for innovation
for reliability
for peace of mind
The Story of I-STOP®

1998  The first tape sold in Europe by Vincent Goria, Gynecare representative

1999-2000  The first reports of complications arising from deformation

2000  Vincent Goria watches a surgeon remove a tape deformed into a thin rope

2001  Vincent Goria and a mechanical engineer revisit the principles of Ulmsten’s Integral Theory to determine the mechanical requirements for a tape to resist the force vectors. A technical weaver with 30 years of experience designs a weave needed to meet the criteria. Vincent Goria set up CL Medical

2002  The first I-STOP® tapes are implanted.

The superior characteristics of I-STOP® in the clinical environment are best described by G. Willy Davila, Cleveland Clinic, Florida in Int Urogynaecol J Vol 23 No 12 Dec 2012, reporting on the 87.4% success rate out of 247 patients treated for ISD.

“As the I-STOP® sling has lower elasticity the surgeon may be able to apply tension more precisely.”

“Being inelastic, there may be less likelihood of tape shrinkage, which can lead to progressive retention and irritative bladder symptoms.”

“Another important characteristic of this tape is its high flexibility compared to other type 1 tapes....This means it may have the capacity to bend, making it more malleable during surgery....more accurately tensioned and may lay flat without deformation suburethrally.”
THE TAPE CHARACTERISTICS NEEDED WERE BASED ON ULMSTEN’S INTEGRAL THEORY

- Arrows show force vectors
- These vectors work to deform the tape
- A new weave design was needed to meet the criteria
- The tape needs to be compliant, soft yet resistant at the same time to resist the force vectors

THE WEAVE NEEDED TO RESIST DEFORMATION

I-STOP®
Non-deforming

- Atraumatic Uncut Mesh
- No particle release
- Unique Fixating Loops
- Stability Chains
- Single-layer

Polypropylene deformable

- Cut Mesh
- Particles release
- Rough edges
- No Stability Chains
- Double layer microporous
I-STOP®
NOT JUST ANOTHER TAPE

In 2002 a mechanical engineer and a weaver worked together to produce a tape to fit Ulmsten’s Theory and to resist deformation and

THE I-STOP® TAPE WAS BORN

- a special type 1 monofilament polypropylene tape

- NON DEFORMING
- HIGH FLEXIBILITY AND LOW ELASTICITY
- NO CUT MESH SO NO ROUGH EDGES
- NO PARTICLE RELEASE

UNCUT MESH
Completely woven with no cut edges ensures mesh integrity and prevents particle release

LOOPED EDGES
Eliminate course, traumatic surfaces and facilitate tissue fixation

STABILITY CHAINS
Prevent mesh deformation despite sustained lateral traction and eliminate the need for introducer sleeves

LIGHTWEIGHT
<50g/sqm provides a strong macroporous sling without excessive foreign material
I-STOP®: AN EXCEPTIONAL TAPE

- I-STOP® FOR RETROPUBIC, TOT OUT-IN, TOT IN-OUT, AND VAULT REPAIR
- I-STOP® FOR MILD, MODERATE AND SEVERE INCONTINENCE
- I-STOP® IS CLINICALLY PROVEN TO IMPROVE OUTCOMES IN ISD PATIENTS
- I-STOP® PATIENTS HAVE LESS RETENTION, LESS DYSURIA AND LESS DE NOVO URGENCY

(1,2,3,4,5, DATA ON FILE AT GENESIS MEDICAL LTD)

CLINICALLY PROVEN

EUROPEAN UROLOGY 2005
- 604 CASES – TOT
- Much less retention, dysuria, De Novo urgency
- 0 erosion

EUROPEAN UROLOGY 2006
- Prospective and randomised trial
- The better results on bladder symptoms repeated

CLEVELAND CLINIC FLORIDA 2010
- 192 case
- 0 erosion

WORLD J UROLOGY 2011
- 4 years of follow up
- 0 erosion

JOURNAL OF UROLOGY 2012
- 5 years of follow up
- 75% success

INTERNATIONAL UROGynaECOLOGY JOURNAL 2013
- 247 cases
- First cases 2007
- 0 erosion
I-STOP™ TAPE FOR FEMALE STRESS URINARY INCONTINENCE
For retropubic, suprapubic, TOT in-out and out-in, approaches for SUI and posterior prolapse repair.

The CL Medical I-STOP tape was first released in France in 2002 with a unique macro pore knit from a single filament which resists deformation when tension is applied. The weave is patented.

The I-STOP tapes are now the leading brand in France. The outcomes are excellent and there are fewer postoperative complications.

The reason for this success is simply that the non-deformation I-STOP tape causes fewer complications.

Dr Willy Davila of the Cleveland Clinic Florida in the most recent clinical paper gives some of the reasons why surgeons prefer the I-STOP tape:

"As the I-STOP sling has lower elasticity [16], the surgeon may be able to apply tension more precisely. Its construct minimizes tape deformability, which may provide a more predictable post-implantation behaviour [20].

Being inelastic, there may be less likelihood of tape shrinkage, which can lead to progressive retention and irritative bladder symptoms, possibly requiring sling revision.

Another important characteristic of this tape is its high flexibility compared with other type I tapes, which have medium flexibility. This means it may have the capacity to bend, making it more malleable during surgery [20].

As a result, it may be more accurately tensioned and may lay flat without deformation suburethrally.

There were no vaginal exposures in our study, whereas in other studies in which TVT or TOT tapes were used, exposure rates were reported between 1.4 % and 3.8 % [6, 7, 21]. However, our median follow-up of 43 weeks was too short to make any definite conclusions regarding mesh exposure following ISTOP sling surgery. Also, the potential benefits of low elasticity and high flexibility need to be assessed in comparative studies."

Int Urogynecol J Vol 23 No 12 Dec 2012

The full Cleveland Clinic Florida article as well as others are enclosed in this binder.

Enclosed is a 2014 Multicentre clinical paper 7 year follow-up of 331 patients support Dr Davila’s comments – there were fewer post-operative complications and just one mesh exposure.

Further details and the texts of more studies are on www.genmedhealth.com
I-STOP™ tape for SUI is the leader in France because for over 10 years it has consistently proven to cause significantly fewer complications

<table>
<thead>
<tr>
<th>Device Manufacturer</th>
<th>I-STOP CL Medical</th>
<th>TVT Gynecare</th>
<th>TVT Secure Gynecare</th>
<th>Monarc AMS</th>
<th>MiniArc AMS</th>
<th>Obtryx Lynx Boston Sc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erosions</td>
<td>0% 1,2,3 ✓</td>
<td>5% 10</td>
<td>6% 6</td>
<td>11% 5</td>
<td>x</td>
<td>4% 7</td>
</tr>
<tr>
<td>85% of success after 3 years</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
<td>x</td>
<td>50% 4</td>
</tr>
<tr>
<td>Abnormal bladder function (dysuria, retention, de novo urgency)</td>
<td>6% 1,2,3 ✓</td>
<td>40% 8,11</td>
<td>23% 6</td>
<td>42% 11</td>
<td>x</td>
<td>27% 7</td>
</tr>
</tbody>
</table>

5. Scheiner et al. Do transobturator slings cause less problems than TVT? 005-IUGA 2009
11. Barber et al. A multi-centre randomized trial comparing the transobturator tape with
I-STOP is not just another tape

I-STOP is type 1 mono-filament polypropylene.

The edges are looped and soft. The patented weave resists deformation.

Other tapes are cut from sheets of mesh, so have rough hard edges and stretch if pulled.

Genesis has sample tapes for anyone to conduct their own stretch tests – the comparative samples of different tapes are available at most conferences.

Elastic and deformable (rope / cheese wire effect) I-STOP hardly deforms and does not release particles when pulled

BEFORE TRACTION AFTER TRACTION BEFORE TRACTION AFTER TRACTION

Manufacturers all strive to minimise deformation of their tapes but have not succeeded in reaching the minimal deformation provided by I-STOP

Some quotes from company brochures:

**Boston Scientific**  "De-tangled portion is to resist deformation"

**Gynecare**  "Of all tested materials, GYNECARE TVT™ has the highest resistance to deformation."  *(they did not test I-STOP)*

**AMS**  Mesh incorporates a tensioning suture "Mesh distorts without suture and carrier knots"

An independent published study compared mechanical tests conducted on several tapes shows deformation just before rupture:  *Copy of the article available from Genesis Medical.*
2014
• Progrès en Urologie Vol 24 issue 12 Oct 2014 750-756
  Seven-year follow-up of 331 I-Stop transobturator sling cases in female urinary incontinence treatment
  J.Lienhart, R Vautherin, M Grisard-Anaf, J-L Frobert

2012
• Int Urogynecol J Vol 23 No 12 Dec 2012
  An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency
  Alfredo Jijon & Aparna Hegde & Beatriz Arias & Vivian Aguilar & G. Willy Davila

2011
• World J Urol DOI 10.1007/s00345-011-0668-1
  Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes
  M. Ballister, C. Bui, J-L Frobert, M Grisard-Anaf, J. Lienhart, H Fernandez, E David-Montefiore, R Rouzier, E Darai

2010
• Journal of Minimally Invasive Gynecology 17 (2010) S1-S24
  I-STOP Suburethral Sling: Outcomes of a Non-Deformable Sling for Intrinsic Sphincter Deficiency
  Karp et al

2009
• White paper
  I-STOP suburethral sling: Less deformation improves outcomes for Intrinsic Sphincteric Deficiency
  Beatriz ARIAS, G.W. Davila, Cleveland Clinic Florida
• Poster presented at AUGS 2009.
  Slings for ISD-associated stress incontinence: Does elasticity or urethral positioning matter?
  Lefevre, T Peterson, Davila, Cleveland Clinic Florida.

2006
• European Urology 49 (2006) 133-138
  Peri-Operative complications and pain after the suburethral sling procedure for urinary stress incontinence: a French prospective randomised multicentre study comparing the retropubic and transobturator routes.

2005
• European Urology 47 (2005) 102-107

2004
The 2003 study continued and published with 12 month follow-up.
• Article in ENDOMAG Juin 2004
  The Trans-Obturator Tape for the treatment of Female Stress Urinary Incontinence. Results on 140 cases one year after.

2003
• Association Francais d’Urologie conference 2003- Poster
  The Trans-Obturator Tape for the treatment of Female Stress Urinary Incontinence. Preliminary results on 140 cases
Seven-year follow-up of 331 I-Stop transobturator sling cases in female urinary incontinence

Jean-Luc FROBERT(1), Maryelle GRISARD-ANAF(2), Jean LIENHART(3)*, Renaud VAUTHERIN(3)

(1)Hôpital de Fleyriat, Service de gynécologie, 900 Route de Paris, 01012 Bourg-en-Bresse, France
(2)Hôpital Privé Jean Mermoz, 55 Avenue Jean Mermoz, 69008 Lyon, France
(3)Clinique Trénel, 575 Rue du Docteur Trenel, 69560 Sainte-Colombe, France

* Corresponding author: Email: jeanlienhart@sfr.fr

Key Points: -

- To evaluate the efficacy of I-Stop transobturator tape with a long-term follow-up for 331 patients with surgery performed by 4 surgeons.
- Follow-up was conducted at 7 years.
- To examine the correlation between age and efficacy of the procedure.

Results: -

- Patient satisfaction was 80% after 7 years.
- 28% were not cured; 3% had no improvement, 25% suffered de novo incontinence after 7 years and increased with age.
- 1 mesh exposure was seen 5 years after surgery, a simple partial resection was performed. At 7 years the mesh was no longer exposed and the patient remained continent.
Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes.

Marcos Ballester¹, Charles Bui¹, Jean Luc Frobert², Maryelle Grisard-Anaf³, Jean Lienhart⁴, Herve Fernandez⁵, Emmanuel David-Montefiore⁴, Roman Rouzier¹, Emile Darai¹
¹Hospital Tenon, Paris
²Hospital de Bourg en Bresse.
³Clinique Sainte Anne Lumiere, Lyon.
⁴Clinique Trenel, Sainte Colombe.
⁵Hospital Bicetre, Paris.

Corresponding author: email: marcos.ballester@tnn.aphp.fr

World Journal of Urology: March 2011

Key Points:-

- To evaluate long term (4 years) functional outcomes and quality of life using retropubic (RPR) and transobturator (TOR) methods.
- Prospective, randomized multicentre study of 88 women with SUI
- Retropubic n=42 with a mean follow up 52.7 months
- Transobturator n=46 with a mean follow up 53.1 months
- Mixed incontinence diagnosed in 3 patients in both groups
- Considered cured when they had no SUI by clinical & urodynamic examination, no SUI during stress provocation test and no urinary retention

Results/Conclusion:-

- Success rates at 4 year follow up was 79.4% in retropubic cases and 86.5% in transobturator cases (excluding cases lost to follow up)
- No erosions reported.

