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Publication	Study Overview	Key Findings	Monarc	TVT	Test for non-inferiority	
<p>Transobturator Tape Compared With Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial</p> <p><i>Obstetrics & Gynecology</i> March 2008</p> <p>Authors: M. Barber S. Kleeman M. Karram M.F.R. Paraiso M. Walters S. Vasavada M. Ellerkmann</p>	<p>Randomized controlled non-inferiority trial of Monarc vs. TVT</p> <p>Patients enrolled Nov 2004-Jan 2006</p> <p>170 patients implanted</p> <p>TVT=88 Monarc=82</p> <p>95% (162/170) patients available for follow-up with mean follow-up of 18.2±6 months</p>	Negative Cough Stress Test at 1-year	87.3%	92.4%	0.033	
		Incontinence severity				
		Dry	62.3%	58.8%	.007	
		Slight	11.7%	14.1%		
		Moderate	16.8%	11.8%		
		Severe	9.1%	15.3%		
		Bladder perforations	0%	7%	0.02 (p-value)	
		Urinary retention ≥ 6 weeks or need for sling release or urethrolisis	2.6%	5.8%	0.003	
		Required retreatment for SUI	1.3%	4.7%	0.002	
		Primary outcome, abnormal bladder function*	42.7%	46.6%	0.006	
Participants who were classified as "dry" (ISI classification)	62.3%	58.8%	0.007			
<p>*a composite outcome assessed 12 months after surgery and defined as the presence of any of the following: 1) incontinence symptoms of any type (ISI score greater than 0), 2) a positive cough stress test, 3)retreatment for stress urinary incontinence, or 4) post-operative urinary retention.</p> <p>Additional Key Findings:</p> <p>Similar results between the two groups for: Mean operating time; blood loss; length of stay; post-operative pain</p> <p>No difference between the two groups for Quality of Life and sexual function</p> <p>Conclusion:</p> <p>"The transobturator tape is not inferior to TVT for the treatment of stress urinary incontinence and results in fewer bladder perforations."</p>						

Publication	Study Overview	Key Findings	Monarc	TVT	p-value
<p>Peri-operative Complications and Adverse Events of the Monarc Transobturator Tape, Compared to the Tension-Free Vaginal Tape</p> <p><i>Am J Obstet Gyn</i> 2006</p> <p>Authors: M.D. Barber A.M. Gustilo-Ashby C.C.G. Chen P. K. Kaplan M.F. R. Paraiso M.D. Walters</p>	<p>Retrospective study</p> <p>418 patients implanted TVT=213 Monarc=205</p>	Bladder perforation	0%	5%	0.004
		Required urethrolisis	1.5%	7%	N/A
		Underwent repeat procedure	1.5%	2.4%	0.51
		Patients use anticholinergic meds	6.4%	13.6%	0.046
		Mesh erosion	0.5%	1%	0.99
<p>Additional Key Findings:</p> <p>Vaginal erosion, major bleeding, retropubic hematoma and nerve injury were not significantly different between groups</p> <p>Conclusion:</p> <p>"Transobturator tape is associated with a lower rate of bladder injury, a decreased incidence of post-operative anticholinergic medication use, and fewer urethrolyses for post-operative voiding dysfunction or urinary urgency than tension-free vaginal tape."</p>					

Publication	Study Overview	Key Findings	Monarc	TVT	p-value
<p>A Multi-Centre, Randomised Clinical Control Trial Comparing the Retropubic (RP) Approach Versus the Transobturator Approach (TO) for Tension-Free, Suburethral Sling Treatment of Urodynamic Stress Incontinence: The TORP Study</p> <p><i>Int Urogynecol J 2007</i></p> <p>Authors: C. Barry Y.N. Lim R. Muller S. Hitchins A. Corstiaans A. Foote H. Greenland M. Frazer A. Rane</p>	<p>Prospective single-blinded multi-centre randomized clinical</p> <p>187 patients implanted TVT=107 Monarc=80</p> <p>Follow up: 3 months (82 TVT; 58 Monarc)</p>	Bladder perforation	0%	8.5%	<0.05
		Urethral perforation	1.7%	0%	0.42
		Bowel injury	0%	0%	0
		Major hemorrhage	0%	0%	0
		Nerve entrapment	1.5%	0%	0.53
		Retropubic hematoma	0%	1.5%	0.53
		Retention of urine catheter > 2 days	8.6%	17.1%	0.21
		Sling protrusion	5.2%	1.2%	0.11
		Sling division	1.7%	3.7%	0.88
		Urinary tract infection	15.5%	13.4%	0.81
		Overactive bladder (new)	0%	1.2%	0.57
		Estimated blood loss (ml)	48.7	63.7	<0.05
		Hospital stay (days)*	0	0	0.35
		Return to activity (days)*	3 (2/6)	5 (3/6)	0.009
		Satisfaction	83%	85%	0.66
<p>*definition in study is unclear</p> <p>Conclusion: "The transobturator tape appears to be as effective as the retro-pubic tape in the short term, with a reduction in the risk of intra-operative bladder injury, shorter operating time, decreased blood loss, and quicker return to usual activities."</p>					

Publication	Study Overview	Key Findings	Monarc	TVT	SPARC	p-value
<p>Detrusor Overactivity and Urge Urinary Incontinence Following Transobturator Versus Midurethral Slings</p> <p><i>Neurourol Urodyn 2007</i></p> <p>Authors: S.M. Botros J.J. R. Miller R. P. Goldberg S. Gandhi M. Akl J. L. Beaumont P. K. Sand</p>	<p>Retrospective study</p> <p>276 patients implanted</p> <p>TVT=99 patients SPARC=52 patients Monarc=125 patients</p>	Detrusor Overactivity (DO)				
		Pre-operative DO	65%	58%	62%	0.612
		Resolution of DO at 3 months	48%	40%	32%	0.39
		<i>De novo</i> DO at 3 months	22%	32%	22%	0.67
		Urge Urinary Incontinence (UUI)				
		Pre-operative UUI	64%	66%	61%	0.682
		Resolution of UUI at 9 months	65%	48%	43%	0.081
		<i>De novo</i> UUI at 9 months	8%	32%	19%	0.041
		<p>Conclusion: "Patients who undergo transobturator procedures have significantly lower rates of <i>de novo</i> UUI than those who undergo midurethral sling procedures. Rates of resolution of DO, UUI and <i>de novo</i> DO not differ between groups."</p>				

Publication	Study Overview	Key Findings	Monarc	TVT-O	p-value
<p>Complications and Short-Term Results of Two Different Transobturator Techniques for Surgical Treatment of Women with Urinary Incontinence: A Randomized Study</p> <p><i>Int Urogynecol J 2008</i></p> <p>Authors: I. But M. Faganelj</p>	<p>Prospective, randomized, head-to-head comparative study</p> <p>120 patients implanted TVT-O=60 Monarc=60</p> <p>Follow-up: average 15.7 weeks (11-30 week range)</p>	Pain during procedure (VAS score 0-10)	3.0	4.7	0.00015
		Pain on discharge (VAS score 0-10)	2.2	2.6	0.15
		Days of post-operative pain	7.5	21.6	0.033
		Pain intensity (0-3)	1.3	1.9	0.000
		Extensive hematoma in region of right thigh		1	N/A
		Extensive hematoma in region of the labia majora		1	N/A
		Moderate hemorrhage	2(3%)	2(3%)	N/A
		Operative failure	2	1	N/A
		Satisfaction score	88.7%	90.7%	0.96
		Stress pad test (g)	0.05	0.92	0.23
		Vaginal erosions	0	0	N/A
		Vaginal wall perforation	3(5%)		N/A
		Minor vaginal mucosa tears	6(10%)	1(1.7%)	N/A
		Difficulty voiding	3	5	0.42
Urinary infections	5	10	N/A		
<p>Conclusion:</p> <p>"...inside-out and outside-in procedures are equally successful methods for the treatment of urinary incontinence at 4 months, however, inside-out procedure appears to be more painful."</p>					

MONARC CLINICAL STUDY SUMMARY

Publication	Study Overview	Key Findings	Monarc	TVT	p-value
TVT vs Monarc: A Comparative Study	Retrospective cohort study	Cure/Improvement	94.8% (55/58)	73.2% (41/56)	0.0018
		Subjective Satisfaction	81.0% (47/58)	58.9% (33/56)	0.014
<i>Int Urogynecol J 2006</i>	114 patients implanted TVT-O=56 Monarc=58				
Authors: H.P. Dietz C. Barry Y. Lim A. Rane	Follow-up: 9 months				
		Additional Key Findings: Monarc seems to have less effect on voiding and is associated with less post-operative urge incontinence			
		Conclusion: "...the Monarc is an effective TVT alternative, achieving cure of stress incontinence by similar means. It may be less obstructive, resulting in improved patient satisfaction."			

