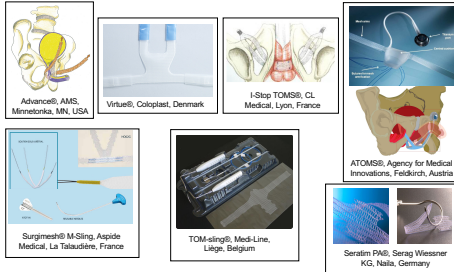
<ul style="list-style-type: none"> - they're not mechanical - they're less expensive 		<p><i>versus</i> artificial sphincter</p>
<ul style="list-style-type: none"> - they don't require bone anchoring 		<p><i>versus</i> bone-anchored slings</p>
<ul style="list-style-type: none"> - they don't enter the pelvis 		<p><i>versus</i> retropubic slings</p>
<ul style="list-style-type: none"> - they allow for physiologic voiding without significant obstruction 		

Clemens JQ et al. Urodynamic analysis of the bulbourethral sling procedure. J Urol 1999
Schaeffer AJ. Prostactomy incontinence. J Urol 2002

The transobturator approach for male slings: Requirements

1. **Anatomic considerations:**
 - pass around ischio-pubic ramus (instrumentation)
 - avoid pelvis (bladder & bowel perforations)
2. **Tension required & must be maintained: no loosening !**
 - ≠ tension-free tapes : Velcro effect not sufficient
3. **Erosion !**
 - appropriate material with correct placement
4. **Concomitant or additional surgery**
 - possibility of placing an AUS in case of sling failure
 - possibility to insert penile prostheses

Transobturator bulbourethral slings : Commercially available kits



Transobturator bulbourethral slings : Mechanisms of action

- Repositioning the lax and descended supporting structures of the sphincter to the former preoperative position (...but postop. retention can occur)
- Bulbar urethra compression (evidenced by urethroscopy)

Transobturator bulbourethral slings : Techniques

Two approaches:

- Outside-in : **Peter Rehder & Christian Gozzi**
Innsbruck, Austria
European Urology 2007 & 2012
ADVANCED®, American Medical Systems
I-STOP TOMS®, CL Medical
ATOMS®, Agency for Medical Innovations
SERATIM®, Serag Weisner
SURGIMESH® M-Sling, Aspide Medical
- Inside-out : **Jean de Leval & David Waltregny**
Liège, Belgium
European Urology 2008 & 2012
TOM-Sling®, Medi-Line
Victor Nitti & Creg Comiter
NY, USA
VIRTUE® (4 arms), Coloplast



Transobturator male slings: clinical evidence

	No. of patients	Patients with ≥5-6 pads/d (%)	Cured (%)	Improved (%)	Sling tensioning technique	Followup (months)	Reference
ADVANCE	20	65	40	30	urethral bulb elevation	1.5	Rehder & Gozzi Eur Urol 2007
	37	51	52	38	urethral bulb elevation	3	Gozzi & al Eur Urol 2008
	42	NR	17	55	NR	mean = 23	Bartsch & al AJUA 2008
	70	49	41(10*)	26	sphincter showing passive contraction of the whole circumference on urethroscopy	12	Bauer & al Eur Urol 2009
	102	0	63	18	same as Rehder & Gozzi Eur Urol 2007	mean = 13	Comu & al Eur Urol 2009
	35	31	9	45	at least 2 cm urethral bulb elevation	12	Cornel & al J Urol 2010
	118	0	74	17	same as Rehder & Gozzi Eur Urol 2007 but change to technique (Bismuth)	12	Rehder & al BJU Int 2010
	137	31	51	25	sphincter showing passive contraction of the whole circumference on urethroscopy	mean = 27	Bauer & al BJU Int 2011
	26	43	62	27	same as Rehder & Gozzi Eur Urol 2007 but proximal relocation of bulb into pelvic outlet at 4 cm & tunneling mesh pulled to elevate the bulb & to relocate it up under the bladder neck	median = 22	Berger & al Int Braz J Urol 2011
	136	0	62	16	bulb & to relocate it up under the bladder neck	mean = 21	Comu & al BJU Int 2011
	156	35	53	24	same as Rehder & Gozzi Eur Urol 2007	mean = 40	Rehder & al Eur Urol 2012
	32	25	56	22	same as Rehder & Gozzi Eur Urol 2007	median = 9	Mueller & al ISRN Urol 2012