- This study shows similar high long-term success rates for both the retropubic and transobturator procedures
- 19% of patients lost to follow up in both groups.
  (Similar to Abdel-Fattah et al (2010) who estimated a drop-out rate of 20% over 3 years should be expected)

I-STOP® used for both routes
An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency
Alfredo Jijon, Aparna Hegde, Beatriz Arias, Vivian Aguilar, G. Willy Davila
Cleveland Clinic Florida

Corresponding author: email: marcos.davilag@ccf.org

Int Urogynecol J Vol 23 No 12 Dec 2012

**Key Points:**

- To evaluate outcomes of an inelastic retropubic sling in 247 patients with intrinsic sphincteric deficiency (ISD) and urodynamically proven SUI
- All patients followed up at 2, 6, and 24 weeks and yearly
- Outcome measures included self-assessed satisfaction, daily incontinence episodes and pad usage, standardised stress test, postvoid residual volume, and surgical complications.
- ISD is associated with a high incidence of failure of between 50% and 86% with the most commonly used slings.
- The surgical approach with the inelastic I-STOP sling is similar to other slings but the desired tension can be more accurately achieved.
- Patient ages: 75% >60.5 years, 25% > 78 years, 68.4% were obese

**Results:**

- 87.4% cured/improved, 6.8% not improved, 5.6% worsened – self assessment.
- 7.2% suffered retention (compares to 26% reported by Wang, 25.7% reported by Guezzi)
- 4 patients developed de novo urge, 2 after surgery, 2 after 12 weeks (no medication required)
- No bladder or urethral exposure (compares to 1.4% to 3.8% in studies with elastic slings)
Sub-urethral tape treatment of female urinary incontinence – morbidity assessment of the trans-obturator route and a new tape (I-Stop®):
A multi-centre experiment involving 604 cases

J.S. Krauth¹, H. Rasomiaramanana¹, H. Barletta², P.Y. Barrier³, M. Grisard-Anaf⁴, Jean Lienhart⁵, J. Mermet⁶, R. Vautherin⁵, Jean Luc Frobert¹,
¹Gynaecology Department, General Hospital, Bourg en Bresse, France
²General Clinic, Valence, France
³Gynaecology Department, General Hospital, Villefranche sur Saone, France
⁴Sainte Anne Lumiere Clinic, Lyon, France
⁵Trenel Clinic, Sainte Colombe, France
⁶Dr Cleret Clinic, Chambéry, France

Corresponding author: jeankrauth@hotmail.com

European Urology 47 (2005) 102-117

Key Points:-

- To assess the morbidity of the transobturator route (TOT)
- Short term clinical examination follow up at 1-3 months for all 604 patients
- 1 year satisfaction rate follow up for the first 140 patients
- 47.3% of patients had pure SUI, 52.7% of patients had mixed incontinence
- Mean patient age of 57 years
- 92% had isolated incontinence procedure, 8% had additional associated surgery and were studied separately

Results:-

- Operative complications were less than 2%
  (Bladder perforation-0.5%, vaginal perforation-0.33%, Haemorrhage-0.83%, Haemotoma-0.33%, immediate section of tape due to perineal bleeding-0.16%, no urethral erosions)
- Post-operative complications were moderate at 7.5%
  (transient retentions-1.5%, transient pain-2.3%, urinary infections-2.5%, transient dysuria-1.3%)
- The 1 year satisfaction rate of 131 patients was 85.5% with 1.5% rate of de novo dysuria and urgency.
  (9 patients lost to follow up at 1 year)
  - No other serious complications or infections of the tape have been noted.
I-Stop® Suburethral Sling: Outcomes of a Non-Deformable Sling for Intrinsic Sphincter Deficiency

Karp DR, Lefevre R, Peterson T, Arias B, Davila GW
Department of Gynecology, Cleveland Clinic Florida

Abstract: Journal of Minimally Invasive Gynecology 17: 2010 S1-S24

**Key Points:**
- To determine the post-operative efficacy of a non-deformable retropubic sling for the treatment of Intrinsic Sphincter Deficiency (ISD).
- These patients require adequate suburethral support to enhance urethral sphincteric function yet are at risk for post-operative voiding dysfunction.
- Mean age 66.5, parity 2, BMI 29.8.
- 44% had previous hysterectomy & 14% previous anti-incontinence procedure
- Concomitant reconstructive procedures were performed in 61% of patients
- Mean follow up of 30 weeks

**Results:**
- Postoperatively, 87% of patients reported no daily stress incontinence events.
- 97% had a negative empty supine stress test.
- Subjective improvement was reported in 91% of patients.
- Urinary tract infections, vaginal pain and symptoms of incomplete emptying were minor complications in less than 0.5% of patients
- No new onset voiding dysfunction observed over the follow-up period
- No vaginal mucosal erosions
  (Author states: “The looped tape ends may be significant positive contributor, as we would expect at least 1-2 erosions to be found in a case series of this size)

**Conclusion:**
- The I-Stop® Sling is an effective treatment modality for ISD patients.
- “The non-deformable tape allows individualized suburethral tensioning for severely incontinent patients without increased voiding dysfunction.”
I-Stop®

Peri-operative complications and pain after the suburethral sling procedure for urinary stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes.

Emmanuel David Montefiore¹, Jean Luc Frobert², Maryelle Grisard-Anaf³, Christophe Porcolet⁴, Jean Lienhart⁵, Karine Bonnet⁶, Emile Darai⁷,
¹Hôpital Tenon, Paris
²Hôpital de Bourg en Bresse
³Clinique Sainte Anne Lumière, Lyon
⁴Clinique Trelay, Sainte Colombe
⁵A. Blecere, Université Paris

Published in European Urology 49 (2006)

Key Points:-

- TVT has become one of the most popular procedures worldwide for treatment of SUI owing to its high long term success rate.
- However de novo urge incontinence and voiding dysfunction may occur following over correction associated with the retropubic approach and/or the use of elastic polypropylene slings.
- The retropubic and transobturator approaches have not been compared using the same non-elastic polypropylene tape.
- Objective was to compare peri-operative complications, pain and the immediate functional results of the sub-urethral sling procedure using the same non-elastic polypropylene tape (I-Stops - CL Medical) and comparing the retropubic and transobturator routes.
- Prospective, randomized multicentre study of 88 women with SUI
- Retropubic (RPR) n=42, Transobturator (TOR) n=46

Results/Discussion:-

- No cases of immediate postoperative dysuria or urinary retention were observed in the study, regardless of the route used.
- (Previous studies of transobturator using non-elastic slings also showed low incidence of dysuria - 1.3% and urinary retention - 1.5%)
- Recent studies using elastic slings and the retropubic route, urinary retention occurred in up to 12.9% of cases.
- Authors consider the main factor influencing immediate postoperative outcome is the use of non-elastic slings rather than route of choice.

Disclaimer: This summary has been composed by Genesis Medical Limited (UK) based on the contents of the stated clinical abstract or paper and in no way represents the comments/views of the author(s) of that abstract/paper.
TRANSLATION FROM THE FRENCH

Summary

Purpose. — The aim was to evaluate results and morbidity for the I-Stop tape using the transobturator approach with seven years of follow-up on a large number of patients.

Material. — Three hundred and thirty-one files out of 430 surgeries performed in 2005 by four different surgeons has been reviewed, collecting data in sending a detailed form. A statistical and correlation analysis has been performed then.

Results. — After seven years, the subjective success rate was 72% and 80% of the patients were satisfied. Cases of revision were rare and a systemic analysis has been performed: 0.9% of second surgery for SUI and 0.3% of tape exposure. Recurrence of SUI and decrease of efficacy occurred on older population.

Conclusion. — Functional results are similar to those published already but complication rate is significantly lower. Decrease of efficacy by time occurred mainly after 80 years old seemed to be related to tissue aging.

Level of evidence. — 5

Introduction

Urinary incontinence affects the quality of life for many women. Its prevalence varies from 4.5 to 53% and increases with age [1]. The impact of urinary incontinence is particularly significant to the quality of life of patients with the disease [2].

Considering that the proportion of people aged over 75 is expected to increase 20 to 34% of the population between 1990 and 2050, the management of urinary incontinence should be made to develop in the future.

Numerous interventions have been described for treating urinary incontinence, using a variety of principles.

Among them, the establishment of a sub-urethral tape has become the gold standard in the surgical management of urinary incontinence in women. The indications for other previously described techniques have gradually become much rarer.

In 1996 Ulmsten et al. introduced the technique of sub-urethral tape without tension by the retropubic route (TVT) [3]. This was the first synthetic tape used in the treatment of urinary incontinence. The long-term results are now well known [4-7] and they confirm the effectiveness of this technique.

Thereafter, different variations have been developed, among which mention must be made of a transobturator route described by Delorme [8].

The objective of this study was to evaluate the efficacy and long-term morbidity of the I-Stop sub-urethral tape sold by CL medical implanted transobturator approach.

The implant has been used since 2002 and has different characteristics [19] to the TVT used by Ulmsten in 1996; the same type of mesh is used for the Treatment of male incontinence. [9]

Materials and methods

This retrospective study was conducted at three centres in the Lyon region with four different operators: a hospital gynaecologist and three urologists in private practice.

Four hundred and thirty patients were treated between January and December 2005. All
patients were the subject of consultation and clinical examination. They had urinary incontinence with suburethral hypermobility, leak on coughing with stable urethra. No urodynamics were performed if consultation revealed stress incontinence and examination revealed an unstable urethra.

This was a first implantation of the tape for all patients. No exclusion criteria were selected. The I-Stop tape (CL Medical, Sainte-Foy-Les-Lyon, France) was implanted via the transobturator route, outside-in and in-out.

This is a tape of knitted polypropylene monofilament macroporous mesh and no cut edges, with high tensile strength, and low elasticity. [20]

Data for this study were collected through a questionnaire (Appendix 1) that was sent to each patient during the month of May 2012 in order to analyse the functional outcome and possible complications. The questionnaire was developed for the study, by taking the elements of a validated questionnaire (UDI-6, 2,3,4,8,10 and 13 questions) and supplementing these with issues related to postoperative care. The main items were: age, number of micturitions day / night, urgency, leaks, leaks during exercise, complications, reoperation, satisfaction.

In cases of no response, the doctor followed-up and if necessary a new questionnaire was sent.

All patients who reported undergoing a second surgery after the introduction of the suburethral tape were re-contacted by telephone by a practitioner of the group, other than the one who performed the initial operation.

A statistical analysis was then conducted by an independent firm (Flateworld Solutions, Princeton, New Jersey, USA) using the following techniques:

- correlation to make predictions;
- Chi² test to estimate if the frequency distribution in a population of \( n \) categories differs from any of the expected frequency hypothesis;
- ratio test in order to establish the likely odds of having a positive test when the person is sick compared to a positive test when the person is not sick;
- standardised residuals to check, a posteriori, the statistical validity, coefficient of contingency \( C \) which measures the strength of the connection existing between the two variables considered.

Results

Final results
The number of acceptable cases was 331 and thus sufficient to support of this study. The loss to follow-up was 24%. The average age was 55 years at the time of surgery and 62 (38/92) at the time of the survey (Fig. 1).

Mean follow-up was 84 months (77/88).

28% of patients (\( n = 90 \)) reported leaking on straining, even if occasional. In which case, coughing triggered most incontinence episodes (71%), then heavy lifting (40%) and then sport activities (24%).
The incontinence rate of 28% was the total of cases where the surgery did not cure incontinence: 3% of patients showed no improvement and 25% of patients suffered de novo incontinence after 7 years. This figure is consistent with the percentage of patients who reported that their continence had deteriorated (25%), and the number of patients who reported leaks with straining seven years after surgery (28%), and the number of patients who said that they had to consult a surgeon again after the intervention (25%).

The number of patients reporting having satisfactory urination was 76% and 16% reported having to "push" to empty their bladder. The analysis of the symptom "urinary urgency" showed that 50% of patients who responded reported having urgent or compelling needs (e.g., contact with cold water or the key in the door syndrome).

In 36% of cases the urgency could lead to unwanted leaks.

Note that only 200 patients responded to the question about the existence of urinary urgency preoperatively. Of these 200 cases, 83% reported having had urgency before the tape was implanted.

The proportion "de novo" urgency was 27% and increased with age to 80 and over. The urinary infection rate over the past 12 months was 19%. The subjective cure rate, no leakage after 7 years was 72%.

The number of repeat surgical interventions to treat incontinence was 0.9% (n = 3), in one case a second tape was implanted and in the other two cases an artificial sphincter was implanted.

A single case of tape exposure was noted at the 5 year follow-up.

The overall satisfaction rate was 80%, with 41% of patients saying they were "very satisfied" and 39% who saying they were "satisfied".

**Statistical correlation analysis**

We identified a relationship between age and having satisfactory micturition (Fig. 2). As age increased, there was less satisfaction with micturition. A contrario, the statistical analysis found no relationship between age and urgency. The breakdown by age groups remained homogeneous.
Figure 2: Correlation between age and micturition. Percentage of patients reporting having satisfactory micturition (postoperative analysis).

Figure 3: Correlation between age and stress incontinence. Percentage of patients reporting stress incontinence leaking (Postoperative analysis).

Figure 4 Correlation between age and efficacy of the surgical procedure. Percentage of patients who feel the outcome after 7 years not as good as the immediate postoperative outcome
A statistical relationship was found between age and urinary incontinence (Fig. 3), increasing age and the likelihood of stress incontinence increased.

Similarly, a relationship was found between age and a decrease in the efficacy of the procedure (Fig. 4). As the age increased, fewer patients felt that the surgery remained effective. The difference was most significant for those older than 79 years.

At the time of evaluation, 7 years after surgery, there was a relationship between stress incontinence and urge incontinence (Fig. 5).

There was statistically much less urgency among patients who no longer presented with stress incontinence.(p <0.0001).

**Discussion**
This study showed that nearly three quarters of patients remained continent 7 years after surgery, with a very low rate of complications or of reoperation.

The loss to follow-up was 24% which appears high but compares with the rate in other studies [4-6,10-15].

An analysis of the available literature shows that studies on a sample of significant size (over one hundred patients) combined with more than 5 years follow-up are relatively rare (22% of studies reviewed) (Table 1).

The success rate of our series, estimated at 72%, remained quite comparable to the results observed in the published studies on the transobturator approach with subjective cure rates between 64 [11] and 73% [14].

Several records relating to the retropubic route published long-term results, with a success rate of 76% target to 10 years [10] and 77% with 11 years of follow-up. [5]

The complication rate in this series is lower than those reported in other studies with reasonably long term follow-up and with a significant number of cases.

A single case of exposure (0.3%) was noted, 5 years after surgery. A simple procedure was performed with partial resection. Two years after this recovery, the tape was covered and the patient remained continent. Published results report an erosion rate after 1 and 2 months of 1% [12] to 2.4% at 6 months rate, and 6.1% at 3 years [16].
The number of patients having further surgery within 7 years was 7.5% (n = 25). But in 60% of cases, these operations were not related urological problems. 10 surgical cases were associated with urinary and pelvic disorders, a rate of 3%.

Among them, a case of exposure at 5 years there were three cases of surgery for overactive bladder (a cured after meatotomy, and after two treatments with neuromodulation of which one was associated with a section of tape), three cases for prolapse, and only 3 cases of reoperation for correction of IUE (two cases with an artificial sphincter for major sphincter deficiency, and one case implanting a second tape with a good result).

The number further surgery for recurrent SUI was 0.9% (n = 3), lower than those recorded in comparable studies results; reoperation ranged from 4% [6], 6% [14] and even 14% in some cases [17].

Schierlitz et al. [18] describe a significantly higher rate of reoperation for the transobturator route (20%) compared retropubic route (1.4%) at 3 years (Table 2).

However, these figures should be considered bearing in mind the 24% lost to follow-up because it is likely that some patients may have been treated by other colleagues in the region.