Publication	Study Overview	Key Findings	Monarc	ObTape
High Rate of Vaginal Erosions Associated with the Mentor ObTape™	Prospective, non-randomized study	Patients with sling erosions	0% (11.55 months follow-up)	13.4% (16.39 months follow-up)
<i>J Urol 2006</i>	123 patients implanted Monarc=56 ObTape=67	Conclusion: "...high rate of vaginal extrusion using ObTape™ has caused us to discontinue the use of this product in our institution."		
Authors: B.S. Yamada F.E. Govier K.B. Stefanovic K.C. Kobashi				

Publication	Study Overview	Key Findings
In Vitro Comparison of Suburethral Sling Materials	Comparison of 3 branded meshes in animal study	Frequent and extensive capsular linkages through the Monarc mesh effectively integrated the fabric with adjacent tissues
<i>Int Urogynecol J 2006</i>		Mentor/Coloplast's Obtape™ -the tortuous, interrupted character of the pores prevented formation of any significant fibrous tissue bridges linking the outer capsule layers through the mesh
		Tyco IVS™-the closely packed filaments in each yarn did not allow any capillary in-growth
Authors: M. Slack J.S. Sandhu D.R. Staskin R.C. Grant	Conclusion: "The much larger diameter monofilament and open knit structure of the Monarc sling permitted the most extensive fibrous tissue integration."	

Publication	Study Overview	Key Findings	Monarc		p-value
<p>Multicenter Experience with the Monarc® Transobturator Sling System to Treat Stress Urinary Incontinence</p> <p><i>Int Urogynecol J 2006</i></p> <p>Authors: G. W. Davila J.D. Johnson S. Serels</p>	Retrospective study		Baseline	26 weeks	N/A
	200 patients implanted	Cure Rate		95.3%	N/A
		Pad Use (per day)	1.7	0.13	N/A
		Urge	62.7%	20.5%	0.0001
	Follow up: 26 weeks (112 patients)	<p>Additional Key Findings:</p> <p>No bladder, bowel, blood vessel or urethral perforations noted</p> <p>Each of the following complications occurred in a single patient: atrial fibrillation, acute congestive heart failure, gluteal hematoma, self-limiting ileus, temporary urethral pain, self-limiting oozing at the right groin site</p> <p>5 patients had lower extremity pain lasting less than 5 days</p> <p>1 patient had exposed mesh which healed spontaneously</p> <p>1 patient underwent additional procedure with collagen bulking</p> <p>1 patient had voiding abnormalities at 26 weeks</p> <p>Mean operative blood loss 66 ml</p> <p>Conclusion:</p> <p>“Transobturator slings are highly effective for treatment of SUI, and may offer increased safety relative to traditional and tension-free retropubic slings.”</p>			

Publication	Study Overview	Key Findings
<p data-bbox="167 317 437 422">Prospective Multicentre Trial of Monarc Transobturator Sling for Stress Incontinence: 24 Month Functional Data</p> <p data-bbox="167 478 288 506"><i>Eur Urol</i> 2006</p> <p data-bbox="167 558 248 585">Authors:</p> <p data-bbox="167 596 288 623">D. De Ridder</p> <p data-bbox="167 634 280 661">B. Jacquetin</p> <p data-bbox="167 672 260 699">A. Fischer</p> <p data-bbox="167 709 316 737">P. Debodinance</p> <p data-bbox="167 747 400 774">A. Marques-Queimadelos</p> <p data-bbox="167 785 272 812">C. Courtieu</p> <p data-bbox="167 823 272 850">M Cervigni</p> <p data-bbox="167 861 252 888">J. Rassler</p> <p data-bbox="167 898 240 926">A. Rane</p> <p data-bbox="167 936 285 963">S. Herschorn</p> <p data-bbox="167 974 252 1001">G. Urwin</p> <p data-bbox="167 1012 264 1039">W. Goetze</p> <p data-bbox="167 1050 260 1077">S. Ouellet</p> <p data-bbox="167 1087 280 1115">M. Schrader</p> <p data-bbox="167 1125 256 1152">G. Mellier</p>	<p data-bbox="467 317 687 344">148 patients implanted</p> <p data-bbox="467 354 671 382">127 patients followed for 2 years</p>	<p data-bbox="730 317 1417 371">Objective measure: post-operative cough stress test was negative in 87.6% of patients</p> <p data-bbox="730 382 1187 409">7% of patients remained substantially incontinent</p> <p data-bbox="730 420 1337 474"><i>De novo</i> urgency seen in 11.5% of pts while 27.9% of patients with pre-operative urge symptoms were relieved of their urgency</p> <p data-bbox="730 512 879 539">Adverse events:</p> <ul data-bbox="730 550 1437 995" style="list-style-type: none"> • 7% patients had UTI • 6% patients had urge • 4% patients had retention • 4% patients had pain • 3% patients had recurrent SUI • 2% patients had increased PVR • 1% patients had urge incontinence • 1% patients had erosion • 0.7% of patients had 1 each of dyspareunia, device malfunction, cystitis, vaginal discharge, vaginal infection, vaginal scar tissue, urethral obstruction, urethral trauma, insufficient suture/sling perforation • 18% of patients had device related adverse events <p data-bbox="730 1005 839 1033">Conclusion:</p> <p data-bbox="730 1043 1426 1098">"24-month data show that Monarc transobturator sling successfully restores continence in women with SUI."</p>

Publication	Study Overview	Key Findings	Monarc	
<p>A Combined Analysis of the Safety and Efficacy of the Monarc® Transobturator Hammock at 12 Months Follow-up in Two Prospective Studies in Nine Countries with 272 Patients</p> <p><i>Int Urogynecol J 2006</i></p> <p>Authors: R.D. Moore B. Jacquetin D. Knoll P. DeBodinace M. Dupont A. Fischer A. Marques-Queimadelos C. Courtieu J. Miklos</p>	<p>2 prospective studies with 1 year data</p> <p>272 patients implanted</p> <p>221 patients followed for 1 year</p>		Baseline:	1 year:
		Positive CST	91.8%	7.8%
		1-h pad weight test (average)	50.2 g	7.2 g
		Pad use (per day)	2.7	0.5
		<p>Additional Key Findings:</p> <p>99.3% of patients went home without a catheter</p> <p>Urge symptoms resolved in 26.8% of patients</p> <p>16.7% of patients developed <i>de novo</i> urge</p> <p>15.6% of patients had possible device related complications: 6.0% UTIs/Cystitis, 2.3% extrusion, and 3.8% urge symptoms</p> <p>Mean blood loss 37 ml</p> <p>Conclusion:</p> <p>"The transobturator approach is a safe and effective method for treating stress urinary incontinence (92.2% of patients in this study had a negative cough stress test at 12 months post-op). There were no major complications reported including no bladder, bowel, or vascular perforations."</p>		

Publication	Study Overview	Key Findings
<p>An Anatomical Study of the Obturator Foramen and Dorsal Nerve of the Clitoris and their Relationship to Minimally Invasive Slings</p> <p><i>Int Urogynecol J 2006</i></p> <p>Authors: C. Achartari B.J. Mckenzi R. Hiscock A. Rosamilia L. Schierlitz C.A. Briggs P. L. Dwyer</p>	<p>10 embalmed hemipelves Devices studied: TVT, TVT-O, Monarc</p>	<p>The mean distance from the obturator canal was greatest with the TVT device (40±4 mm) compared to the TVT-O (19±3 mm) and Monarc (27±4 mm)</p>
		<p>There was no significant difference in distance to the dorsal nerve of the clitoris, with Monarc possibly being the safest given its outside-in course</p>
		<p>Conclusion: "Given the course of the DNC (dorsal nerve of the clitoris) along the medial aspect of the ischiopubic ramus the out-in technique may be safer. The in-out technique came closest to the obturator canal."</p>