Transobturator male slings: clinical evidence

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TOMS	20	40	45	40	ALPP ≥ 100 cm H ₂ O	6	de Leval & Waltregny Eur Urol 2008
	55	41	54	34	ALPP ≥ 100 cm H ₂ O	12	Waltregny & al ICS 2009
	173	44	49	35	ALPP ≥ 100 cm H ₂ O	mean = 25	Lenz & al Eur Urol 2012
P	50	0	30	32	arms pulled to see a 2-mm visible mark on the bulbospongiosus muscle	12	Grise & al Int Braz J Urol 2009
	69	7	59	20	arms pulled to see a 2-mm visible mark on the bulbospongiosus muscle	12	Grise & al Urology 2012
ATOMS	99	49	30	32	postoperative adjustments using 2 ml of saline solution starting 6 wks after implantation and then every 6 wks until desired result (dryness, improvement and/or patient satisfaction) reached	mean = 18	Hoda & al BJU Int 2012
	ND	ND	ND	ND	ND	ND	ND

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	<ul style="list-style-type: none"> • Variability in sling tensioning techniques: bulb elevation (how much?), urethroscopy, mark on bulbo-spongiosus muscle, adjustments, intraoperative urodynamics... • Variability in surgical techniques: bulbospongiosus muscle dissection, perineal body section, number of stitches, subcutaneous tunneling, number of arms, width of the mesh, shape of passers, TO approach, ... 							

Transobturator male slings: clinical evidence

No. of patients	Patients with ≥5-6 pads/d (%)	Cured (%)	Improved (%)	Definition of cure & improvement	Followup (months)	Reference
20	65	40	30	0 pads/d, 1 pad/d	1.5	Rahbar & Gozzi Eur Urol 2007
37	51	52	38	0 pads/d, ≤ 2 pads/d	3	Gozzi & al Eur Urol 2008
42	NR	17	55	0 pads/d, ≤ 2 pads/d	mean = 23	Bartsch & al AJUA 2008
70	49	41(10P)	26	0 pads/d or 1 dry security pad/d, ≤ 2 pads/d or ≥ 50% pad reduction	12	Bauer & al Eur Urol 2009
102	8	63	18	0 pads/d or 1 dry security pad/d, ≤ 2 pads/d and ≥ 50% pad reduction	mean = 13	Comu & al Eur Urol 2009
35	31	9	45	0 pads/d or 1 nonconcomitant pad/d, ≥ 50% pad reduction	12	Cornel & al J Urol 2010
118	8	74	17	0 pads/d or 1 dry security pad/d, ≤ 2 pads/d and ≥ 50% pad reduction	12	Rahbar & al BJU Int 2010
137	31	51	25	0 pads/d or 1 dry security pad/d, ≤ 2 pads/d or ≥ 50% pad reduction	mean = 27	Bauer & al Int Braz J Urol 2011
26	43	62	27	0 pads/d, ≤ 2 pads/d	median = 22	Berger & al Int Braz J Urol 2011
136	8	62	16	0 pads/d, ≥ 50% pad reduction	mean = 21	Comu & al BJU Int 2011
156	35	53	24	0 pads/d or 1 dry security pad/d, ≤ 2 pads/d and ≥ 50% pad reduction	mean = 40	Rahbar & al Eur Urol 2012
32	25	56	22	0 pads/d, ≤ 2 pads/d or ≥ 50% pad reduction	median = 9	Mueller & al ISRN Urol 2012
25	NR	32	24	0 pads/d, ≤ 2 pads/d	mean = 29	Li & al J Urol 2012
69	20	22	29	1 safety pad or less/d, ≥ 50% pad reduction	mean = 32	Siegler & al Prog Urol 2013
102	35	40	22	1 dry safety pad or less/d, ≥ 50% pad reduction & or satisfaction	mean = 36	Zuckerman & al Urol 2014

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173	44	49	35	0 pads/d, ≤ 2 pads/d and ≥ 50% pad reduction	mean = 25	Leruth & al Eur Urol 2012
50	8	30	32	0 pads/d, 1 pad/d	12	Grise & al Int Braz J Urol 2009
69	7	59	20	0 pads/d, 1 pad/d	12	Grise & al Urology 2012
29	3	21	38	0 pads/d, 1 pad/d	3	Ej-Jemane & al Prog Urol 2014
99	49	63	29	0 pads/d, ≤ 2 pads/d or ≥ 50% pad reduction	mean = 18	Hoda & al BJU Int 2013
ND	ND	ND	ND	ND	ND	ND

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- Variability in definitions of cure and improvement used
- Variability in selection of patients:
 - %age of pts with mild/moderate vs severe SUI
 - %age of pts with irradiation and/or urethral stricture
- Variability in cure & improvement rates, even with the same device (e.g. Advance®)
- Short followup (1.5 to 36), usually ± 1 year, max 3 years
- Longer followup: reduction in cure rates ? (shown for I-Stop®: 77% 0-1 pad @ 1y → 22% @ 5 y)
- Small cohorts of patients