The low rate of reoperation for SUI leaks suggests that if 28% of patients reported having deterioration of results at 7 years, especially for those aged 80+ years, the problem remains moderate.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Study</th>
<th>n</th>
<th>% lost to follow-up</th>
<th>Period (years)</th>
<th>Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serati et al. [15]</td>
<td>Prospective</td>
<td>63</td>
<td>8</td>
<td>10</td>
<td>TVT</td>
</tr>
<tr>
<td>Nilsson et al. [4]</td>
<td>Prospective</td>
<td>90</td>
<td>23</td>
<td>11</td>
<td>TVT</td>
</tr>
<tr>
<td>Rajendra et al. [16]</td>
<td>Retrospective</td>
<td>419</td>
<td>55</td>
<td>3</td>
<td>TVT-O</td>
</tr>
<tr>
<td>Svenningsen et al. [10]</td>
<td>Prospective</td>
<td>603</td>
<td>20</td>
<td>10</td>
<td>TVT</td>
</tr>
<tr>
<td>Groutz et al. [6]</td>
<td>Prospective</td>
<td>60</td>
<td>13</td>
<td>10</td>
<td>TVT</td>
</tr>
<tr>
<td>Abdel-fattah et al. [14]</td>
<td>Prospective</td>
<td>341</td>
<td>30</td>
<td>3</td>
<td>TVT-O</td>
</tr>
<tr>
<td>Olsson et al. [5]</td>
<td>Retrospective</td>
<td>147</td>
<td>15</td>
<td>10</td>
<td>TVT</td>
</tr>
<tr>
<td>Angioli et al. [17]</td>
<td>Prospective</td>
<td>72</td>
<td>16</td>
<td>5</td>
<td>TVT</td>
</tr>
<tr>
<td>Schierlitz et al. [18]</td>
<td>Prospective</td>
<td>164</td>
<td>10</td>
<td>3</td>
<td>TVT / TVT-O</td>
</tr>
</tbody>
</table>

It also seemed important to follow the evolution of urge incontinence "de novo" patients treated by sub-urethral tape for treatment of SUI, quality of life and feelings on the effectiveness of the intervention being strongly impacted by this occurrence.

Seventy-six percent of patients reported not having urinary problems. Svenningsen et al. [10] were announcing a comparable rate: 22% of patients reported problems with micturition. The de novo OAB rate ranged between 18.9 in the studies [15] and 21% [6], which is comparable to the result that we observed (18%).

Satisfaction, a very subjective element, was 80% after 7 years, which is also comparable to other studies: 89% in Serati et al. [15], and 86% for Svenningsen et al. [10].
The results were also similar with respect to patients who consulted a surgeon since the implantation of the tape (25%), dissatisfied patients (20%), those leaking on straining, even occasionally (28%), and those have de novo urgency (18%).

The questions on the level of "satisfaction" remains subjective and do not address the possible voiding disorders. The objective was to assess the overall level of satisfaction with functional pathology and treatment.

One limitation of our study is the absence of a preoperative urodynamic evaluation, and the a 7-year urodynamic evaluation, so it is not possible to correlate the results with the sphincter tone. This would have helped show the evolution of sphincter function with time and probably shown a direct relationship between the sphincter degradation and reduction of improvement in results after 80 years of age. Such a protocol would have been demanding for patients, costly for Social Security, and without direct impact on treatment options. It has therefore not been included but would have been intellectually interesting.

Another limitation of the study is its retrospective nature.

Finally, we can also criticise the fact that the preoperative assessment was based on an interview and a physical examination while evaluation at the end of follow-up is based on a non-validated questionnaire. The scientific value is thereby reduced, but certainly this study still allows one to have a snapshot of "real life" and answer the following question: does this tape associated with this technique, present results meeting our expectations?

Conclusion
After 7 years, the continence rate was 72%, with few postoperative complications (0.3% erosion and 0.9% for recurrent SUI). Eighty percent of patients reported being satisfied. The technique and implant used show their safety and effectiveness.

Voiding disorders linked to "de novo" urgency impact the quality of the outcome and must be followed carefully.

Degradation of higher results were observed without surprise among older patients.

Declaration of interest
The authors participated in the development and testing of the I-Stop tape sold in 2002

Appendix 1 Questionnaire
File no ……………………… NAME ………………………….. FIRST NAME …………………
Questionnaire for women operated sub-urethral tape 2005
Date of intervention: ………………… Current Age:……………… Phone:………………..
How many times do you get up at night to urinate? ……
How often do you urinate the day? ………
Do you urinate in with a good flow? ☐ Yes ☐ No
Do you push to urinate? ☐ Yes ☐ No
Do you have urgent or compelling need to urinate (contact with cold water, key in the door)? ☐ Yes ☐ No
If yes, does this lead to leaks? ☐ Yes ☐ No
If yes, did you have these difficulties before surgery? ☐ Yes ☐ No
Do you have leaks during exercise or coughing? ☐ Yes ☐ No
If yes, when coughing: ☐ doing sport ☐ lifting heavy loads ☐ normal activity
Have you had urinary infections in the last 12 months? ☐ Yes ☐ No
If yes, approximately how many per year? ……
Do you think the outcome of the surgery has deteriorated? ☐ Yes ☐ No
Have you needed further consultations since the surgery? ☐ Yes ☐ No
Have you had further surgery? ☐ Yes ☐ No
How have you found the result so far? ☐ Very satisfying ☐ Satisfactory ☐ Unsatisfactory

Please write any personal comments below:
Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes

Marcos Ballester · Charles Bui · Jean-Luc Frobert · Maryelle Grisard-Anaf · Jean Lienhart · Herve Fernandez · Emmanuel David-Montewore · Roman Rouzier · Emile Daraï

Received: 21 September 2010 / Accepted: 28 February 2011 © Springer-Verlag 2011

Abstract

Purpose To evaluate long-term (over 4 years) functional outcomes and quality of life of transobturator (TOR) and retropubic (RPR) routes in the cure of stress urinary incontinence (SUI).

Methods Prospective, randomized multicentre study involving 88 women with SUI from March 2004 to May 2005 (RPR group \( n = 42 \), TOR group \( n = 46 \)). Long-term functional results and quality of life were evaluated using validated questionnaires and compared with those observed at the Wrst year.

Results Eight patients (19%) in the RPR group and 9 patients (19.5%) in the TOR group were lost to follow-up (NS). The mean follow-up in the RPR and the TOR groups was 52.7 months and 53.1 months, respectively. In intention to treat, the success rate at 4 years was 64.3% in the RPR group and 69.5% in the TOR group (NS). At 4 years, no significant diVerences in the ICIQ scores were observed in either group compared to the preoperative scores with no diVerence between the groups (RPR group: 32 vs. 14.9 (NS), TOR group: 25.7 vs. 21.4 (NS)). Compared to 1 year UDIQ and ICIQ scores, a decrease in quality of life was observed for both groups at 4 years (RPR group: 4.7 vs. 34 \( P < 0.0001 \) and 2.6 vs. 14.9 \( P < 0.001 \), TOR group: 12 vs. 38.7 \( P < 0.0001 \) and 0 vs. 21.4 \( P < 0.0001 \)) without diVerence between the groups. Conclusions This study shows similar relatively high long-term success rates for both the RPR and TOR procedures. Patients should be informed about a possible time-dependent alteration in functional results.

Keywords Stress urinary incontinence · Transobturator route · Retropubic route · Long-term results

Introduction

Midurethral sling surgery has become the gold standard surgical treatment of female stress urinary incontinence (SUI) since Ulmsten introduced the tension-free vaginal tape (TVT) by the retropubic route (RPR) [1]. In 2001, Delorme et al. [2–7] described the placement of a tape by the transobturator route (TOR). Similar short-term functional results were obtained and intraoperative complications related to bladder injury by penetration of the retropubic space were reduced.

In a meta-analysis of randomized control trials comparing TOR with RPR, Latthe et al. [8] reported that adverse events, including bladder injuries, were lower for the TOR route.
procedure. Voiding difficulties were also slightly lower for the TOR procedure without reaching significance. Vaginal injuries were more frequent for the TOR procedure while mesh erosion was similar for both procedures. Both subjective and objective cure rates were similar for both routes [8]. However, all these data are from trials with a short follow-up. Hence, the authors concluded that a randomized control trial with an adequate long-term follow-up was desirable to establish the long-term continued effectiveness of transobturator tapes [8].

Therefore, the aims of the present prospective multicentre randomized study were to compare the success rate, functional results and quality of life of the RPR and TOR procedures with a follow-up of over 4 years and to compare these results with those observed at 1 year.

**Material (patients) and methods**

This prospective randomized multicentre study involved three departments of gynecology and two departments of urology and was conducted in France from March 2004 to May 2005. Women with SUI referred to the centers were randomized to undergo the suburethral sling procedure by either RPR or TOR, by using a predetermined computer-generated randomization code. At the beginning of the procedure, the surgeon called to the Turen hospital to know in which group the patient was included. Women were eligible if they were over 18 years old with SUI proven by clinical and urodynamic examinations. Women with a previous history of radio- or chemotherapy, women with anticoagulant or antipsychotic treatment, neurogenic bladder, and pregnant women were not included. Forty-two and 46 women were enrolled in the RPR and TOR groups, respectively.

The preoperative workup included a standardized physical examination and a urodynamic test. Urinary incontinence was classified as recommended by the International Consultation on Incontinence [9]. The preoperative SUI grades did not differ between the groups. Women in the RPR group had SUI stages 1, 2, and 3 in, respectively, eight (19%), 30 (71.4%), and four (9.5%) cases (72.7%), and women in the TOR group had SUI stages 1, 2, and 3 in, respectively, six (13%), 33 (71.8%), and seven cases (15.2%). Mixed incontinence was diagnosed in 3 cases in the RPR group (7%) and in 3 cases in the TOR group (6.5%). Patients were considered cured with success when they had no stress incontinence by clinical and urodynamic examinations, no incontinence during the stress provocation test during coughing, and no urinary retention (deemed by an inability to void spontaneously the bladder) evaluated during hospital stay or a residual urine volume of less than 150 ml evaluated at the week postoperative visit. Patients were considered cured with improvement when no incontinence occurred during the stress provocation test. All other cases were considered failures.

All the women completed validated questionnaire assessing quality of life (Urinary Distress Impact Questionnaire (UDIQ), the Incontinence Impact Questionnaire (IIQ)) available online (http://www.wfubmc.edu/Research/WHCOE/IIQ-and-UDI-Instrument.htm) as well as a semi-quantitative evaluation on urinary symptoms (dysuria (difficulty with pain to void), pollakiuria (frequency of miction superior to 5 per day), urgency (impossibility to retain urine), and nocturia (necessity of miction over-night superior or equal to 2), on global discomfort and social and emotional discomfort before surgery, at the 1st postoperative visit (4–6 week after surgery), at 3 and 6 months (10-point analogue rating scale; 0 = no discomfort, 10 = unbearable discomfort) [10]. The symptoms were quoted as present in case of result >0. Scores on the UDIQ (ability to do household chores, physical recreational activities, entertainment activities, ability to travel, participating in social activities, and emotional health) range from 0 to 300 and were then recalculated from 0 to 100 with higher scores indicating greater distress. Scores on the IIQ (frequent urination, urine leakage related to the feeling of urgency, urine leakage related to physical activity, coughing or sneezing, small amounts of urine leakage, difficulty emptying bladder, pain in the lower abdominal or genital area) range from 0 to 400 and were then recalculated from 0 to 100 with higher scores indicating more negative effect on quality of life.

All the women underwent a systematic urodynamic evaluation preoperatively and at the 3-month postoperative visit. The preoperative urodynamic evaluation showed that urethral closure was signified lower in the RPR group (46 § 22 cm H2O) than in the TOR group (60 § 31 cm H2O) (P = 0.02). No difference was observed between the groups concerning the maximum flow rate (RPR group: 30 § 13 ml/s and TOR group: 25 § 9 ml/s, P = 0.17) and the residual urine volume (RPR group: 13 § 40 ml and TOR group: 11 § 46 ml, P = 0.8).

The epidemiologic characteristics and surgical histories of the women in the RPR and TOR groups did not differ between the groups [11].

Statistical analysis was based on the Student's t-test and the Mann-Whitney test for parametric and non-normally distributed continuous variables, respectively, and the chi-square test or Fisher exact test, as appropriate, for categorical variables. P < 0.05 was considered to denote statistical significance.

Statistical analysis was based on the Mann-Whitney test because variables were non-normally distributed (tested with the Kolmogorov–Smirnov test) for continuous variables, respectively, and the chi-square test for the categorical variables. To control for multiple comparisons (four at each time point), we applied a Bonferroni correction, setting the...
significance level at 0.002): \( P < 0.0125 \) was considered to denote statistical significance.

Results

Comparison of the RPR and Tor Populations

Eight of the 42 patients (19%) in the RPR group and nine of the 46 patients (19.5%) in the TOR group were lost to follow-up without difference between the groups. Among the remaining patients, one patient in the RPR group (3%) and two patients in the TOR group (5.4%) had mixed urinary incontinence at preoperative urodynamic exploration. The mean follow-up in the RPR and the TOR groups was 52.7 months (range 48–61) and 53.1 months (range 48–63), respectively. All the patients had at least 4 years of follow-up, and no difference in the mean follow-up was noted between the groups.

Success rates after the suburethral sling procedures

In intention to treat, the success rate in the RPR and TOR groups at 4 years was 64.3% (27 patients) and 59.5% (32 patients) without difference between the groups. These rates were lower than those observed at 1 year of follow-up in both groups \( P < 0.001 \).

Excluding the patients lost to follow-up, the success rates at 4 years in the RPR and TOR groups were 79.4 and 86.5%, respectively \( P = 0.63 \). The proportions of women who were cured with success, cured with improvement, and unimproved did not differ between the groups.

Urinary symptoms after the suburethral sling procedures

A trend for a higher rate of dysuria was observed in the RPR compared to the TOR group (50 and 27%, respectively; \( P = 0.08 \)), without difference in the rate of de novo dysuria (Table 1). The rate of nocturia was similar in both groups, while a trend for a higher rate of de novo nocturia was observed in the TOR group (26.5 and 48.6%, respectively; \( P = 0.09 \)). No difference in the rate of pollakiuria and urgency was observed between the groups.

Global and emotional and social discomfort before and after the suburethral sling procedures Global and emotional and social discomforts were evaluated in patients with a follow-up of at least 48 months (RPR group: 34 patients, TOR group: 37 patients). Table 2 summarizes the evolution in both groups at one and 4 years showing a significant improvement compared to preoperative results. At 4 years, an alteration was found for global discomfort and for emotional and social discomfort in the TOR group \( P < 0.0001 \) and the RPR group \( P < 0.001 \), respectively.