Publication	Study Overview	Distance from the obturator canal	TVT-O	TOT
<p>Transobturator Surgery for Female Stress Incontinence: a Comparative Anatomical Study of Outside-In vs Inside-Out Techniques</p> <p><i>BJU Intl 2007</i></p> <p>Authors: J.P. Spinosa P.Y. Dubuis B.M. Riederer</p>	<p>7 fresh female cadavers</p> <p>5 cadavers fitted with one tape using standard outside-in technique, and with one tape using the inside-out (TVT-O) technique, alternating sides between successive specimens</p> <p>2 cadavers had bilateral implants - 1 each of the outside-in tape and of the inside-out tape.</p>	Severed	1	0
		<1	4	0
		1-3	1	0
		Not found	1	1
<p>Additional Key Findings:</p> <p>TVT-O: VASC (deep external pudendal vascular structures) was identified 4 times at a distance of <1 cm, once at > 1 cm and once severed Mean distance between the TVT-O and POSTB (posterior branch) was 0.9 cm With TVT-O the surgical risk is affected by the position of the patient; due to fixed exit points and a longer distance of blind tape routing</p> <p>TOT: Distance between the VASC and the tape was always > 3 cm With TOT the tape was always >2.1 cm from the POSTB With TOT the surgical risk is unaffected by the position of the patient</p> <p>Conclusion: "The two techniques are not equivalent, with a lower risk of injury to vascular and nerve structures with the outside-in technique."</p>				

STUDY SUMMARY - ANATOMICAL

Publication	Study Overview	Distance Between the Transobturator Tapes and Obturator Canal According to Left and Right Side Placement																										
<p>Anatomic Comparison of Two Transobturator Tape Procedures</p> <p><i>Obstet Gynecol 2007</i></p> <p>Authors: C.M. Zahn S. Siddique S. Hernandez E. G. Lockrow</p>	<p>Monarc (outside-in) and TVT-O (inside-in) were placed bilaterally in 7 frozen cadaver specimens</p>	<table border="1"> <thead> <tr> <th>Side</th> <th>Procedure</th> <th>n</th> <th>Mean (cm)</th> <th>Standard Deviation</th> <th>P</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Left</td> <td>Outside-in</td> <td>7</td> <td>2.5</td> <td>0.32</td> <td rowspan="2">.001</td> </tr> <tr> <td>Inside-out</td> <td>7</td> <td>1.5</td> <td>0.42</td> </tr> <tr> <td rowspan="2">Right</td> <td>Outside-in</td> <td>7</td> <td>2.2</td> <td>0.49</td> <td rowspan="2">.010</td> </tr> <tr> <td>Inside-out</td> <td>7</td> <td>1.2</td> <td>0.42</td> </tr> </tbody> </table>	Side	Procedure	n	Mean (cm)	Standard Deviation	P	Left	Outside-in	7	2.5	0.32	.001	Inside-out	7	1.5	0.42	Right	Outside-in	7	2.2	0.49	.010	Inside-out	7	1.2	0.42
Side	Procedure	n	Mean (cm)	Standard Deviation	P																							
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		<p>Conclusion:</p> <p>“The outside-in technique results in the mesh being placed farther from the obturator canal and closer to the ischiopubic ramus, theoretically reducing the risk of neurovascular injury.”</p>																										

Transobturator Tape Compared with Tension-Free Vaginal Tape for the Treatment of Stress Urinary Incontinence

Barber M, Kleeman S, Karram M, Paraiso MF, Walters M, Vestavia S, Ellerkmann M

American College of Obstetricians and Gynecologists. Vol. 111, No. 3, March 2008

Purpose: The aim of this study was to compare the safety and efficacy of the transobturator tape (TOT) to tension free vaginal tape (TVT®) in the treatment of stress urinary incontinence in patients with and without concurrent pelvic organ prolapse using a non-inferiority designed study.

Materials and Methods: Subjects were randomized to receive TVT or TOT on the day of surgery. Of 180 subjects who enrolled in the study, 170 underwent surgery and 168 (98.8%) returned for follow-up, with a mean follow-up of 18.2 ±6 months. TVT or TOT alone was performed in 65 subjects (39%) while the remainder received additional surgical procedures.

Results: Mean operating time, blood loss, length of stay and post-operative pain scores were similar between the two groups. Bladder perforations occurred more frequently in the TVT group (7% vs. 0%, $p=0.2$), otherwise the incidence of peri-operative complications was similar between the two groups. TOT was not inferior to TVT for the primary outcome or any of the secondary efficacy outcome measures. The primary outcome, abnormal bladder function¹, occurred in 46.6% of TVT subjects and 42.7% of TOT subjects (mean difference: 3.9% favoring TOT (95% CI (-11% to +18.6%, $p=.006$)). One year after surgery, a negative cough stress test was demonstrated in 92.4% and 87.3% of subjects in

the TVT and TOT groups respectively ($p=.033$). SUI symptoms were reported post-operatively in 15% of both groups, $p=0.91$. Using the ISI classification, 58.8% of TVT and 62.3% of TOT subjects were classified as "dry" (ISI=0), while 14% had "slight" incontinence and 28% had "moderate" or severe" incontinence, $p=.90$. Urinary retention (catheterization ≥6 weeks after surgery or need for sling release or urethrolisis) occurred in 5.8% of the TVT group and 2.6% of the TOT group, $p=.003$. Re-treatment for SUI (surgery or bulking agent injection) occurred in 4.7% and 1.3% respectively, $p=.002$. HRQOL and sexual function improved in both groups with no differences between the groups.

Although several studies have previously compared TVT to TOT, none have had adequate sample size or length of follow-up to evaluate the equivalency or not inferiority of these two techniques. This multi-center trial demonstrates that TOT is not inferior to TVT by more than 15% with a mean follow-up of over 1 year. The primary outcome measure used in this study "abnormal bladder function" was chosen a priori in order to provide a measure that captures both efficacy and common lower urinary tract adverse events (e.g. prolonged urinary retention, *de novo* urge incontinence) consistent with the goals of the U.S. National Institute of Health consensus guidelines.

Conclusions: The Monarc TOT is not inferior to TVT for the treatment of urodynamic stress urinary incontinence and results in less bladder perforations.

Peri-operative complications were infrequent and similar between the two groups with the exception of bladder perforations which occurred more frequently in those who received a TVT.

¹ A composite outcome assessed 12 months after surgery and defined as the presence of any of the following: 1) incontinence symptoms of any type (ISI score greater than 0), 2) a positive cough stress test, 3)retreatment for stress urinary incontinence, or 4) post-operative urinary retention.

This study was funded in part by a research grant from American Medical Systems.

Peri-operative Complications and Adverse Events of the Monarc® Transobturator Tape, Compared with the Tension-Free Vaginal Tape

Barber MD, Gustilo-Ashby AM, Chen CCG, Kaplan PK, Paraiso MFR, Walters MD

Section of Urogynecology and Pelvic Reconstructive Surgery, Department of Obstetrics and Gynecology, Cleveland Clinic, Cleveland, OH

Am J Obstet Gynecol 2006 epub

Purpose: The objective of the study was to compare the incidence of peri-operative complications of the Monarc transobturator tape (TOT) with the tension-free vaginal tape (TVT) in women undergoing surgical treatment for stress urinary incontinence.

Materials and Methods: A retrospective review of all patients undergoing either a TOT or TVT between January 2003 and August 2005 was performed. The incidence of intra-operative and post-operative (6 weeks or less) complications was compared between groups.

Results: Two hundred five women underwent a TOT and 213 women underwent a TVT during the study period. TVT resulted in a significantly higher rate of bladder perforation than did TOT (11 of 213 [5%] versus 0 of 205 [0%], $P < .001$). Post-operatively, subjects who received TVT were significantly more likely to require urethrolysis for voiding dysfunction or urinary urgency (adjusted odds ratio 3.2 [95% confidence interval 1.2 to 10.1], $P = .026$) and more likely to use anticholinergic medications (adjusted odds ratio 2.1 [95% confidence interval 1.02 to 4.70], $P = .046$) than those who received a transobturator tape.