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156	35	53	24	0 pads/d or 1 dry security pad/d, ≤ 2 pads/d and ≥ 50% pad reduction	mean = 40	Rahbar & al Eur Urol 2012
32	25	56	22	0 pads/d, ≤ 2 pads/d or ≥ 50% pad reduction	median = 9	Mueller & al ISRN Urol 2012
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- Longest series (2-3 years follow-up):
 - ± half "cured" (no pad or 1 security pad)
 - ± a third "improved" (reduction ≥ 50% in pads/d)
 - ± 10%-20% failed

TOM-Sling®: Impact of risk factors on failure rates – consecutive cohort of 156 patients

	Failure rate		
Radiation therapy	71.4% (15/21)	9.6% (13/135)	No radiation therapy
Concomitant urethrotomy	75.0% (6/8)	14.9% (22/148)	No concomitant urethrotomy
Urethral stenosis	35.5% (11/31)	16.8% (17/125)	No urethral stenosis
BMI ≥ 30	37.5% (9/24)	14.4% (19/132)	BMI < 30
Severe SUI	24.3% (18/74)	12.2% (10/82)	Mild/moderate SUI
Severe SUI excluding pts with RxT or urethral stenosis	8.3% (4/48)	3.3% (2/61)	Mild/moderate SUI excluding pts with RxT or urethral stenosis

Transobturator male slings: clinical evidence

Risk factors for failure:

1. Pelvic radiation therapy: major risk factor... (before & after the sling surgery !)
2. Urethral stenosis: should be treated first
3. Severe incontinence (> 5 pads/d): debated
4. Post-TURP SUI (as compared with post-RP SUI)
5. Previous surgery for post-RP SUI
6. No intraoperative "urodynamics" (RLPP, MUP, ALPP...)
7. Detrusor overactivity: difficult cases... (importance of micturition diary and penile clamp)

Transobturator male slings: clinical evidence

For whom, how and how to counsel ?

- **Selection of patients ?**
 - Mild to moderate SUI ?
 - Exclusion criteria ? **Radiation therapy, untreated urethral stricture, DO, post-TURP SUI...** ?
- **Surgery: standardization...**
 - Which sling ? No head to head comparison...
 - Technique standardization: Urodynamics ? Which parameters ?
- **Long term results ?** Decline with time ? Not unexpected because "native" sphincter still in place... old patients...
- **Loss of chance ?** AUS in case of failure, penile implant...

Flexible urethroscopy was performed to evaluate the sphincter function and the mobility of the posterior urethra. During urethroscopy, the "repositioning" test was done to simulate sling function. Repositioning and elevation of the posterior urethra can be achieved by perineal pressure. Patients who showed no sphincter contraction in this test were excluded from the study. Patients with sphincter contraction but not total sphincter closure were included. In clinical practice under real life conditions, functional sling is effective regardless of the degree of SUI if no intrinsic sphincter deficiency is present.

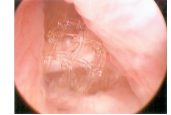
Transobturator male slings: clinical evidence

Complications:

- Pain (perineal and scrotal): frequent, mostly transient
- Retention: 5%-15%, mostly transient
- Bleeding/hematoma: rare
- Urethra/bladder erosion: very rare
- Sling infection:
 - very rare with fixed slings
 - not infrequent with adjustable slings (Reemex®, Argus®, ATOMS®): 5-20% explantation rate

Case Report Urethral Erosion of Transobturator Male Sling

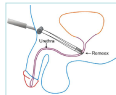
Prosser J, Turner, McNeil, Grahame, and P. G. O'Connell



Transobturator male slings: clinical evidence

The Panel of the 2018 EAU guidelines on Urinary Incontinence has issued the following recommendations regarding readjustable male slings (LE 3):

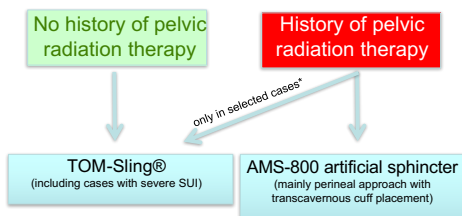
- there is limited evidence that readjustable male slings can cure or improve SUI in men
- there is limited evidence that early explantation rates are high
- there is no evidence that readjustability of the male sling offers additional benefit over other types of sling



Transobturator male slings: Conclusions

1. Full workup before implantation (history, diary, urodynamics, endoscopy)
2. Efficient and safe in selected patients (no radiation therapy)
3. Few complications (less than with AUS)
4. No loss of chance (AUS implantation if failure)
5. Possibility to insert penile prostheses concomitantly to the sling procedure
6. Long term FU and comparative studies needed...

Our algorithm for the surgical treatment of post-RP male SUI



Selected cases: non obese, no urethral stenosis, and only mild stress urinary incontinence