Quality of life before and after the suburethral sling procedures

No difference in the 4-year UDIQ and IIQ scores was noted between the RPR and TOR groups \( P = 0.48 \) and \( P = 0.85 \). Table 3 summarizes the evolution of both scores at one and 4 years showing a significant alteration between 1-year and 4-year results in both groups.

Discussion

This study demonstrates that both the RPR and TOR procedures offer similar relatively high long-term success rates on SUI. However, a time-dependent alteration in quality of life emerged for both groups. This study has proved that success rates were similar for both routes in women with a long follow-up over 4 years. In intention to treat, the success rates in the RPR and TOR groups were, respectively, 64.3 and 69.5%. Excluding the patients lost to follow-up, the success rate in the RPR and the TOR groups were, respectively, 79.4 and 86.5% without difference between the groups. These results are in accordance with those of previous non-randomized studies showing that patients had a long-term success rate comprised between 84 and 95% for the RPR procedure and between 85 and 93% for the TOR procedure [2, 12–14]. In intention to treat, our results suggest an alteration of success rate for both routes with long term. However, these results are impinged by a relatively high rate of patients lost to follow-up reaching 19% in both groups. When comparing preoperative and 4-year postoperative global discomfort, emotional and social discomfort, a significant improvement was observed in both groups without.
Table 2 Pre- and postoperative numerical rating scores of global discomfort, and emotional and social discomfort

<table>
<thead>
<tr>
<th>Scores (mean ± SD [range])</th>
<th>Preoperative</th>
<th>First year</th>
<th>Four years</th>
<th>$P$ values*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global discomfort:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>7.4 ± 1.7 (3–10)</td>
<td>1.2 ± 1.9 (0–7)</td>
<td>2 ± 2.3 (0–8)</td>
<td>0.0001 0.02</td>
</tr>
<tr>
<td>TOR</td>
<td>6.5 ± 1.9 (2–10)</td>
<td>0.5 ± 0.9 (0–3)</td>
<td>2.1 ± 2.6 (0–8)</td>
<td>&lt;0.0001 &lt;0.0001</td>
</tr>
<tr>
<td>Emotional and social discomfort:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>6.2 ± 2.5 (0–10)</td>
<td>1 ± 1.7 (0–6)</td>
<td>0.2 ± 0.6 (0–2)</td>
<td>&lt;0.0001 &lt;0.001</td>
</tr>
<tr>
<td>TOR</td>
<td>5.4 ± 2.8 (0–10)</td>
<td>0.5 ± 0.8 (0–3)</td>
<td>0.5 ± 1.6 (0–7)</td>
<td>0.003 1</td>
</tr>
</tbody>
</table>

* Mann–Whitney, significant $P$ values after Bonferroni correction are in bold
  a $P$ values comparing preoperative to results at four years
  b $P$ values comparing first- to four-years results

RPR retropubic route, TOR transobturator route, SD one standard deviation

Table 3 Pre- and postoperative quality-of-life scores (UDIQ) and social and emotional scores (IQ questionnaire)

<table>
<thead>
<tr>
<th>Scores (mean ± SD [range])</th>
<th>Preoperative score</th>
<th>Score at one year</th>
<th>Score at four years</th>
<th>$P$ values*</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDIQ:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>64.2 ± 54.3 (0–127)</td>
<td>4.7 ± 10 (0–127)</td>
<td>34 ± 37.6 (0–125)</td>
<td>0.002 &lt;0.0001</td>
</tr>
<tr>
<td>TOR</td>
<td>62 ± 53 (0–172)</td>
<td>1.2 ± 5 (0–33)</td>
<td>38.7 ± 58.3 (0–225)</td>
<td>0.02 &lt;0.0001</td>
</tr>
<tr>
<td>IQ:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR</td>
<td>32.7 ± 57.6 (0–251)</td>
<td>2.6 ± 16 (0–105)</td>
<td>14.9 ± 29.5 (0–124)</td>
<td>0.36 &lt;0.001</td>
</tr>
<tr>
<td>TOR</td>
<td>25.7 ± 43.5 (0–168)</td>
<td>0</td>
<td>21.4 ± 43 (0–143)</td>
<td>0.49 &lt;0.0001</td>
</tr>
</tbody>
</table>

* Mann–Whitney, significant $P$ values after Bonferroni correction are in bold
  a $P$ values comparing preoperative to four-year results
  b $P$ values comparing first- to four-year results

UDIQ urinary distress impact questionnaire, RPR retropubic route, TOR transobturator route, UDIQ urinary distress impact questionnaire, SD one standard deviation

difference between the groups. When comparing Wrst postoperative year with that noted at 4 years, a significantly greater adverse effect of global discomfort was observed in the TOR group, while a significantly greater improvement in emotional and social discomfort was noted in the RPR group. These data taken together are associated with a decrease in success rates and reinforce the hypothesis of time-dependent functional results.

Using the UDIQ, a significantly greater improvement was noted for the RPR group when comparing preoperative and 4-year postoperative values, while no difference was observed in the TOR group. Although this improvement remains significant, comparison of values at one and 4 years also demonstrated an improvement in quality of life. Recent studies have suggested that alteration in functional results and satisfaction was more frequent when using TORS in patients with mixed incontinence than in women with genuine SUI [15, 16]. In a multivariate analysis, Hovenv et al. [17] noted that mixed urinary incontinence, previous incontinence surgery, and detrusor overactivity were significantly related to the failure of midurethral sling procedures, while no P values exceeding the type of urinary incontinence. Using the IQ questionnaire, no difference was noted between preoperative and 4-year postoperative scores for both groups without difference between the RPR and TOR groups. Several factors can be put forward to explain this improvement in quality of life. First, our data clearly support a progressive improvement in functional results whatever the type of suburethral tape. Second, there might be some variation in the way patients interpret the various items of the questionnaire items according to age. To our knowledge, no data have demonstrated that the impact of SUI evaluated by a validated questionnaire varies according to age. However, Barber et al. [18] underlined that risk factors of SUI symptoms recurrence were correlated with the patient’s age and preoperative anticholinergic medication use for both RPR and TOR.
In both groups, though, the rate of dysuria increased when compared with the percentage observed at one and at 4 years of follow-up. Similarly, the number of patients experiencing urgency increased during the period without difference between the routes. All these symptoms have been suggested to be related to retraction of elastic tapes [11, 19]. But our results suggest that this complication can occur even using non-elastic tape indicating that it is not exclusively related to tape retraction but probably also to Wblasis associated with mesh. Moreover, these symptoms are probably also related to the length of the tape through pelvic structures. Previous anatomical studies support that the length of the tape using the RPR procedure is longer than that using TOV representing a potential cause [20, 21]. In contrast, the rate of de novo and persistent pollakiuria remained steady during the period study without divergence between the groups.

Some limitations of this study can be underlined. First, the study was not designed to evaluate long-term results, representing a potential bias. Second, the relatively high rate of patients lost of follow-up could represent another potential bias. However, in a study comparing inside-out to inside-in TOR techniques, Abdel-Fattah et al. [22] estimated that a drop-out rate of 20% over 3 years should be considered similar to that reported in this study. Another potential explanation is the absence of long-term results after stress urinary incontinence cure especially on the risk of long-term failure that did not encourage the patients to continue the follow-up. Finally, the number of patients with mixed urinary incontinence at preoperative urodynamic exploration was too low to state on its impact on long-term functional results.

Conclusions

This study supports that both RPR and TOR offer a similar long-term functional results. However, patients have to be informed about the possible time-dependent alteration in functional results. The TOR procedure could be recommended for women with SUI due to the lower intra- and postoperative complications. Further studies are required to identify patients with determinant factors of alteration including the presence of a mixed incontinence.

ConXict of interest All authors conXict that they have no conXict of interest.

References


was used to locate and remove the sentinel lymph nodes. Systematic pelvic and paraaortic lymphadenectomy was further carried out. Histological evaluation was assessed by hematoxylin-cosin and immunohistochemistry in case of histological negativity.

**Setting:** Tertiary level oncological hospital.

**Patients:** 77 patients were enrolled in this study, 10 were excluded.

**Intervention:** Histological results of sentinel node and non sentinel node were analyzed to assess the diagnostic accuracy of this method.

**Measurements and Main Results:** In all but three cases at least one sentinel node was detected using radio-guided surgery. In all the cases more than one site was positive to Tc. In four patient sentinel nodes and non sentinel nodes where histologically positive for cancer, in 6 cases sentinel nodes where histologically positive and non sentinel nodes where negative. In 45 cases no cancer cells where found in removed lymph nodes.

**Conclusion:** The hysteroscopic injection of Tc99 labeled human albumin colloid particles in the detection of sentinel node(s) in endometrial cancer is a feasible technique. This study confirms the good sensitivity and specificity of this technique.

### Evaluation of a Polypropylene Mesh Coated with Antibiotics in an Infection Model of Vaginal Surgery in Rabbits

**Study Objective:** Development of a polypropylene mesh coated with ofloxacin, evaluation in vitro and in vivo in an infectious model of vaginal surgery in rabbits.

**Design:** Animal model, study, basic science.

**Setting:** University hospital Ni’ mes (France).

**Patients:** New Zealand White Rabbits (n = 20).

**Intervention:** Tests of bacterial adhesion and bactericidal activity were performed in vitro using immunofluorescence, the used bacterial strain expressing a fluorescent protein (GFP + ) allowed a quantitative and qualitative analysis. The agreement of the regional ethics committee on animal experiments was obtained. The animals were divided into four groups: infected or not and the polypropylene mesh coated or not with ofloxacin. The mesh was located between the vaginal wall anteriorly and the rectum posteriorly. Bacterial inoculation intraoperatively was conducted with a strain of E. coli. Explantation at 1 month led to the production of bacteriological tests.

**Measurements and Main Results:** Immunofluorescence of the mesh coated with ofloxacin and infected by Escherichia coli was similar to the control (uninfected mesh). The bactericidal tests performed in the in vivo model of vaginal surgery in rabbits did not reveal any evidence of E. coli in the polypropylene mesh coated with ofloxacin and infected group. A statistical significant association between infection and erosion was obtained (p<0.001). Our data suggests that erosion is strongly associated with infection and mesh coated with antibiotics could reduce erosion rate.

<table>
<thead>
<tr>
<th>Post Void Residual (ml)ᵃ</th>
<th>162 (85)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative Complications</td>
<td></td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Mesh Erosion</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Mean Follow-up (wks)</td>
<td>30 (range 6-57)</td>
</tr>
<tr>
<td>Mean PVR was 49ml</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion:** This work demonstrated the interest of a polypropylene mesh coated with ofloxacin and placed in contact with a vagina. We were able to validate a model of surgical infection recurring vaginal complications observed in clinical pathology. Our animal model of vaginal surgery in rabbits is very promising and could be used as amodel to study vaginal erosion.

### 17 Plenary Session 4dUrogynecology

**11:01 AMl 11:21 AM**

**1STO P Suburethral Sling: Outcomes of a Non-Deformable Sling for Intrinsic Sphincter Deficiency**

**Karp DR, Lefevre R, Peterson T, Arias B, Davila GW. Department of Gynecology, Cleveland Clinic Florida, Weston, Florida**

**Study Objective:** To determine the post-operative efficacy of a nondeformable retropubic sling for the treatment of intrinsic sphincter deficiency (ISD).

**Design:** Retrospective case-series of patients who underwent an I-STOP suburethral sling for surgical management of ISD between 2007 and 2009. Inclusion criteria were all stress incontinent patients with a urodynamic diagnosis of ISD, urethral hypermobility, and candidates for surgical therapy.

**Setting:** Tertiary referral center for urogynecology and pelvic floor disorders.

**Patients:** Stress incontinent patients with ISD are a challenging population to treat surgically. These patients require adequate suburethral support to enhance urethral sphincter function yet are at risk for postoperative voiding dysfunction. The I-STOP sling is a monofilament, macroporous polypropylene tape with looped mesh edges that maintains rigidity, allows fibrous ingrowth, and minimizes tape shrinkage and migration. The characteristics may translate into more predictable urethral support with less postoperative voiding difficulties. 191 patients with mean age 66.5, parity 2, BMI 29.8 were identified. 44% had previous hysterectomy and 14% prior anti-incontinence procedure. Concomitant reconstructive procedures were performed in 61%. Mean follow-up was 30 weeks. Intervention: The I-STOP sling was performed in a standardized manner. A 3 centimeter incision was made at the bladder neck and the endopelvic fascia dissected from the vaginal epithelium. After application of the fascia, needle introducers were placed through the retropubic space and delivered through ipsilateral suprapubic incisions. The sling was tensioned with a cystoscope in the urethra at a 45 degree angle and the tape sutured to the bladder neck to prevent tape migration.

**Postoperative outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subjective</strong></td>
<td></td>
</tr>
<tr>
<td>Daily Stress Incontinence</td>
<td>7 (13)</td>
</tr>
<tr>
<td>Any Stress Incontinence</td>
<td>14 (7)</td>
</tr>
<tr>
<td>Any Urge Incontinence</td>
<td>40 (21)</td>
</tr>
<tr>
<td>Any Mixed Incontinence</td>
<td>15 (8)</td>
</tr>
<tr>
<td><strong>Objective</strong></td>
<td></td>
</tr>
<tr>
<td>Positive Empty Supine Cough Stress Test</td>
<td>6 (3)</td>
</tr>
</tbody>
</table>

**Conclusion:** This work demonstrated the interest of a polypropylene mesh coated with ofloxacin and placed in contact with a vagina. We were able to validate a model of surgical infection recurring vaginal complications observed in clinical pathology. Our animal model of vaginal surgery in rabbits is very promising and could be used as amodel to study vaginal erosion.