The overall rate of vaginal mesh erosion after surgery was low (0.7%) and not significantly different between the two groups. No mesh erosions into the urethra were noted. Three subjects in the TOT group (1.5%) and 5 subjects in the TVT group (2.4%) underwent repeat surgery or bulking agent injection for recurrent stress incontinence during the study period ($P = .51$).

In this study, we found a lower rate of voiding dysfunction and less post-operative use of anticholinergic medications in subjects who received a TOT than those who underwent a TVT. This is consistent with a sling that is less obstructive and may be a distinct advantage of the obturator approach.

Conclusions: The Monarc TOT is a safe procedure that may have a lower complication rate than the TVT, particularly with regard to bladder injuries and post-operative voiding dysfunction. Early reports of the efficacy of TOT are promising; however, whether its long-term efficacy is similar to that of the TVT or other standard continence operations is not currently known.

M.F.R.P. is a consultant for American Medical Systems Inc, (Minnetonka, MN) and a paid instructor for Ethicon Women's Health and Urology, Ethicon Inc (Somerville, NJ). M.D.W. is a paid instructor for American Medical Systems Inc (Minnetonka, MN).

Incidence of peri-operative complications

Complication	TOT (n=205)	TVT (n=213)	P value
Major bleeding*	9 (4)	4 (2)	.16
Retropubic hematoma	4 (2)	2 (1)	.44
Bladder injury/perforation	0 (0)	11 (5.1)	.004
Ureteral injury	1 (0.5)	0 (0)	.30
Bowel injury	0 (0)	0 (0)	1.00
Nerve injury	4 (2)	2 (1)	.44
Recurrent urinary tract infections	15 (7.4)	27 (12.7)	.08
Voiding dysfunction	6 (2.9)	19 (8.9)	.01
Leg/obturator complication	1 (0.5)	1 (0.5)	.89
Mesh erosion	1 (0.5)	2 (1)	.99

Presented as n (%)

* Defined as any post-operative hematocrit less than 24% or having received a blood transfusion

However, the anatomic orientation of the TOT may also have important implications on the efficacy of this procedure. A less obstructive sling may translate into a lower cure of stress incontinence.

Because of the retrospective nature of this study and the short-term follow-up, we made no attempt to compare the efficacy of TOT and TVT in our population.

A Multi-Centre, Randomised Clinical Control Trial Comparing the Retropubic (RP) Approach Versus the Transobturator Approach (TO) for Tension-Free, Suburethral Sling Treatment of Urodynamic Stress Incontinence: The TORP Study

Barry C, Lim YN, Muller R, Hitchins S, Corstiaans A, Foote A, Greenland H, Frazer M, Rane A

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Purpose: To compare the safety and efficacy of the transobturator tape (Monarc®, TOT) with the retropubic tape (tension-free vaginal tape, TVT®) for the treatment of urodynamic stress incontinence (USI) a prospective, single-blinded, multi-centre randomised clinical controlled trial was undertaken in four urogynaecology units in Australia.

Materials and Methods: One hundred and eighty seven women with USI were randomly allocated to undergo surgery with either the Monarc sling (n=80) or TVT (n=107). Outcome measures were intra-operative complications (especially bladder injury), as well as peri-operative complications, symptomatology, quality of life, incontinence impact and urodynamic outcomes.

Results: At 3 months, data were available on 140 women, 82 (59%) TVT and 58 (42%) Monarc. The TVT group was significantly more likely to be complicated by bladder injury (7 TVT, 0 Monarc, $p<0.05$). Blood loss and operative time were significantly less in the Monarc group, which was 49 mls (31) vs that of the TVT group, which was 64 mls (41) $p<0.05$; 18.5 min (6.5) TVT vs 14.6 min (6) Monarc ($p<0.001$). The subjective and objective stress incontinence cure rates were 86.6% (71) vs 72.4% (42) $p=0.77$ and 79.3 vs 84.5%, $p=0.51$ for the TVT and Monarc groups, respectively. Both groups reported similar improvement in incontinence impact and satisfaction with their operation, although return to activity was significantly quicker with the transobturator route ($p=0.029$). The transobturator tape appears to be as effective as the retro-pubic tape in the short term, with a reduction in the risk of intra-operative bladder injury, shorter operating time, decreased blood loss, and quicker return to usual activities.

Primary Outcome Variables

	TVT % (n)	Monarc % (n)	p value
Bladder perforation	8.5 (7)	0	<0.05
Urethral perforation	0	1.7 (1)	0.42
Bowel injury	0	0	0
Major hemorrhage	0	0	0
Nerve entrapment	0	1.5 (1)	0.53
RP haematoma	1.5 (1)	0	0.53

Comparison of immediate, and short term, complications after surgery. Significance level taken as $p<0.05$.

Post-operative Data for Complications and Return to Activity

	TVT % (n)	Monarc % (n)	p value
Retention of urine catheter >2 days	17.1 (14)	8.6 (5)	0.21
Sling protrusion	1.2 (1)	5.2 (3)	0.11
Sling division	3.7 (3)	1.7 (1)	0.88
UTI	13.4 (11)	15.5 (9)	0.81
New OAB	1.2 (1)	0 (0)	0.57
(quartiles)	median	median	
How long in hospital (days)*	0 (0/1)	0 (0/1)	0.35
Return to activity (days)*	5 (3/6)	3 (2/6)	0.009

Significance level taken as $p<0.05$
* Definition in study is unclear

Peri-operative Data

	TVT mean (SD)	Monarc mean (SD)	p value
Operative time (min)	18.5 (6.5)	14.6 (6.0)	0.001
Estimated blood loss (ml)	63.7 (41.4)	48.7 (31.2)	<0.05
	% (n)	% (n)	
Indwelling catheter at op	20.1 (17)	17.2 (10)	0.67
Vaginal pack	17.1 (14)	10.3 (6)	0.33

Significance taken as $p<0.05$

Conclusions: Both techniques appear to be safe with respect to major complications, although as these are rare events, this needs to be interpreted with caution. However, the main hypothesis with regards to bladder injury holds true, in that, bladder perforation appears to be more common for retropubic procedures. Whether clinicians feel that this is of significant morbidity to the patient to stop performing this procedure is a matter for debate. It does, however, provide further information with which to counsel patients pre-operatively. There was no significant difference in cure rates for stress incontinence between the two groups at 3 months.

Detrusor Overactivity and Urge Urinary Incontinence Following Transobturator Versus Midurethral Slings

Botros SM, Miller JJR, Goldberg RP, Gandhi S, Akl M, Beaumont JL, Sand PK.

NeuroUrol Urodyn 2007;26:42-45

Purpose: To compare the rates of resolution of detrusor overactivity (DO) and subjective urge urinary incontinence (UUI) as well as *de novo* DO and UUI between the Monarc, TVT, and SPARC midurethral sling procedures.

Materials and Methods: Two hundred and seventy-six subjects with urodynamic stress or mixed urinary incontinence underwent retropubic midurethral slings (TVT, N = 99; SPARC, N = 52) or transobturator slings (Monarc, N = 125). All evaluable subjects had a routine office evaluation, subjective assessment of UUI, and multichannel urodynamic testing pre-operatively and 3 months post-operatively. Comparisons were made using Student's t-test, ANOVA, McNemar's test, and Chi-Square test where appropriate. Multivariate logistic regression was performed to detect possible confounding factors such as sling type, and differences in concomitant surgical procedures.

Results: *De novo* subjective UUI differed significantly between the Monarc and the other two slings (33% TVT vs. 8% Monarc vs. 17% SPARC, P = 0.04). Fourteen to 16 percent of patients with pre-operative UUI who underwent TVT or SPARC had worsening of their UUI symptoms while only 6% of the Monarc group did (P=0.02). There was no difference in rates of resolution of DO among the three groups (40% vs. 48% vs. 32%, P = 0.39) or *de novo* DO (32% vs. 22% vs. 22%, P = 0.64) at 3 months.