**Urasonographic Scan Evaluation of Synthetic Mesh Used for Vaginal Cystocele Repair Comparing Four Arons Trans Obturator Techniques to Anterior Blateral Sacro Spinous Ligament and Arcus Tendinous Suspension**

**Lefevre V, Mousty E, Haberlandt S, Pouget O, Mares P, de Tayrac R. Gynecology, CHU Caremeau, Nimes, Gard, France, Metropolitan**

**Study Objective:** The main objective is the evaluation by ultrasonographic scan of mesh contraction after vaginal cystocele repair and surgical procedure impact.
An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency

Alfredo Jijon - Aparna Hegde - Beatriz Arias - Vivian Aguilbar - G. Willy Davila

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Abstract
Introduction and hypothesis. We evaluated outcomes of an inelastic retropubic sling in patients with intrinsic sphincteric deficiency (ISD).
Methods. This is a retrospective review of women diagnosed with ISD according to urodynamic parameters who underwent a retropubic suburethral sling surgery using a tape with minimal elasticity. All patients in the study who followed up at 2, 6, and 24 weeks and yearly. Outcome measures included self-assessed satisfaction, daily incontinence episodes and pad usage, standardized stress test, postvoid residual volume, and surgical complications.
Results. Two hundred and forty-seven patients were involved in this study, with a median follow-up of 43 [interquartile range (IQR) 22–77] weeks and a minimum of 12 weeks. Two patients (0.008%) had a positive stress test postoperatively. There was a decrease in daily incontinence events (median 1.5–0) (p<0.001) and pad usage per day (median 1.5–0) (p<0.001). Two hundred and sixteen (87.4%) patients reported subjective improvement in symptoms. Urinary retention was found in 18 (7.2%) patients, and 19 (7.7%) patients required reintervention, mostly with bulking agent injections for persistent incontinence. No tape-related mesh exposures were reported.
Conclusion. Retropubic suburethral inelastic slings represent a good option for treating patients with ISD, with satisfactory continent rates and low postoperative complications.

Keywords. Intrinsic sphincteric deficiency · Stress urinary incontinence · I-ST0P sling

Introduction

Although intrinsic sphincter deficiency (ISD) is a commonly used phrase, it is not consistently defined in the urodynamic literature [1]. What is clear, however, is that as the name states, the urethral sphincter fails to hold urine, producing involuntary leakage [2]. Approximately 30 years ago, McGuire defined ISD as the worst form of stress urinary incontinence (SUI) (Type III), in which sphincter impairment was so significant that a minimal increase in abdominal pressure could lead to urine leakage [3]. Maximal urethral closure pressure (MUCP) of <20 cm H2O and/or Valsalva leak-point pressure (VLPP) of ≤60 cm H2O, a urodynamic measure described by McGuire, remain the accepted diagnostic criteria despite the controversy that exists about the definition of this condition [4].

Urodynamic parameters are the most objective means of assessing urethral function, although data available on the value of these parameters in predicting sling success, short- or long-term, is limited. However, women with a VLPP or MUCP in the lowest quartile are nearly twofold more likely to experience SUI 1 year after transobturator or retropubic midurethral sling placement [5].

There have been substantial improvements in the treatment of female SUI (SUI). However, ISD is still associated with a high incidence of surgical failure [2]. Success rates with transvaginal tape (TVT) or transobturator sling (TOT), the most commonly used slings in ISD patients, range between 50% and 86% in long-term follow-up studies [6–9]. In an attempt to improve outcomes, several
novel slings have become available with different tape characteristics (elasticity, flexibility, variation in material), as well as different implantation techniques (adjustable, helical, etc.), each one with its touted benefits and risks. Reduction in elasticity may be beneficial because unlike high elasticity slings that deform under strain, an inelastic sling allows individualized tensioning in patients in whom some tension may be beneficial due to poor urethral function.

We performed a retrospective study to evaluate outcomes of patients diagnosed with ISD who underwent suburethral sling procedures with an inelastic [10] type I polypropylene sling [11] placed at the proximal urethra via a retropubic approach.

Materials and methods

Patients with urodynamically proven SUI with ISD who underwent a suburethral sling procedure with an inelastic monofilament, macroporous sling with looped edges (Fig. 1) (I-STOP, CL Medical, Lyon, France) between February 2007 and November 2011 at the Cleveland Clinic, Florida, USA, with a minimal follow-up of 12 weeks, were reviewed. The institution’s comprehensive urogynecological database was queried for patient data after obtaining Institutional Review Board approval.

Inclusion criteria for sling placement were based on urodynamic parameters with a MUCP of ≤40 cm H₂O and/or a VLPP at ≤60 cm H₂O capacity and urethral hypermobility [4]. These urodynamic parameters were chosen because MUCP and VLPP are commonly used tests to assess urethral function. MUCP of 40 cm H₂O was chosen based on our center’s data on a higher failure rate of transobturator slings with MUCP ≤40 cm H₂O and/or VLPP at capacity ≤60 cm H₂O [4]. Self-reported pad usage per day was not used as a study inclusion criterion, as it is an unreliable measure of incontinence severity with a significant age bias [12]. Older patients have been previously reported to have a higher gram per pad urinary loss into fewer total pads [12].

All patients were examined by the primary surgeon prior to surgery and evaluated at the postoperative follow-up visits by one of five clinicians, including postgraduate fellows. Patient data consisted of demographic variables such as age, body mass index (BMI), gravidity, parity, menopausal status, and tobacco use. Urogynecologic symptomatology, including incontinent events and pad usage per day and post urogynecologic procedures was recorded. Preoperative evaluation included physical examination to determine vaginal support anatomy and degree of urethral mobility via a Q-tip test, urinalysis and culture, and empty supine stress test (ESSST). Multichannel urodynamic testing was performed using air-charged catheters and routine technique in all patients [13]. All surgical procedures were performed by two experienced urogynecologic surgeons. Perioperative factors considered were type of anesthesia, blood loss, concomitant procedures, and complications.

Follow-up visits where scheduled at the 2, 6, and 24 weeks postoperatively and then yearly. At each visit, data collected included reporting of subjective satisfaction, incontinent events and pad usage per day, standardized stress test, pelvic examination, postvoid urine residual measured by ultrasound (US), urinalysis, and sexual activity symptoms. The standardized stress test was performed with 250 cc of urine in the bladder in supine and standing (if no leakage when supine) positions. Incontinence events and pad usage were reported. Bladder diaries were not routinely completed, and quality of life questionnaires were not used routinely. However, patients completed a 5-point standardized global improvement scale comprising cured, greatly improved, improved, not improved, worsened, which was administered on intake by a clinic nurse. Subjective success was defined as cured or greatly improved. Outcome measures analyzed were daily incontinence episodes and pad use, stress test results, the 5-point standardized global improvement scale, postvoid residual urine volume, and perioperative and postoperative complications.

Statistical analysis was performed using PASW STATISTICS 18 (SPSS, Chicago, IL, USA). Continuous variables were tested for normality using Shapiro–normality test. Normal continuous data was described as mean and standard deviation (SD), with 95% confidence interval (CI), and abnormal continuous data was described as median and interquartile range (IQR). Normal continuous variables were analyzed with paired t test, and abnormal data was analyzed with Wilcoxon signed rank test. Categorical data was analyzed using the chi-square test. Fisher’s exact test was used if the value of any cell in the 2 × 2 contingency table was <5. A p value <0.05 was considered significant.

Fig. 1 Mesh used for the I-STOP sling.

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Operative technique

Proximal urethral placement of the sling was based on previously reported pubovaginal sling techniques, which have been described as indicated for severe SUI or ISD. This technique is designed to mimic the mechanism of such traditional pubourethral slings [14]. The surgical approach for I-STOP sling is similar to other retropubic slings. Two small (1-cm) incisions were made 2 cm above and lateral to the pubic symphysis for later passage of the sling needles. The anterior vaginal wall was infiltrated with 1% lidocaine with epinephrine and incised vertically suburethrally for a length of 3 cm. The endopelvic fascia was dissected off the vaginal mucosa bilaterally to the vaginal sulcus and urogenital diaphragm. This allowed sufficient bladder-neck mobility so that the desired sling tension could be achieved by the surgeon. The sling needles were guided ipsilaterally through the urogenital diaphragm and space of Retzius and through the suprapubic incisions. Cystoscopy was performed to rule out injury to either urethra or bladder. A suprapubic catheter was placed under cystoscopic visualization, if required. The ends of the sling tape were then connected to the needles, and both needles were pulled upward through the suprapubic incisions. The sling was secured by a suture to the proximal urethra. Sling tensioning was performed using a 21-F cystoscope held in a 45° angle to the horizontal plane [15]. The excess tape was cut just below the skin line. Closure of the suprapubic and vaginal incisions was accomplished with surgical glue and 2-0 Vicryl suture, respectively.

Results

Our query yielded 247 patients who had undergone I-STOP sling surgery for ISD during the study period. Table 1 displays patient demographic data. The vast majority were menopausal, with 75% being older than 60.5 years and 25% older than 78.0 years; 68.4% were overweight (BMI >24.9), with 27.9% categorized as obese (BMI >29.9). Thirty-three patients had undergone previous anti-incontinence surgery, with three having undergone more than one.

Preoperative urodynamic parameters were as follows: median (IQR) MUCP was 28 (20.5), VLPP at capacity 42 (27.5) cm H2O, peak flow 14.6 (7.05) ml/min, mean flow 5 (4.45) ml/min, and detrusor pressure at maximal flow 10.2 (4.6) cm H2O. Median blood loss was 100 ml (IQR 50), with no events of postoperative hemorrhage or blood transfusion. One hundred twenty-eight patients (51.8%) underwent spinal anesthesia, 118 (47.8%) general anesthesia, and one (0.004%) both. One hundred ninety-seven (79.8%) patients had concomitant procedures, specific surgeries are listed in Table 2. There were few complications associated with surgical procedures or during the immediate recovery period. One patient developed a vaginal hematoma, which required drainage 6 weeks after the procedure, and one developed a rectovaginal fistula unrelated to the sling, which required intervention. One bladder laceration with a sling needle was recognized during cystoscopy and required suturing during surgery without having any later consequences or affecting the patient’s continence. There were no vaginal or bladder tape exposures reported during the follow-up period.

Median follow-up was 43 (IQR 22–77) weeks. Median number of postoperative visits was four (IQR 3–6). Table 3 shows subjective and objective outcomes after surgery: 87.4% of patients reported being cured or improved; >71% reported being cured at the last follow-up recorded; 12.4% stated they did not improve or got worse.

Median number of incontinence events per day and pad usage revealed a significant decrease from preoperative to the postoperative values. Occult incontinence was reported in 85 (34.4%) patients who had concomitant prolapse. The

---

Table 1: Demographic data (N=247 patients)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>69.4 (17.5)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>68.2 (15.3)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>160 (60.1)</td>
</tr>
<tr>
<td>BMI</td>
<td>27.0 (6.0)</td>
</tr>
<tr>
<td>Parity</td>
<td>2.00 (1.00)</td>
</tr>
<tr>
<td>Menopausal status</td>
<td></td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>221 (89.5%)</td>
</tr>
<tr>
<td>Premenopausal</td>
<td>26 (10.5%)</td>
</tr>
<tr>
<td>Smoker</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>187 (59.5%)</td>
</tr>
<tr>
<td>Past + current</td>
<td>135 (40.5%)</td>
</tr>
<tr>
<td>Previous surgeries</td>
<td></td>
</tr>
<tr>
<td>TAH</td>
<td>76 (30.76%)</td>
</tr>
<tr>
<td>TVH</td>
<td>31 (12.55%)</td>
</tr>
<tr>
<td>Anti-incontinence surgery</td>
<td>33 (13.4)</td>
</tr>
<tr>
<td>Pelvic repair surgery</td>
<td>27 (10.9)</td>
</tr>
</tbody>
</table>

*Median (interquartile range)

Table 2: Concomitant procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hysterectomy</td>
<td>39</td>
<td>15.79</td>
</tr>
<tr>
<td>Anterior repair</td>
<td>108</td>
<td>43.72</td>
</tr>
<tr>
<td>Posterior repair</td>
<td>130</td>
<td>60.73</td>
</tr>
<tr>
<td>Abdominal apical suspension</td>
<td>8</td>
<td>3.24</td>
</tr>
<tr>
<td>Vaginal apical suspension</td>
<td>109</td>
<td>44.13</td>
</tr>
</tbody>
</table>
remaining 162 (65.5 %) patients had a positive stress test during pelvic examination. All had urodynamically documented ISD. One hundred and twenty-five patients had mixed urinary incontinence (MUI) prior to surgery, of whom 40 had significant bother at 6 weeks following surgery and were given anticholinergic medication. Four patients developed de novo urge following surgery, of whom two reported symptoms 12 weeks following surgery but did not require medication; two developed urge 2 years after surgery and were given anticholinergic medication. Eighteen (7.2 %) patients had postvoid residual urine volume >100 mL at the last follow-up visit; 12 (66.7 %) of them were asymptomatic, and six (33.3 %) reported having voiding abnormalities (slow, interrupted, dribbling). The number of sexually active patients decreased from 100 (40.5 %) before to 80 (32.4 %) after the surgery. The proportion reporting dyspareunia among sexually active women remained similar, with 35 (35 %) prior to surgery and 36 (33.8 %) after surgery. Nineteen (7.7 %) patients required reintervention: 11 underwent bulking agent injection for persistent incontinence; five underwent sling take-down or transection for urinary retention. Sling transection was performed at least 3 months postoperatively to allow full integration of the sling arms and reduce the likelihood of recurrent SUI.

Discussion

The principal focus of our study was to evaluate the use of an inelastic suburethral sling in patients with ISD, a challenging, severe form of SUI. The I-STOP sling is a type 1 polypropylene, monofilament, macroporous, mesh tape [16] similar to the traditionally used synthetic slings except that it is woven to be much less elastic. It is now well known that monofilament tapes decrease the risk of infection compared with multifilament meshes [17]. Multifilament slings do not allow white blood cells to enter interstices between filaments <10 μm, making infection more likely [18]. Monofilament slings have less risk of producing healing abnormalities (i.e., mucosal exposures) compared with multifilament slings (1.3 % vs. 5 %, respectively) [19]. I-STOP tapes are macroporous, which means that the pore size is >75 μm [17]. This allows fibroblasts, mononuclear phagocytes, and polymorphonuclear neutrophils to infiltrate through pores and create a better environment to permit tissue incorporation into the tape material [18].