Conclusions: Patients who undergo transobturator procedures have significantly lower rates of *de novo* UUI than those who undergo midurethral sling procedures. Rates of resolution of DO, UUI, and *de novo* DO do not differ between groups.

Rates of Pre-operative and Post-operative DO

	Pre-operative DO	3 months post-operative	
		Resolution of DO	<i>De novo</i> DO
TOT n = 125	76/117 (65%)	25/52 (48%)	5/23 (22%)
TVT n = 99	53/91 (58%)	14/35 (40%)	9/28 (32%)
SPARC n = 52	32/52 (62%)	8/25 (32%)	4/18 (22%)
P values	0.612	0.39	0.67

Rates of Pre-operative and Post-operative UUI

	Pre-operative UUI	9 months post-operative	
		Resolution of UUI	<i>De novo</i> UUI
TOT n = 125	79/125 (64%)	36/55 (65%)	3/37 (8%)
TVT n = 99	65/98 (66%)	24/50 (48%)	9/28 (32%)
SPARC n = 52	31/51 (61%)	12/28 (43%)	3/16 (19%)
P values	0.682	0.081	0.041

Complications and Short-Term Results of Two Different Transobturator Techniques for Surgical Treatment of Women with Urinary Incontinence: A Randomized Study

But I, Faganelj M

Clinical Department of General Gynecology and Gynecologic, Slovenia

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Purpose: The aim of the study was the analysis of peri-operative complications in women who were randomly assigned to receive two different techniques for the treatment of stress and mixed urinary incontinence.

Materials and Methods: Our study included 120 women in whom we performed either TVT-O or Monarc procedure in local anesthesia. The duration of the operation and its likely complications were followed up. The success of treatment was evaluated after 3 months. Surgical time was identical for both procedures (13 min). The prevalence of vaginal wall perforation and laceration was higher during the outside-in procedure. The inside-out procedure was more painful ($p < 0.000$), the pain persisted significantly longer (21.6 vs 7.5 days; $p = 0.03$) and was more intense after discharge in these patients.

Results: The quality of life of the women improved significantly after both procedures. The average satisfaction rate score (based on the modified visual analog scale) 4 months after surgery was 89.7%; there was no significant difference in satisfaction rate score between both procedures ($p = 0.96$), the mean scores for inside-out and outside-in procedure being 90.7% and 88.7%, respectively.

Peri-operative Evaluation of the Course of Monarc and TVT-O Procedures

	Monarc	Means TVT-O	Mann-Whitney <i>p</i> value
During the procedure:			
Local anesthesia (min)	3.9	4.1	0.06
Total operation time incl. anesthesia (min)	12.9	13.0	0.82
Pain during procedure (VAS score 0-10)	3.0	4.7	0.00015
After the procedure:			
No. of analgetic doses/patient (up to 6 hr post-op)	0.3	0.5	0.038
No. of analgetic doses/patient (up to 24 hr post-op)	0.7	0.9	0.21
PVR in the evening (ml)	106	111	0.53
Pain on discharge (VAS score 0-10)	2.2	2.6	0.15

Comparison of Some Clinical Parameters after Surgery

	Monarc	Means TVT-O	Mann-Whitney <i>p</i> value
Follow-up (weeks)	15.2	16.1	0.42
Days of post-op pain	7.5	21.6	0.033
Pain intensity (0-3)	1.3	1.9	0.0000
Number of pads	0.4	0.25	0.87
Stress pad test (g)	0.05	0.92	0.23
Relative Q-tip angle	34.5	33.9	0.82
UDI stress score	9.4	8.9	0.73
UDI total score	27.3	30.8	0.74
IIQ total score	41.7	34.3	0.92
Success of treatment (VAS score 0-100%)	88.7	90.7	0.96

Conclusions: Both inside-out and outside-in procedures are minimally invasive, safe, and are accompanied with minor complications only. However, the inside-out approach seems to be more painful, and the pain after this procedure is more intense and lasts longer after discharge from the hospital. Our results showed that both procedures are equally successful in treating of women with SUI and MUI at 4 months.

TVT vs Monarc: A Comparative Study

Dietz HP, Barry C, Lim Y, Rane A

University of Sydney, Western Clinical School, Nepean Campus, Penrith, NSW, Australia

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Following the success of the tension-free vaginal tape (TVT), there has been considerable interest in technique modifications such as the transobturator approach for implant placement. We attempted to elucidate possible anatomical and clinical differences between the two methods in a retrospective cohort study. One hundred and fourteen women who had undergone TVT or Monarc implantation were assessed by or under the supervision of the senior author, with identical tensioning technique. They were followed up by an interview, uroflowmetry, and translabial 3D ultrasound. There were significant differences for patient satisfaction ($P=0.013$), subjective overall cure/improvement ($P=0.0018$), and the symptom of poor stream ($P=0.03$), all favoring the Monarc group.

On imaging, Monarc tapes appeared more proximal at rest ($P=0.006$) and Valsalva ($P=0.002$) and remained further from the symphysis pubis on Valsalva ($P=0.01$). At 9 months follow-up, there was no significant difference as regards to cure rates for stress incontinence between the two suburethral slings. Monarc tapes are located more proximally and may be less obstructive, judging from a lower incidence of symptoms of voiding dysfunction. Patient satisfaction and overall subjective cure/improvement were higher after Monarc.

While any such retrospective and nonrandomized study has obvious limitations, the methodology is useful for generating pilot data prior to a randomized controlled trial, simplifying power calculations and helping with the selection of outcome parameters.

Nevertheless, we believe that a number of useful conclusions can be drawn from our study. In the short-to-medium term, there does not seem to be any significant difference between TVT and Monarc in terms of their effectiveness in curing stress incontinence. The Monarc is located more proximally. The curative principle which has been postulated for TVT-type suburethral slings, i.e., a dynamic compression of the urethra between tape and symphysis pubis [11, 12], seems to apply equally to the Monarc transobturator sling. This study has shown that in both groups, there was a highly significant reduction in the gap between the inferomedial margin of the symphysis pubis and the tape. The magnitude of this reduction after Monarc implantation seems similar to that which is observed after TVT.

Despite this similarity in the presumptive mode of action, however, the Monarc seems to have less effect on voiding than the TVT, judging from the prevalence of symptoms of

Results of ultrasound imaging and post-operative flowmetry after Monarc and TVT surgery

	Monarc	TVT	P=
Tape position at rest (vertical)	14.3 (5.7)	11.1 (5.9)	0.006
Tape position at rest (horizontal)	17.7 (4.3)	16.9 (4.7)	n.s.
Tape position, Valsalva (vertical)	-3.0 (7.7)	-6.8 (4.7)	0.002
Tape position, Valsalva (horizontal)	11.5 (6.1)	8.5 (5.8)	0.01
Total mobility (cm)	19.7 (7.6)	20.4 (6.3)	n.s.
Change in max flow rate centile	-8 (31.7)	-13.1 (24.4)	n.s.

Imaging data given in mm relative to the inferoposterior margin of the symphysis pubis

Subjective cure/improvement, satisfaction, and symptoms of bladder dysfunction after Monarc® and TVT surgery (Fisher's exact test)

	Monarc	TVT	P=
Cure/improvement	55/58	41/56	0.0018
Subjective satisfaction	47/58	33/56	0.014
Stress incontinence	14/58	10/56	n.s.
Urge incontinence	27/58	36/56	0.06
Symptoms of voiding dysfunction	19/58	27/56	0.12
Poor stream	6/58	15/56	0.03

voiding dysfunction. One may speculate that, as opposed to TVT-type slings, transobturator slings probably do not provide for much lateral compression as they form a bar underneath, rather than a loop around the urethra. This finding may help explain as to why subjective satisfaction and overall subjective cure/improvement rates were significantly higher after Monarc. As regards to the fact that the Monarc tape is on average found more proximal, i.e., closer to the bladder neck, this may be due to the greater degree of dissection required for the Monarc, or due to the different course of the tape towards the obturator foramen. At any rate, the design of this study allows no speculation as to the possible impact of variations in placement on subjective or objective outcomes.

Conclusions: This comparative study of 114 women after Monarc and TVT surgery has demonstrated that the mode of action of transobturator tapes seems to be largely identical to that of TVT-type slings. Despite this, the Monarc tape seems to have less effect on voiding and is associated with less post-operative urge incontinence. Possibly as a consequence, the transobturator tape was associated with higher patient satisfaction and subjective overall cure/improvement at approximately 9 months follow-up.

High Rate of Vaginal Erosions Associated with the Mentor ObTape

Yamada BS, Govier FE*, Stefanovic KB, Kobashi KC**

Department of Urology, Virginia Mason Medical Center, Seattle, Washington USA.

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Purpose: The transobturator tape method is a newer surgical technique for the treatment of stress urinary incontinence. Limited data exist related to complications with this approach or the types of mesh products used. We report our experience with vaginal erosions associated with the Mentor ObTape and American Medical Systems Monarc transobturator slings.

Materials and Methods: Beginning in December 2003 selected female patients with anatomic urinary incontinence were prospectively followed after placement of the Mentor ObTape. Beginning in January 2004 we also began using the American Medical Systems Monarc in similar patients. Patients were admitted overnight after surgery, discharged on oral antibiotics, and seen in the clinic at 6 weeks post-operatively.

Results: A total of 67 patients have undergone placement of the Mentor ObTape and 9 of those patients (13.4%) have had vaginal extrusions of the sling. Eight patients reported a history of persistent vaginal discharge. One patient presented initially to an outside facility with a left thigh abscess tracking to the left inguinal incision site. Each patient was taken back to the operating room for mesh removal. A total of 56 patients have undergone placement of the AMS Monarc and none have had any vaginal erosions.

We have demonstrated a significantly higher extrusion rate using the ObTape sling vs the Monarc sling (13.4% vs 0%, $p = 0.004$). The surgical indications, surgical technique, antibiotic protocol, and the primary surgeons (FG and KK) were the same in each group. The mean time interval since surgery is greater in the ObTape group vs the Monarc group (16.39 vs 11.55 months, $p = 0.00$). However, the follow-up time in the Monarc group appears adequate for observation of vaginal erosions.

Demographics of the ObTape™ and Monarc® populations

	ObTape		Monarc		P value
No. pts	67		56		
No erosions (%)	9	(13.4)	0	(0)	0.004*
Mean pt age (range)	55.9	(36-77)	55.5	(33-86)	0.838
Mean mos since surgery (range)	16.39	(6.6-23.7)	11.55	(4.2-22.8)	0.000*
Mean cmH2O pre-operative oVLPP	77.9		73.9		0.596
Mean BMI	29.7		30.1		0.744
No. concomitant surgery (%):					
Hysterectomy	5	(7.5)	6	(10.7)	0.529
Anterior repair	30	(44.8)	17	(30.4)	0.101
Posterior repair	26	(40)	17	(30.4)	0.269
Vault suspension	6	(9.0)	3	(5.4)	0.508
No. prior surgery (%):					
Anterior repair	3	(4.5)	2	(3.6)	1.000
Enterocoele repair	0	(0)	1	(1.8)	0.455
Posterior repair	5	(7.5)	2	(3.6)	0.453
Sling/suspension	7	(10.6)	3	(5.4)	0.340
Vault suspension	3	(4.5)	0	(0)	0.250
Hysterectomy	40	(59.7)	22	(39.3)	0.024*

Statistical significance evaluated using the t-test for continuous variables and the chi-square test (with Fisher's exact correction) for counts

* Statistically different at $p < 0.05$ (2-sided test).

Conclusions: Our experience performing the transobturator sling has demonstrated a high rate of extrusion using the ObTape. In light of our experience, we have discontinued the use of this product and will continue to closely follow these patients. For those with vaginal extrusion of the ObTape, we recommend immediate surgical excision of all mesh that can be reasonably removed.

* Financial interest and/or other relationship with Mentor, American Medical Systems, Lilly Icos, Bayer and Pfizer

** Financial interest and/or other relationship with Menotr and American Medical Systems

In Vivo Comparison of Suburethral Sling Materials

Slack M, Sandhu JS, Staskin DR, Grant RC*

Addenbrooke's Hospital

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In Vivo tissue responses were compared for three commercially available polypropylene suburethral slings that differ markedly in fabric structure and in size of resulting interstices and pores. The much larger diameter monofilament and open knit structure of the Monarc® sling permitted the most extensive fibrous tissue integration.

To assess tissue in-growth, sterile samples of each sling were implanted subcutaneously on the ventral abdominal wall in male Sprague-Dawley rats. Four samples were implanted in each animal, including at least one sample of each mesh.

In Vivo Study: None of the fabrics changed significantly in length or width after implantation. At harvest each specimen was covered by a thin translucent layer of tissue. There was no gross evidence of inflammation or edema. No significant changes in gross pathology were observed between the initial harvest on day 13 and the succeeding 1, 2 and 3 month harvests.

Tissue Response to Monarc Mesh: By day 13 new fibrous connective tissue and capillaries filled the large volume pores in the mesh. A thin layer of macrophages covered the surface of each filament. A moderate number of lymphocytes was distributed throughout the newly formed tissue. As time passed, the collagenous fibrous tissue within the pores gradually became more dense.

The frequent and extensive capsular linkages through the Monarc mesh effectively integrated the fabric with adjacent tissues. This extensive integration should enhance stress transfer between sling and tissue, thereby reducing the risk of mechanical irritation.

Tissue Response to IVS Tunneller Mesh: By day 13 macrophages had begun penetrating the multifilament yarn bundles. A thin layer of fibrous tissue had formed along the upper and lower surfaces and penetrated through the larger pores in the mesh. By day 28 macrophages and multinucleated giant cells surrounded nearly every filament within each yarn.

The appearance of the chronic inflammatory infiltrate changed little between days 28 and 91, except for formation of additional multinucleated giant cells. The closely packed filaments in each yarn did not allow any capillary in-growth.

Tissue Response to ObTape: The multidirectional orientation and close spacing of ObTape's small monofilaments form no large, direct, uniform pores that communicate between the outer surfaces of the fabric.

The tortuous, interrupted character of the pores prevented formation of any significant fibrous tissue bridges linking the outer capsule layers through the mesh. Occasional capillaries were present within ObTape at each observation time, but both the density and size of the vascular elements appeared reduced compared with those observed in association with Monarc and Tyco mesh implants.

Polarized Light Analysis of Tissue Reaction: We also examined tissue sections using polarizing filters to highlight collagen-rich tissues. New collagen formation was evident within the pores of Monarc mesh on day 13. From day 28 onward the large pores were filled with collagenous tissue. Collagen fibers surrounded segments of individual filaments and closely spaced clusters of filaments. The fibrous tissue capsule was integrated throughout the Monarc mesh.

Sections through day 13 Tyco IVS Tunneller mesh samples revealed collagen fibers along the outer surfaces of yarn bundles. Some collagen was also present in the larger pores, but none between the closely-spaced filaments of the yarn. On day 28 the mesh was completely surrounded by a prominent collagenous capsule. The capsule layers were joined by bridges of fibrous tissue through the larger pores in the mesh. Thus, IVS Tunneller mesh structure limited formation of connective tissue bridges between the outer capsular layers. Tyco mesh was markedly less well integrated than Monarc®.

Encapsulation was the prominent tissue response to implants. Collagen-rich capsule was present along ObTape's outer surfaces from day 13 through day 91. ObTape's interior volume was almost completely filled with macrophages and multinucleated giant cells from day 13 to day 57.

ObTape was surrounded by a fibrous capsule with effectively no integration between the mesh and adjacent tissues. Without integration there is a greater risk of mechanical irritation due to relative motion between the sling and its capsule.