As the I-STOP sling has lower elasticity [16], the surgeon may be able to apply tension more precisely. Its construct minimizes tape deformability, which may provide a more predictable postimplantation behavior [20]. It was initially thought that in order to prevent urinary retention, sling tapes had to have high elasticity, but new studies have proven otherwise [10]. Being inelastic, there may be less likelihood of tape shrinkage, which can lead to progressive retention and irritative bladder symptoms, possibly requiring sling revision. Another important characteristic of this tape is its high flexibility compared with other type I tapes, which have medium flexibility. This means it may have the capacity to bend, making it more malleable during surgery [20]. As a result, it may be more accurately tensioned and may lay flat without deformation suburethrally. Another unique characteristic of this tape is the presence of looped tape edges [20]. This may help decrease mucosal exposure into adjacent tissue and may improve tissue fixation. There were no vaginal exposures in our study, whereas in other studies in which TVT or TO T tapes were used, exposure rates were reported between 1.4 % and 3.8 % [6, 7, 21]. However, our median follow-up of 43 weeks was too short to make any definite conclusions regarding mesh exposure following I-STOP sling surgery. Also, the potential benefit of low elasticity and high flexibility need to be assessed in comparative studies.

Results of our study are encouraging when compared with other published articles on the use of suburethral slings for ISD treatment. Gungorduk et al. reported an overall cure rate of 52.5 % with TVT and 78.3 % when using TVT [7]. Similarly, Choo et al. reported a success rate of 76.6 % after
a minimum follow-up of 3 years in ISD patients using TVT [6]. In both those studies, however, the mean age was 50.6 and 58.7 years, respectively. Deo et al. found an overall cure rate of 50% after 5 years of follow-up in a retrospective study of 134 patients with VLPF of ≤50 cm H₂O treated with TVT [8].

A retrospective study by Jeon et al. found that cure rates following TVT in ISD patients decreased from 86.94% to 55.09% between the 2- and 7-year follow-up [22]. On the other hand, Rezaee et al. reported an overall improvement of 86% using TVT in a prospective study [9]. However, the majority of patients in whom TVT failed were >70 years of age. It must be noted that almost 50% of patients in our study were >70. This supports the fact that the incidence of ISD increases as women age, as does SUI severity.

In a randomized controlled trial of 164 patients, Schieritz et al. compared the efficacy of TVT and TOT in patients with ISD. They reported a 45% and 21% failure rate 6 months after surgery in TOT and TVT, respectively. Similarly, when an intention-to-treat analysis was undertaken, they found that one of every six patients with TOT and one of every 16 patients with TVT would have required surgical reinervention for further correction [23]. Sling tensioning with a cystoscope at a 45° angle was based on a study by Ostermann et al., in which the MUCP was measured intraoperatively while performing the sling tensioning procedure. The authors reported that using this technique for tensioning, there was a normalization of MUCP when the scope was held at a 45° angle without excessive tensioning, which could lead to urinary retention [15].

There were 19 (7.7%) patients who required reinervention in our study. In contrast, Araco et al. reported a 17% recrudescence rate: 12 for bladder obstruction and 17 for failure to cure incontinence [24]. Intervention was uncommon in our patients. We were very careful during tensioning to avoid overcorrection. That may explain the need to perform bulking agent injections in patients with persistent SUI.

Urinary retention is the most frequent complication in sling surgery for SUI [25]. In our study, 18 (7.2%) patients had urinary retention at the last recorded visit, with five (1.6%) patients requiring sling takedown with simple transection. Studies involving TVT slings have reported a similar or higher retention rate and sling removal. Wang et al. reported a 26% rate of voiding dysfunction after undergoing a TVT procedure for SUI or MUI [26]. Similarly, Aubassouly et al., in a retrospective study using TVT sling, reported a 32% rate of retention longer than 48 h, 20% requiring intermittent catheterization and 4.5% required sling takedown or transection for urinary retention [27]. Guazzi et al. reported voiding difficulties in 25.7% of patients, with 5.7% of the patients requiring sling takedown [28].

Our study is not exempt from weaknesses. It was a retrospective study without comparison to a control group or the use of validated questionnaires. Inclusion criteria were based on urodynamic parameters, and hence, a proportion of our study patients had occult incontinence. However, a previous study that established that poor urethral function, as determined by urodynamic parameters, is associated with sling failure also included 20% with occult incontinence. Thus, the presence of occult incontinence in our study population may not be a confounding factor for assessing the efficacy of the I-STOP sling. Median follow-up was 43 weeks. This could be considered a short-term follow-up, and there should be a delayed analysis performed of the same group of patients to determine long-term outcomes of this sling.

**Conclusion**

From the results of this investigation, we can conclude that an inelastic retropubic suburethral sling is effective for patients with ISD. Further research is necessary using this type of sling in a randomized, prospective, comparative trial to corroborate these findings.

**Conflicts of interest** GW Davila: honoraria, American Medical Systems; CL Medical, Astellas, Vavel-Chilecot; consultant, American Medical Systems, Coloplast, CL Medical, Astellas: research funding. CL Medical. Other authors: No conflict of interest

**References**

I-STOP Suburethral Sling: Outcomes of a Non-Deformable Sling for Intrinsic Sphincter Deficiency
DR Karp, R Lefevre, TV Peterson, BE Arias, GW Davila
Section of Urogynecology and Pelvic Reconstructive Surgery
Department of Gynecology
Cleveland Clinic Florida

SUI: Spectrum of disease
- Spectrum of urethral dysfunction in SUI patients
  Good sphincteric function/
  Hypermobile urethra
  Poor sphincteric function/
  Immobile urethra
- ISD patients:
  - More severe incontinence & urgency symptoms
  - Greater incidence of associated voiding dysfunction
  - More scarring from previous anti-incontinence procedures
  - Lower chance for surgical success
  - Higher rate of sling-related complications
  Rezaapoor M, Faliczer C. Int Urogyn J 2001

TOT slings for ISD have inferior results

RCT. TOT vs. TVT
- RCT comparing TOT vs TVT for ISD
  - 6 month follow-up:
    21% TOT vs 35% TVT urodynamic SUI (p=0.034)
    9.7% TOT vs no TVT had repeat SUI surgery
  - 3 year follow-up (IUGA/ICS B2010):
    16.3% TOT vs 12.7% TVT underwent additional SUI surgery due to sling failure (p<0.001)
    Performing TVT over TOT avoids 1 in 5 failures

Biomechanical properties of sling types
- Softness ↔ Hardness
- Shrinkage ↔ Stability
- Elasticity ↔ Stiffness

I-STOP Sling
- Monofilament, macro porous
- Looped mesh edges
- Maintains rigidity across width
- Fibrous ingrowth
- Low erosion risk
- Minimal tape shrinkage & migration
  More predictable urethral support & less postoperative voiding difficulties?

*CL Medical, Boston, MA
To determine the post-operative efficacy and safety of a non-deformable retropubic sling for the treatment of stress incontinence due to intrinsic sphincter deficiency.

Why is non-deformability important in ISD?
- Allows for a more precise individualized tensioning in order to optimize sphincteric function.
- More predictable support to the proximal and mid-urethra upon appropriate tensioning.
- Lack of deformation may reduce tape shrinkage and thus lead to less post-operative voiding difficulty and dysfunction.

Pariante J, Vilars F et al. Prog Urol. 2005

Methods
- Retrospective case-series of all patients who underwent an I-STOP suburethral sling at Cleveland Clinic Florida between 2007-2009
- Inclusion criteria:
  - Symptomatic stress incontinence
  - Urodynamic diagnosis of ISD with urethral hypermobility
  - Valsalva LFP ≤ 60
  - MUCP ≤ 20
Methods

Intraoperative
- Complications
- EBL
- Bladder perforation

Postoperative outcomes
- Subjective
  - Complaint of SUI
  - Incontinent events/day
- Objective
  - Standardized cough stress test
  - Postvoid residual

I-STOP Procedure
- Similar technique to standard TVT or other retropubic sling
- 3cm suburethral incision & 2 small suprapubic incisions
- Full urethral mobilization is performed
- 2 introducers guided through Space of Retzius, delivered through ipsilateral suprapubic incisions
- Cystoscopy to confirm bladder integrity

Individualized Tensioning
- Tape secured w/ suture suburethrally
- Tensioned with a cystoscope in the urethra at a 45° angle (normalization without overcorrection)
- Tape flat beneath urethra

Results: Baseline patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>191</td>
<td>66.5 (12.6)</td>
</tr>
<tr>
<td>Vaginal parity</td>
<td>191</td>
<td>2.4 (1.5)</td>
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<tr>
<td>BMI</td>
<td>191</td>
<td>29.8 (7.3)</td>
</tr>
<tr>
<td>Postmenopausal</td>
<td>191</td>
<td>161 (84)</td>
</tr>
<tr>
<td>Previous surgery</td>
<td>191</td>
<td>84 (44)</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>191</td>
<td>19 (10)</td>
</tr>
<tr>
<td>Burch/MMK</td>
<td>191</td>
<td>7 (4)</td>
</tr>
</tbody>
</table>

Results: Concomitant surgical procedures

<table>
<thead>
<tr>
<th>ASSOCIATED PROCEDURES</th>
<th>N</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>I-STOP Alone</td>
<td>60</td>
<td>31.4%</td>
</tr>
<tr>
<td>+ VVS-A/P Repair</td>
<td>34</td>
<td>17.6%</td>
</tr>
<tr>
<td>+ Lefort Colposis</td>
<td>27</td>
<td>14.1%</td>
</tr>
<tr>
<td>+ A/P Repair</td>
<td>23</td>
<td>12.0%</td>
</tr>
<tr>
<td>+ TVH-McCall-A/P Repair</td>
<td>20</td>
<td>10.5%</td>
</tr>
<tr>
<td>+ Post Repair</td>
<td>18</td>
<td>9.4%</td>
</tr>
<tr>
<td>+ ASC-A/P Repair</td>
<td>5</td>
<td>2.6%</td>
</tr>
<tr>
<td>+ Pengee-A/P Repair</td>
<td>3</td>
<td>1.2%</td>
</tr>
<tr>
<td>+ Elevate + Post Repair</td>
<td>1</td>
<td>0.5%</td>
</tr>
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</table>

Results: Other intraoperative characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia</td>
<td>129</td>
<td>103 (57)</td>
</tr>
<tr>
<td>General</td>
<td>78</td>
<td>41 (41)</td>
</tr>
<tr>
<td>Spinal</td>
<td>5</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Combined</td>
<td>129</td>
<td>103 (57)</td>
</tr>
<tr>
<td>Estimated blood loss</td>
<td>129</td>
<td>1230cc ± 54</td>
</tr>
<tr>
<td>Bladder perforation*</td>
<td>1</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

n(%) = Mean ± standard deviation
* Requiring continuous bladder drainage
Results: Postoperative outcomes

<table>
<thead>
<tr>
<th>Postop</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Cure&quot; or &quot;Greatly improved&quot;</td>
<td>174 (91)</td>
</tr>
<tr>
<td>Reported daily leakage</td>
<td>26 (15)</td>
</tr>
<tr>
<td>Negative cough stress test</td>
<td>185 (97)</td>
</tr>
</tbody>
</table>

- n(%)  
- Mean follow-up: 33 weeks (range 6-60)

Results: Postoperative complaints

<table>
<thead>
<tr>
<th>Preop</th>
<th>Postop</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress incontinence</td>
<td>79 (41)</td>
</tr>
<tr>
<td>Mixed incontinence</td>
<td>77 (40)</td>
</tr>
<tr>
<td>Urgency/Urge incontinence</td>
<td>35 (18)</td>
</tr>
</tbody>
</table>

- n(%)  
- Denovo urgency: 3 (2%)

Results: Postoperative (other)

- No significant voiding dysfunction postoperatively
  - Mean post-void residual (PVR) at first post-operative visit = 45 cc
- No sling revisions for BOO performed
- No tape exposures/erosions

Conclusion

- The I-STOP sling is a safe and effective treatment for ISD
- Non-deformable tape construction
  - Individualized suburethral tensioning
  - Less risk of tape shrinkage
  - High continence rate → minimal risk of denovo urgency & voding dysfunction
- A non-deformable tape can be beneficial in the surgical treatment of severely incontinent patients with ISD
I-STOP suburethral sling: Less deformation improves outcomes for Intrinsic Sphincteric Deficiency

Beatriz ARIAS, G.W. DAVILA
Department of Gynecology, Section of Urogynecology and Reconstructive Pelvic Surgery
Cleveland Clinic Florida, Weston, Florida, USA

Contact author:
G. Willy DAVILA, M.D
Cleveland Clinic Florida, 2950 Cleveland Clinic Blvd., Weston, Florida 33331.
[p] 888-978-0004. [fax] 954-659-5560 [email] davilag@ccf.org

Key words:
Stress urinary incontinence (SUI), Intrinsic sphincteric deficiency (ISD), Urodynamic parameters, I-STOP Sling

Abstract:
Objective: To evaluate urinary outcomes of patients who underwent an I-STOP low deformation sling procedure for Intrinsic Sphincteric Deficiency (ISD). Materials and methods: This was a retrospective case-series review. Patients with ISD by urodynamic criteria underwent an I-STOP suburethral sling. Baseline characteristics and preoperative symptoms were described. Subjects underwent postoperative evaluation at 2, 6 and 24 weeks, which included a standardized stress test and postvoid residual measurement. Registered outcomes include reported and objective continence, complications and voiding dysfunction. Results: A total of 191 patients were included. The mean postoperative follow-up was 30.17. Subjective cure was reported by 91% of the patients. 81% reported no daily stress urinary incontinence events. Urinary tract infections, vaginal pain and symptoms of incomplete emptying were minor complication in less than 0.5%. Mean postoperative postvoid residual was 49.42 cc. No vaginal wall erosions or need for sling revision were identified. There were no differences in outcomes or complications when a sling was done alone or along with other surgical procedures for pelvic organ prolapse repair. Conclusions: The I-STOP sling represents an effective treatment modality for ISD patients with no significant postoperative voiding dysfunction being identified.

Mid urethral slings has been used as a primary surgical choice for female stress urinary incontinence (SUI) over the past 12 years. Ulmsten and Peters introduced the TVT sling procedure (retropubic approach) in 1996, and many variations have been developed since then [1]. In 2001, Delorme introduced the transobturator approach TOT (Out-to-in) and De Leval in 2003 modified the needle placement to TVT-O (In-to-Out) [2,3]. These surgical options have been compared to each other as well as with the gold standard Burch colposuspension and traditional pubovaginal slings. These novel slings have demonstrated similar overall efficacy with distinct advantages over older surgical techniques; namely simplicity and reduced morbidity. However, some unexpected perioperative complications have been described, primarily related to tape construct (types II and III), voiding dysfunction and suboptimal outcomes in more severe SUI types [4].

Slings and Type III stress urinary incontinence (ISD)

SUI has been classified as types I-II (urethral hypermobility), and III (intrinsic sphincteric deficiency, ISD) [4]. Although both retropubic and transobturator slings can be used for SUI, a special situation occurs in patients with ISD. This frequent entity demonstrates a wide spectrum of stress urinary incontinence severity and is diagnosed basically by urodynamic findings including a maximum urethral closure pressure (MUCP) < 20 cm H2O and leak point pressure at capacity (LPP) < 60 cm H2O [5,6].

ISD is a challenging situation for any surgeon, and usually has been surgically treated with a retropubic sling, which provides better support to the bladder neck and posterior urethra, thus enhancing sphincteric function. Transobturator slings have demonstrated inferior results in ISD patients in various studies. Miller found in a cohort study, that low maximum urethral closure pressure was a risk factor for failure with the transobturator technique [7]. It was 6 times more likely to fail than tension-free vaginal tapes at 3 months after surgery. Similar findings were published by Schieritz, in a prospective, randomized controlled
study comparing the efficacy of TOT with TVT in 164 women with ISD [8]. In the intention-to-treat analysis, the risk ratio for need of repeat surgery was 2.6 times higher in the TOT group than in TVT. Other series have likewise demonstrated poor outcomes with TOT and TVT slings for ISD [9,10,11].

When TVT is used in SU1/ISD patients, voiding dysfunction is a frequently reported complication, likely due to a surgeon’s likelihood of over-tensioning the sling. It can range from 1.9% to 19.7%, and can be present as urinary retention, difficult emptying or weak urinary stream [12]. Many patients consider postoperative voiding dysfunction to have a greater negative quality of life impact than stress incontinence.

The I-Stop sling is constructed from a monofilament macroporous, polypropylene mesh, that maintains rigidity across its entire width despite sustained traction. This construction is important for fibrous ingrowth and mesh infection prevention. Also, pore size can be a direct determinant factor in tape rigidity and possible shrinkage after implantation [13]. Due to its specific weave, the tape maintains its shape during implantation and tensioning and has looped mesh edges which may translate into reduced tape shrinkage and erosion risk. This "less stretchability" feature allows for a more precise individualized tensioning in order to optimize sphincteric function. These mesh characteristics translate to more predictable support to the proximal and mid-urethra upon appropriate tensioning with less postoperative voiding dysfunction [14].

![Figure 1 - I-STOP sling tape physical characteristics](image)

**Objective**

To evaluate urinary outcomes of patients who underwent I-STOP low elasticity sling procedure for Intrinsic Sphincteric Deficiency (ISD).

**Materials and Methods**

A urogynecologic database review was performed at Cleveland Clinic Florida for all patients who underwent I-Stop slings for Intrinsic Sphincteric Deficiency from February 2007 to February 2009.

Inclusion criteria included patients who had a diagnosis of ISD and urethral hypermobility demonstrated at preoperative urodynamics. The parameters used were Maximal Urethral Closure Pressure (MUCP) ≤ 20 cm H2O and Valsalva leak point pressures (VLPP) ≤ 60 cm H2O. At the first visit, patients underwent structured interview and physical exam, including POP-Q examination and multichannel urodynamic testing.

Baseline characteristics evaluated were age, BMI, parity, vaginal deliveries, menopausal status and genital atrophy. Intraoperative data included: blood loss, concomitant procedures, intra-operative complications and anesthesia type. The selected outcome measures were self-reported continence, reported daily stress urinary incontinence episodes and standardized stress test. Voiding function and post-void residual were recorded postoperatively as well as any complications. Patients were seen for follow up at 2, 6, 24 weeks and yearly.

**Operative technique**

After receiving prophylactic antibiotics and under general or spinal anesthesia, the patient is placed in high lithotomy position and the anterior vaginal wall is injected with 1% lidocaine with epinephrine. Two small incisions are made 2 cm above and lateral to the pubic symphysis. The anterior vaginal wall is incised vertically, approximately 3 cm, and the endopelvic fascia is dissected off the vaginal mucosa laterally towards the lateral vaginal sulcus, and up to the urogenital diaphragm. The endopelvic fascia is then imbricated in the midline using interrupted 2-0 Vicryl sutures along the mid and proximal urethra.

The needle introducer is then guided through the space of Retzius and delivered through the ipsilateral suprapubic incision. The same was done on the contralateral side. Cystoscopy is then performed. A suprapubic catheter is placed under direct cystoscopic visualization if indicated. The bladder is then drained, the tape is sutured to the bladder neck, the sling ends are pulled through the abdominal incisions and tensioning is performed with the scope at 45 degrees angle.

![Figure 2 - Tensioning of I-Stop sling for ISD](image)
The excess tape ends are cut at the level of the skin. The suprapubic incisions are closed with surgical glue. A Foley catheter is then replaced, and the vaginal mucosa is closed using 2-0 Vicryl suture. A vaginal packing is placed for homeostasis. Voiding is encouraged as soon as the patient is ambulatory. If additional reconstructive procedures are performed, the patient is kept in the hospital overnight.

Results

Our query yielded 191 women who had undergone an I-STOP sling for SUI/ISD.

Table 1 summarizes their demographic data:

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>ISTOP</th>
<th>MEAN (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVH</td>
<td>26</td>
<td>13.61%</td>
</tr>
<tr>
<td>TAH</td>
<td>38</td>
<td>30.30%</td>
</tr>
<tr>
<td>TVH</td>
<td>19</td>
<td>9.88%</td>
</tr>
<tr>
<td>Burch</td>
<td>7</td>
<td>3.6%</td>
</tr>
<tr>
<td>Table 1 - Demographics</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Almost a half (44%) of subjects had undergone previous hysterectomy and 14% a prior anti-incontinence procedure (Table 2):

Mean estimated blood loss was 125.47cc ± 54.08cc and no subject required intraoperative or postoperative blood transfusion. Intraoperative complications included 1 bladder perforation that was managed with bladder catheter for 3 days. No urethral or bowel injury due to sling procedure was recorded. The mean post-operative follow-up period was 30.17 weeks (Range 6-50)

Subjective improvement (cured and greatly improved) was reported by 91% of the patients (Table 5):

<table>
<thead>
<tr>
<th>Table 5 - Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>Cured-Greatly Improved</td>
</tr>
<tr>
<td>Some Improved</td>
</tr>
<tr>
<td>Not Improve</td>
</tr>
<tr>
<td>Worsened</td>
</tr>
</tbody>
</table>

87% of the patients reported no daily stress urinary incontinence events or less than 1 weekly. 97% had no leakage in standardized stress test. A comparison between pre and postoperative urinary symptoms was made and no significant difference was found in urge symptoms, with a significant decrease in stress and mixed symptoms (Table 6):

Table 6 - Incontinence Symptoms

Urinary tract infections, vaginal pain and symptoms of incomplete emptying were minor complication in less than 0.5%. Postoperative postvoid residual at 2 and/or 12 weeks were not elevated by ultrasound or catheterization with a media of 49.42 cc (Range 5-101 cc).

No need for sling revision or vaginal wall erosion were identified. There were no differences in outcomes or complications when a sling was alone or along with any other surgical procedure for pelvic organ prolapse repair.

Discussion

The results of this retrospective study demonstrate that the I-STOP sling represents an effective treatment modality for ISD patients with low MUCP and ALPP. The overall cure was over 91%, using various objective and subjective parameters with no significant postoperative voiding dysfunction been identified. The large number of patients included were selected by strictly urodynamic criteria thus preoperative urinary symptoms included significant irritative symptoms, as in any ISD population.

All the procedures were performed by same surgeon and included procedures other than an I-STOP sling in approximately 70%.

This study cannot be compared to previous published I-STOP sling series as ISD likely represents a distinct patient population. It demonstrates clearly the necessity
for prospective series to enhance knowledge about differences in performance between I-STOP and other slings (TVT/TOT) in women with ISD.

The I-STOP sling tape has special characteristics described by Palente J et al, who compared in vitro biomechanical characteristics of six slings used for urinary stress incontinence [14]. The mechanical properties were quite different and varied widely among mesh softness/hardness, elasticity/stiffness, shrinkage/stability, etc. I-STOP showed less deformation capacity over its initial length, over the other slings. The authors suggest that different sling types and individualized tensioning may be of significant benefit to specific SUI patients especially those with ISD.

<table>
<thead>
<tr>
<th>Sling Type</th>
<th>Maximum Deformation (%) of initial length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sparc®</td>
<td>108.24 ± 11.5</td>
</tr>
<tr>
<td>TVT®</td>
<td>94.5 ± 10.2</td>
</tr>
<tr>
<td>Uratape®</td>
<td>68.04 ± 5.4</td>
</tr>
<tr>
<td>Uretex®</td>
<td>61.36 ± 11.8</td>
</tr>
<tr>
<td>IVS®</td>
<td>31.4 ± 1.8</td>
</tr>
<tr>
<td>I-STOP®</td>
<td>17.25 ± 2.59</td>
</tr>
</tbody>
</table>

Table 7. In vitro characteristics

ISD clearly constitutes a complex clinical problem, which frequently impacts other parts of lower urinary tract function such as voiding. Besides lack of agreement on diagnostic urodynamic parameters, few recommendations exist as to which sling should be used in this specific patient condition.

Just as lack of tension may lead to persistent SUI such as when an ISD patient undergoes a TOT or TVT-O, too much tension can readily lead to voiding dysfunction and urinary retention. If a sling is to be tensioned on an individual basis, the behavior of the tape after implantation must be very predictable. Any tape shrinkage can lead to progressive retention and irritative bladder symptoms, possibly requiring sling revision. The lack of deformation of the I-STOP sling appears to be maintained after implantation, as we did not observe any new onset voiding dysfunction over the follow up time period.

The definition of postoperative urge retention is not standardized, but it usually signifies a post-void residual of greater than 50-100 mls, for at least 1 week. This complication may require intermittent self-catheterization. If improvement is not seen within 4 weeks, early simple sling lysis and transaction should be considered and it could be required in 0.1% to 7% of cases. In this series, only 15.18% of subjects had a postvend residual > 100 cc.

We did not note any vaginal mucosal erosions in this series. The looped tape ends may be significant positive contributor, as we would expect at least 1-2 erosions to be found in a case series of this size.

The I-STOP sling has special features making it a rational option when a surgeon is looking to perform a tensioned sling. Being able to apply a desired tension force with less deformation capacity relative to other slings types with less likelihood of shrinkage and reduced erosion risk are unique positive attributes of this sling. The I-STOP sling has an important role in management of SUI especially type III (ISD).

REFERENCES

Comparison of non-elastic slings for ISD associated stress incontinence

Marjorie Jean-Michel, Roger Lefevre, G.W Davila. Cleveland Clinic Florida

Objective: To compare the efficacy of 2 non-elastic retropubic slings in the management of intrinsic sphincter deficiency: I-STOP and Anterior IVS.

Background: Retropubic slings are commonly recommended for patients with urethral hypermobility and intrinsic sphincter deficiency (ISD). Inherent mesh characteristics such as filament structure, pore size and type of material have been shown to be significant factors in erosion rates. Elasticity is the ability of a material to deform under external stress but return to its original shape. A "non-elastic" mesh is used synonymously as "non-deformable" mesh in the Urogynecologic literature and this property plays a role in its tensioning ability. The use of a polypropylene tape with minimal elasticity allows for a more precise individualized tensioning in order to improve sphincteric function¹.

We investigated the efficacy of 2 commonly used non-elastic slings: I-STOP suburethral sling (CL Medical) and Anterior IVS (Tyco/US surgical) for the treatment of ISD.

Methods: Our Urogynecologic clinical database was queried for all patients with: stress incontinence with urethral hypermobility and maximal urethral closure pressure (MUCP) ≤ 20 cm H2O and valsalva leak point pressures (VLPP) ≤ 60 cm H2O who underwent Anterior IVS or I-STOP slings. Patients' demographics such as age, parity, history of previous urogynecologic surgery, as well as patient self-assessment responses, incontinence episodes per day, pad use per day, results of standardized stress test (ST) and presence of postoperative urge and urge incontinence were obtained. Success was defined as: cured or greatly improved on patient self-assessment, no incontinence episodes/day, no daily pad use and a negative ST. A 2-sample t-test or Wilcoxon rank sum test was used to compare continuous measures. A Pearson Chi-square test or a Fisher's exact test was used for comparing success rates within each category, as well as comparing pre and post-operative urge incontinence rates. All analyses were performed using SAS software (Cary, NC) or R 2.5.1 software.

Results: Between I-STOP and Anterior IVS, a total of 318 slings were performed from March 2001 and January 2009. Of these, 187 patients (73 vs. 114, respectively) with follow-up time >/= 6 months were included for analysis. Mean post-operative follow-up period was 73 weeks (range 24-240 weeks). Anterior IVS patients were older (72.9 vs. 68.6 years, p = 0.009). There was no difference in height, weight, parity, or menopausal status. I-STOP patients fared better than Anterior IVS patients, based on self-assessment ratings (93.2% vs. 81.6%, p = 0.026). There was no difference in any of the remaining outcome measures (Table 1). De novo urge incontinence rates were similar in each group (22.2% vs. 18.9%, respectively, p = 0.68). There were eight erosions requiring excision in the IVS group and none in the I-STOP group.

<table>
<thead>
<tr>
<th></th>
<th>Overall</th>
<th>I-STOP</th>
<th>Ant IVS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success Rates</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Self-Assessment</td>
<td>161(86.1)</td>
<td>68 (93.2)</td>
<td>93 (81.6)</td>
</tr>
<tr>
<td>Incontinence/day</td>
<td>154 (82.4)</td>
<td>62 (84.9)</td>
<td>92 (80.7)</td>
</tr>
<tr>
<td>Pads/day</td>
<td>160 (85.6)</td>
<td>64 (87.7)</td>
<td>96 (84.2)</td>
</tr>
<tr>
<td>ST</td>
<td>184 (98.4)</td>
<td>73 (100)</td>
<td>111 (97.4)</td>
</tr>
</tbody>
</table>

Conclusion: I-STOP suburethral sling demonstrated better success rates than Anterior IVS sling based on patient selfassessment scoring. There were no differences in incontinence episodes per day, pad use per day, ST, or de novo urge incontinence. The low complication rate and high success rate demonstrates the utility of the I-STOP sling inpatients with ISD.