Conclusions: In vivo Monarc, IVS Tunneller mesh and ObTape slings elicited inflammatory responses. The response noted with Monarc diminished over time with an increased collagenous formation. Over the same period of time, a greater inflammatory response was noted with the IVS Tunneller mesh and the ObTape sling. Substantially different amounts of collagenous tissue formed within the three meshes. The fibrous capsule around Monarc was continuously integrated from top to bottom through each of the large ($\approx 1 \text{ mm}^2$) pores and most of the smaller spaces between monofilaments, firmly anchoring the mesh within the tissue. The smaller and more closely spaced filaments in IVS Tunneller mesh and ObTape resulted in greater volumes of chronic inflammatory cells and markedly less fibrous tissue within each mesh. The irregular structure of ObTape severely restricted formation of collagenous bridges through the mesh connecting the outer capsule layers.

These differences may be of interest to physicians considering clinical use.

* American Medical Systems employee.

Multicenter Experience with the Monarc® Transobturator Sling System to Treat Stress Urinary Incontinence

Davila GW, Johnson JD, Serels S

Cleveland Clinical Florida, USA.

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Purpose: This study was conducted to report on the safety and efficacy of a transobturator sling approach for treatment of urodynamic stress incontinence (USI). Women with urodynamic stress incontinence were offered a novel polypropylene mesh sling procedure, implanted beneath the lateral pubic rami rather than retropubically. Retrospective data were collected at three U.S. sites. Two hundred women with a mean age of 59 years (range 27–93) underwent the sling procedure. Mean follow-up was 21.5 weeks (range 3–43).

Mean operative time to implant the Monarc mesh was 13.8 min (range 7–34 min). Mean operative blood loss was 66 ml (all below 100 ml) for the Monarc procedures. Mean length of stay was 1.2 days (range 0–5), including patients who underwent other reconstructive procedures.

Based on our definition of cure, 95.3% with 26 weeks follow-up were cured. Performance of additional reconstructive procedures did not adversely impact outcomes in terms of continence or voiding dysfunction. Cure rates were also similar between USI and mixed incontinence patients. There were marked reductions in pad usage overall as well as number of pads used per day. Mean pre-operative pad use was 1.7 per day (range 0–25, SD 2.3), and 0.1 at 26 weeks (range 0–3, SD 0.59). At baseline, 75% of USI and 80.7% of mixed incontinence patients wore pads; at 26 weeks, only 5.3% reported wearing protective pads for urine loss. Urinary urgency symptoms were reported by a significantly smaller percentage of patients during the post-operative phase, with only 20.5% reporting urge at week 26, compared to 62.7% at baseline ($p=0.0001$). In addition, only 13.6% required anticholinergic medications for urgency. No subjects reported worsening urgency post-operatively.

A flowchart details outcomes at time periods <26 weeks and ≥26 weeks according to urinary incontinence type. Voiding abnormalities, urinary retention or an abnormal urinary stream, as described by the patient, was identified in three (2.0%) patients at 14 weeks, and one (0.9%) patient at 26 weeks. One patient required urethrolisis at 20 weeks due to suspected outflow obstruction. Two or more UTIs during the healing phase were noted in six patients, none requiring chronic suppression therapy.

On intra-operative cystoscopy, no bladder or urethral perforations were noted. No intra-operative complications were noted. Specifically, no hemorrhage occurred, and there was no evidence of bowel or vascular injury. One device-related technical complication occurred, consisting of a single mesh connector breaking requiring the use of a second surgical kit. Lower extremity pain lasting less than 5 days occurred in five patients, none along an adductor longus muscle or obturator nerve distribution. The following complications occurred, each in a single patient: atrial fibrillation and acute congestive heart failure, gluteal hematoma in a patient who underwent posterior colporrhaphy, self-limiting ileus, temporary urethral pain, and self-limiting oozing at the right groin site. No groin pain, new onset sexual dysfunction, or tape infection/erosion were reported. One patient was noted to have an area of exposed mesh along the vaginal incision site during the early healing phase. The mucosa healed spontaneously, without need for surgical intervention. No other healing abnormalities, including mesh erosions, were noted at subsequent follow-up visits. One patient underwent one treatment with collagen bulking agent for persistent USI.

Outcomes of the Monarc® sling procedure-op

	Pre-operative	Post-operative (26 weeks)			
		Overall	Monarc only	Monarc + repair	Mixed incontinence
Cured (total %)	0	95.3	95.9	95	73
Completely dry (%)	0	87	93.9	93.4	68
Substantially dry ^a (%)	0	8.3	2	1.6	5
Pad use (pads/day)	1.7	0.13	0.2	0.08	0.13
Not using pads (%)	25	94.7			95
Urgency (%)	62.7	20.5	12	28	
Medicated for urgency (%)	41.5	13.6	14	14	
PVR>60 ml (%)	0	0.9	0	1	

^a Not requiring protection

Conclusions: Monarc transobturator slings are effective for surgical treatment of USI at 6 months and may offer increased safety relative to traditional or tension-free retropubic slings. Additional follow-up along with comparison to other anti-incontinence procedures is needed.

Funding for data collection was provided by American Medical Systems

Prospective Multicentre Trial of Monarc Transobturator Sling for Stress Incontinence: 24 Month Functional Data

Deridder D, Jacquetin B, Fischer A, Debodinance P, Marques-Queimadelos A, Courtieu C, Cervigni M, Rassler J, Rane A, Herschorn S, Urwin G, Goetze W, Ouellet S, Schrader M, Mellier G

University hospital KU Leuven, Dept of Urology, Leuven, Belgium

Eur Urol Apr 2006; 5(2 suppl.): 267 abstract 978. 21st Annual Congress of the European Association of Urology

Purpose: To evaluate 24-month longitudinal outcomes of Monarc transobturator sling as treatment for women with stress incontinence.

The study was designed as a multicentre prospective nonrandomised trial, involving 15 European, Canadian and Australian sites.

Results: 148 patients were enrolled between Jan 03 and Feb 04. One hundred and twenty seven reached 24 month follow-up and are included in this analysis. Patient assessment of continence revealed 82% cure rate: 63% completely dry and 19% substantially continent (needing no protection). Some additional protection was needed in 10% and 7% remained substantially incontinent. Assessment by the physician correlated strongly with these numbers. The post-operative cough test was negative in

87.6%. Pad use per day was reduced from 3.4 ± 2.2 to 0.6 ± 1.3 ($p < 0.001$). Urine loss during a 1 h pad test ($n=106$) was reduced from a mean of $65.8 \text{ g} \pm 74.5$ to 9.5 ± 31.5 ($p < 0.001$). The UDI-6 showed significant improvement (45.9 ± 16.4 to 13.4 ± 17.6 , $p < 0.01$) as did the IIQ-7 (53.7 ± 24.8 to 11.6 ± 24.5 , $p < 0.001$). *De novo* urgency was seen in 11.5% while 27.9% of patients with pre-operative urge symptoms were relieved of their urgency. Fifty two device-related adverse events were experienced by 27 patients (18% of patients). Adverse events included: 11 UTI (7% of patients), 9 urge (6%), 6 retention (4%), 6 pain (4%), 4 recurrent SUI (3%), 3 increased PVR (2%), 2 urge incontinence (1%), 2 erosion (1%) and 1 each (0.7%) of: dyspareunia, device malfunction, cystitis, vaginal discharge, vaginal infection, vaginal scar tissue, urethral obstruction, urethral trauma, insufficient suture/sling perforation.

Conclusions: 24-month data show that Monarc® transobturator sling successfully restores continence in women with SUI. Patient and physician assessed continence rate (completely dry and substantially continent) were both 82%. UDI-6 and IIQ-7 were significantly improved from baseline. Given the 11.5% of patients with *de novo* urge and the 27.9% of patients who were cured of their pre-operative urge, patients implanted with Monarc are significantly more likely to be cured of urge symptoms than to develop urge symptoms ($p < 0.005$).

A Combined Analysis of the Safety and Efficacy of the Monarc Transobturator Hammock at 12 Months Follow-Up in Two Prospective Studies in Nine Countries with 272 Patients

Moore, RD¹; Jacquetin, B²; Knoll, D³; DeBodinance, P⁴; Dupont, M⁵; Fischer, A⁶; Marques-Queimadelos, A⁷; Courtieu, C⁸; Miklos, J¹;

1: Atlanta Urogynecology Associates, USA; 2: Maternite Hotel Dieu, France; 3: Center for Urologic Treatment, USA; 4: Maternite Les Bazennes, France; 5: Dupont Center for Urology, Urogynecology, USA; 6: Krankenhaus Sankt Josef, Germany; 7: Hospital Clinico Universitario, Spain; 8: Clinique Beau Soleil, France

Int Urogynecol J 2006;17(suppl):S203 31st annual IUGA meeting, Athens, Greece, 6-9 September 2006, abstract 259

Purpose: We are reporting on 1-year follow-up data of two prospective studies with similar protocols in nine countries in Europe, Australia, and North America on evaluating the safety and efficacy of the Monarc Subfascial Hammock Sling system.

Operative data was gathered on 265 participants, of which 211 completed their 1-year follow-up.

Results: The mean operative time for sling placement was 12.8 min. Mean blood loss was 37 ml; time to urinate without a catheter was 10 h. Of patients, 99.3% went home without a catheter. At 1-year follow-up, patients show a marked improvement compared to all of their pre-operative measurements. Positive results on the cough stress test

dropped from 245/267 (91.8%) pre-operative to 15/192 (7.8%) at follow-up. The 1-h pad weight test dropped from an average weight gain of 50.2 to 7.2 g at 1-year follow-up. Pad use dropped to 0.5 pads/day, from 2.7 pads/day pre-operative. Improvements in global QOL scores were statistically significant ($p < 0.001$). Urge symptoms remained unchanged in 118 (56.5%) of patients. Urge symptoms resolved in 56 of 118 patients (26.8%) of patients. Thirty-five (16.7%) patients developed *de novo* urge. Eighty-two complications that could possibly have been related to the device were reported in 41 patients (15.6%); the most common of which were UTIs/Cystitis 16 (6.0%), extrusion 6 (2.3%), and urge symptoms 10 (3.8%).

Conclusions: Both objective and subjective data demonstrate that the Monarc transobturator approach is a safe and effective method for treatment of SUI.

Disclosure: Was this work supported by industry? Yes: American Medical Systems.
Do you act as a consultant, employee or shareholder with this industry? Yes.

An Anatomical Study of the Obturator Foramen and Dorsal Nerve of the Clitoris and their Relationship to Minimally Invasive Slings

Achtari C, Mckenzie BJ, Hiscock R, Rosamilia A, Schierlitz L, Briggs CA, Dwyer PL.

Urogynaecology Dept, Mercy Hospital for Women, Victoria, Australia.

Int Urogynecol J Jun 2006;17(4):330-4

Purpose: The objective of the study is to clarify potential risks to the dorsal nerve of the clitoris (DNC) and obturator canal using different minimally invasive slings.

Materials and Methods: Ten embalmed hemipelves were dissected to demonstrate the course of the DNC and the obturator canal. On each cadaver, tension-free vaginal tape (TVT), transobturator in-out (TVT-O) and transobturator out-in (Monarc®) procedures were performed. Distances between the DNC and the obturator canal to the different devices were measured.

Conclusions: We found significant differences between TVT, TVT-O and Monarc devices and their proximity to the obturator canal, with TVT being the furthest and TVT-O the closest. There was no significant difference to the DNC, with Monarc possibly being the safest given its outside-in course.

Results: The DNC passes beneath the pubic bone at a distance of 14.3 ± 4.7 mm of the midline. The distances of the different devices to the DNC were similar.

The mean distance from the obturator canal was greatest with the TVT device (40 ± 4 mm) compared to the TVT-O (19 ± 3 mm) and Monarc (27 ± 4 mm). Mean distance to DNC was not significantly different between the three techniques.

Transobturator Surgery for Female Stress Incontinence: A Comparative Anatomical Study of Outside-In vs Inside-Out Techniques

Spinosa JP, Dubuis PY, Riederer BM

Department Obstetrics and Gynaecology, Morges Hospital, Morges, and Perineology Unit, Lausanne, and Department of Cellular Biology and Morphology, Lausanne University, Lausanne, Switzerland

BJU International 2007;100:1097-1102

Purpose: To assess the specific risks of injury to neural and vascular structures inherent in two approaches to transobturator surgery for inserting a sub-urethral sling, i.e. the outside-in (standard technique) and inside-out approaches.

Materials and Methods: The study comprised seven cadavers, providing 14 obturator regions. Five specimens had a tape inserted outside-in on one side, and inside-out on the other; of the remaining two cadavers, one had an inside-out tape and one an outside-in tape, bilaterally. After tape insertion, the cadavers were dissected. Particular attention was paid to the distances between the tape and the deep external pudendal vessels, and between the tape and the posterior branch of the obturator nerve.

Results: With the inside-out technique, the safety margins were reduced, and the external pudendal vessels (VASC) and the posterior branch (POSTB) of the obturator nerve were at greater risk of injury.

Conclusions: The present anatomical study in fresh cadavers showed that the two surgical approaches used for the management of SUI, outside-in and inside-out, do not incur the same surgical risk. The inside-out route, as described by its inventor [De Leval Eur Urol 2003;44:724-30], has a greater risk of surgical injury. The more lateral exit point puts the VASC and the POSTB at risk.

Distances from the VASC to the Tapes, and from the Tapes to the POSTB

Distance	TVT-O (inside-out)	TOT (outside-in)
VASC to tape, cm		
Severed	1	0
<1	4	0
1-3	1	0
>3	0	6
Not found	1	1
Tape to POSTB, cm		
Mean (range)	0.9 (0-1.2)	2.7 (2.1-3.3)

Anatomic Comparison of Two Transobturator Tape Procedures

Zahn CM, Siddique S, Hernandez S, Lockrow EG

Obstet Gynecol Mar 2007;109(3):701-706

Purpose: Both outside-in and inside-out methods are available for transobturator tape placement. Our objective was to compare these methods regarding proximity of the tape to the obturator canal and ischiopubic ramus.

Materials and Methods: Using seven fresh frozen cadavers, transobturator tapes were placed using the inside-out (TVT-Obturator System, Gynecare, Ethicon Inc, Somerville, NJ) and outside-in (Monarc, American Medical Systems, Minnetonka, MN) methods bilaterally in each cadaver. We dissected to the level of the obturator membrane and measured the distance from the closest aspect of the obturator canal and ischiopubic ramus to each tape.

Distance Between the Transobturator Tapes and Obturator Canal According to Left and Right Side Placement

Side	Procedure	n	Mean (cm)	Standard Deviation	P
Left	Outside-in	7	2.5	0.32	.001
	Inside-out	7	1.5	0.42	
Right	Outside-in	7	2.2	0.49	.010
	Inside-out	7	1.2	0.42	

Results: Transobturator tapes placed by using the inside-out technique were significantly closer to the obturator canal than with the outside-in method (mean distances: 1.3 ± 0.44 cm compared with 2.3 ± 0.41 cm, respectively, $P < .001$); the greater proximity of the inside out method was noted in all dissections. Tapes placed with the inside-out method were also farther from the ischiopubic ramus than those placed with the outside-in approach (mean distances: 0.39 ± 0.44 cm compared with 0.04 ± 0.13 cm, respectively, $P = .008$). When distances between the tapes relative to the obturator canal were further analyzed according to left or right side, the difference between methods was maintained. Additionally, the distances were consistently farther from the obturator canal on the left side than on the right side regardless of transobturator tape approach.

Conclusions: The outside-in technique results in the mesh being placed farther from the obturator canal and closer to the ischiopubic ramus, theoretically reducing the risk of neurovascular injury.

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American Medical Systems, Inc.
World Headquarters
10700 Bren Road West
Minnetonka, MN 55343 USA
Phone: 952 930 6000
Fax: 952 930 6157
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www.greenlightps.com

**American Medical Systems
Europe B.V.**
Straatweg 66H
3621 BR Breukelen
THE NETHERLANDS
Phone: 31 346 258 100
Fax: 31 346 258 130

**American Medical Systems
Australia Pty. Ltd.**
Suite 2, Level 2
460 Church Street
North Parramatta 2150
NSW AUSTRALIA
Phone: 61 2 8838 8800
Fax: 61 2 9890 9899

**American Medical Systems
Canada Inc.**
P.O. Box 461
Guelph, Ontario
N1H6K9 CANADA
Phone: 519 826 5333
Fax: 519 821 1356