Female Urology-Incontinence

Peri-Operative Complications and Pain After the Suburethral Sling Procedure for Urinary Stress Incontinence: A French Prospective Randomised Multicentre Study Comparing the Retropubic and Transobturator Routes

Emmanuel David-Montefiore, Jean-Louis Frobert, Marielle Grisard-Anaf, Jean Lienhart, Karine Bonnet, Christophe Poncelet, Emile Darai

Service de Gynécologie-Obstétrique, Hôpital Trousseau, Université Saint-Antoine Paris IV, Assistance Publique des Hôpitaux de Paris, 4 rue de la Chêne, 75020 Paris Cedex 11, France
2 Service de Gynécologie, Hôpital de Bourg en Bresse, France
3 Clinique Sainte Anne Lumière, Lyon, France
4 Clinique Trévèl, Saintes Colombe, France
5 Service de Gynécologie-Obstétrique, Hôpital A. Béclère, Université Paris XI, Assistance Publique des Hôpitaux de Paris, France

Abstract

Objective: To compare peri-operative complications, pain, and the immediate functional results of the sub-urethral sling procedure for urinary stress incontinence by the retropubic and transobturator routes, using a non-elastic polypropylene sub-urethral sling.

Patients and Methods: This prospective, multicentre study involved 88 women undergoing the sub-urethral sling procedure for stress urinary incontinence (SUI). The retropubic route (RPR) and the transobturator route (TOR) were used in respectively 42 and 46 cases. The characteristics of the women in the RPR and TOR groups were as follows: mean age (± standard deviation) 56.8 ± 12 years and 53.4 ± 10 years, respectively; mean BMI: 25 ± 4 and 26 ± 4; mean parity: 2.1 ± 0.9 and 2 ± 1 children; post-menopausal status: 66.7% and 58.7%; prior surgery for SUI: 7.1% and 6.5%; and prior hysterectomy: 21.4% and 26.1%. None of these characteristics differed significantly between the groups. Likewise, pre-operative urinary functional status (SUI stage, and pollakiuria, nocturia and urgency rates) was similar in the two groups.

Results: Mean hospital stay and overall morbidity rate were not significantly different between the RPR and TOR groups. Mean operating time was longer in the RPR group. Bladder injury was significantly more frequent in the RPR group and vaginal injury was significantly more

* Please visit www.eu-acme.org to read and answer the EU*ACME questions online. The EU*ACME credits will then be attributed automatically.
* Corresponding author. Tel. +33 1 56 01 73 18; Fax. +33 1 56 01 73 17.
E-mail address: emile.darai@h.ap-hop-paris.fr (E. Darai).
frequent in the TOR group. Pain scores were significantly lower in the TOR group. The objective functional results at one month did not differ between the groups. Quality of life, evaluated with questionnaires and numerical rating scales, was similarly improved in the two groups.

Discussion: The suburethral sling procedure was less painful by the TOR route than by the RPR route. Bladder injury, haematomas and abscesses were only observed in the RPR group, while vaginal injury only occurred in the TOR group. The immediate functional results of the two approaches were similar.

1. Introduction

Since the first description of the tension-free vaginal tape (TVT) procedure by Ulmsten et al. in 1996, using an elastic polypropylene tape (TVT™, Gynecare) for the treatment of female stress urinary incontinence (SUI) [1], TVT has become one of the most popular procedures worldwide for the treatment of SUI, owing to its high long-term success rate [2]. However, potential immediate surgical complications include bladder perforation [3], and injury to the pelvic vessels [4], bowel [5,6] and ilioinguinal nerve [7]. Moreover, de novo urge incontinence and voiding dysfunction may occur following over-correction associated with the retropubic approach and/or the use of elastic polypropylene tape [3].

In 2001, Delorme et al. advocated the use of the transobturator route in order to avoid the complications associated with the retropubic route [8]. Insertion through the obturator and pubococcygeus muscles reproduces the natural suspension fascia of the urethra while preserving the retropubic space. In a preliminary study, Delorme showed that the transobturator route was associated with a high success rate, no bladder injury, and few peri-operative complications in women with urinary incontinence [8]. These results were recently confirmed in a large series of women, using non-elastic polypropylene tape [9]. Salomon et al. [10] also used the transobturator route for anterior vaginal wall prolapse repair, and confirmed its safety in terms of vessel and bladder injury. The retropubic and transobturator approaches to SUI treatment have not been compared using the same polypropylene tape. The aims of this prospective randomised multicentre study were to evaluate post-operative pain, peri-operative complications, and the immediate functional outcome of the TVT procedure for SUI, using the same non-elastic polypropylene tape and comparing the retropubic and transobturator routes.

2. Population and methods

This prospective randomised multicentre study involved three gynaecology units and two urology units, and was conducted in France from March 2004 to May 2005. All the surgeons had lengthy experience with the retropubic route and had performed at least 30 procedures by the transobturator route. Women with SUI were randomised to undergo suburethral sling procedure by either the retropubic route (RPR) or the transobturator route (TOR), by using a predetermined computer-generated randomisation code. The ethics committee approved the study protocol, and all the women gave their written consent after receiving full information on the study.

The preoperative work-up included a standardised history and physical examination and a urodynamic evaluation. Urinary incontinence was classified as recommended by the International Consultation on Incontinence [11]. All the women completed validated questionnaires on quality of life (urinary distress impact questionnaire: UDI) [12], and on the social and emotional impact of SUI (incontinence impact questionnaire: IQI) [12], before surgery, at the first post-operative visit (4-6 weeks after surgery), and 3, 6, 12 and 24 months postoperatively. This preliminary report describes only peri-operative complications, pain, and the immediate functional results evaluated at the first postoperative visit.

The I-STOP® device (Cl. Medical, Lyon, France) was used for both the RPR and the TOR procedure. The tape consists of macroporous (>75-micron pore size) non-elastic monofilament polypropylene mesh.

All the procedures were performed in the modified dorsal lithotomy position. Blood pressure, the ECG and transcutaneous oxygen saturation were continuously monitored. The RPR procedure was performed as described by Ulmsten et al. [1] and the TOR procedure was performed as described by Delorme et al. [8]. The choice between general and regional anaesthesia was made in each centre. The prosthetic implant was placed under the midurethra. A vertical 15-mm vaginal incision was made 10 mm below the urethral meatus. Dissection of the paraurethral space on each side of the incision was performed with scissors, towards the ischiopubic ramus.

For RPR, ancillary was similar to that use for TVT procedure.

In the TOR approach, the needle of the device was introduced on each side through a 5-mm incision in the
<table>
<thead>
<tr>
<th>Table 1 – Epidemiological characteristics of the study population</th>
</tr>
</thead>
<tbody>
<tr>
<td>RPR (n = 42)</td>
</tr>
<tr>
<td>Mean age (SD [range])</td>
</tr>
<tr>
<td>Mean BMI (SD [range])</td>
</tr>
<tr>
<td>Mean parity ± SD (range)</td>
</tr>
<tr>
<td>Nulliparity n (%)</td>
</tr>
<tr>
<td>Mean weight of first baby (g) ± SD (range)</td>
</tr>
<tr>
<td>Macrosomia (&gt;4500 g) n (%)</td>
</tr>
<tr>
<td>Post-menopausal status n (%)</td>
</tr>
<tr>
<td>Prior surgery for SUI n (%)</td>
</tr>
<tr>
<td>Prior hysterectomy n (%)</td>
</tr>
</tbody>
</table>


3. Results

3.1. Epidemiological and urodynamic characteristics of the RPR and TOR groups

The epidemiological characteristics and surgical histories of the women in the RPR and TOR groups were not significantly different (Table 1). The preoperative SUI grades, and urinary symptoms

are shown in Table 2. Urodynamic parameters in the two groups are summarised in Table 3. There were no significant differences between the groups as regards the SUI grade distribution or the frequency of mixed incontinence, pre-operative polliakuria, or nocturia. Pre-operative urinary urgency tended to be more frequent in the RPR group (p = 0.06). Pre-operative urodynamic parameters, including the urinary residual volume and bladder capacity, were similar in the two groups. Urethral closure pressure was lower in the RPR group (p = 0.02).

3.2. Operating time and peri-operative complications

The mean operating time was significantly longer in the RPR group. No difference in the postoperative urinary residual volume was noted. None of the women required bladder self-catheterisation postoperatively (Table 4).
Intra- and postoperative complications and postoperative pain intensities are shown in Table 5. The overall complication rate was similar in the two groups. Vaginal injury was significantly more frequent in the TOR group than in the RPR group (p = 0.02), whereas the bladder injury rate was significantly higher in the RPR group (p = 0.03). No vascular, nervous or intestinal injuries occurred.

Two women had haematomas, complicated by an abscess in one case; all these complications occurred in the RPR group. The woman with the abscess was re-admitted and was treated with antibiotics; further surgery was not necessary. Postoperative pain was less severe in the TOR group than in the RPR group (p = 0.0008) (Table 5). The mean hospital stay in the RPR and TOR groups was 1.8 ± 1.7 (1-8) and 1.4 ± 0.5 (1-2) days, respectively (no significant difference).

### 3.3. Functional results and quality of life

The impact of surgery on urinary status at one month is shown in Table 6. The cure rate was similar in the two groups. Likewise, the rates of postoperative pollakiuria, nocturia and urinary urgency were not different between the groups.

The UDI questionnaire (Table 7) showed a significant improvement in both groups. The postoperative UDI scores did not differ between the groups.

### 4. Discussion

This prospective randomised study shows that the suburethral sling procedure by the transobturator route (TOR) is associated with less postoperative pain but a higher risk of vaginal injury than the retropubic route (RPR). In contrast, bladder injury was more frequent in the RPR group. The RPR and TOR routes gave similar rates of immediate success in the treatment of urinary incontinence.

The most striking finding is the lower postoperative pain scores among the women in the TOR group compared to those in the RPR group. These are the first comparative data on postoperative pain after the two procedures. In a study of 450 women, Duckett and Jain [13] reported that 1% of women had groin pain after the suburethral sling procedure by the retropubic route. In a series of 235 retropubic suburethral sling procedures, Borrut et al. [14] found that postoperative pain impaired the quality of life of 30% of patients. Tsivian et al. [15]
reported that the most common complaint after the TVT procedure was persistent urethral pain. Barrington et al. [16] suggested that suprapubic pain directly over the iliopelvic ligaments (“post-colposuspension syndrome”) after the TVT sling procedure was related to dense adherence to the iliopelvic ligaments. Persistent pain can be controlled by local injections of steroids plus local anaesthetics, but some women nonetheless require sling excision [14]. Few data are available on pain after the suburethral sling procedure by the transobturator route. In a preliminary study, Delorme et al. [8] reported no pain among women undergoing the transobturator procedure. Using 1-stop tape and the transobturator route, Krauth et al. [9] observed cases of transient pain requiring anti-inflammatory drugs or minor analgesics, and also pain lasting two months after the procedure, but it should be noted that postoperative pain was not systematically evaluated. There is no clear explanation for the lower incidence of pain associated with the transobturator route. It is conceivable that differences in the nervous and venous anatomy lead to a lower risk of nerve injury and compression (due to haematoma) with the transobturator approach [17].

The overall complication rates associated with the TOR and RPR routes were similar in this study. Vaginal injuries were always located in the lateral fornix and only occurred in the TOR group. They were treated by simple suturing and healed without further consequences. Delorme et al. [8] did not report observing this complication. In contrast, Krauth et al. [9] reported a vaginal injury rate of 0.3% in a retrospective multicentre study. The high incidence of vaginal injury in our study may have been due to inadequate lateral dissection, needed to introduce the finger through vaginal incision and thus to guide the needle. Another potential explanation is the use of an outside-in transobturator procedure, requiring a downwards then inwards orientation of the needle in an oblique direction. In contrast, the inside-out procedure, beginning with needle placement behind the ischiopubic ramus, avoids initial vaginal perforation. Although Bonnet et al. [17] found that the tape placed by the inside-out route remained far from the dorsal nerve of the clitoris and from the obturator nerve and vessels in a study of 12 cadavers, further clinical studies are needed to evaluate the specific risks associated with this approach.

Bladder injury is the main concern when using the retropubic route for suburethral sling placement, with an incidence of up to 24% during TVT and SPARC procedures [3,18]. This complication is not always recognised during initial cystoscopy [19] and can be a source of late complications such as chronic pain and urinary tract infection requiring further surgery. No bladder injury occurred with the transobturator route in our study, tending to confirm that routine cystoscopy is not needed during the outside-in TOR procedure [20,21]. Nevertheless, bladder injury was recently reported after TOR suburethral sling placement [9,22].

The RPR route, contrary to the TOR route, was associated with complications such as haemorrhage, retropubic haematoma and pelvic abscess. Our data are in keeping with those of previous outside-in and inside-out TOR studies showing no bladder or urethral injuries and no vascular or neurological complications [23,24]. Our results for the retropubic route are also compatible with reported incidence rates of haemorrhage, suprapubic infection and haematoma of respectively 2.1% [25], 0.4% and 1.9% [26]. In contrast, in the largest published series of transobturator sling procedures [9], the incidence of haemorrhage and perineal haematoma was only 0.8% and 0.33%, respectively.

No cases of immediate postoperative dysuria or urinary retention were observed in our study, regardless of the route used. This was probably due to the non-elastic nature of the slings. Previous studies of TOR using non-elastic polypropylene slings also showed a low incidence of dysuria and retention (1.3% and 1.5%, respectively) [9,24]. In recent studies using elastic slings and the retropubic route, urinary retention occurred in up to 12.9% of cases [26,27]. Using elastic slings and the transobturator route, de Leval et al. [23] observed a retention rate of 2.8%, although voiding disorders were not routinely analysed.

The main aims of this study were to document pain, peri-operative complications and immediate functional results, and further follow-up is clearly required to determine long-term outcomes. However, it is noteworthy that the immediate cure rate was similar with the two approaches, and was in keeping with previously reported rates observed with suburethral slings [18]. Likewise, the rates of postoperative pollakiuria, nocturia and urinary urgency, and quality of life, were similar in the TOR and RPR groups. Previous studies of TVT procedures have shown high rates of de novo dysuria and urinary urgency (5% to 38% and 1% to 36%, respectively) [28,29]. Like us, Krauth et al. [9] observed low rates of de novo urinary urgency and dysuria, and suggested that these good results were attributable to the use of the transobturator route. In contrast, we consider that the main factor influencing immediate postoperative outcome is the use of non-elastic slings rather than the choice of route.
In conclusion, this prospective study shows that TOR is less painful than RPR. Bladder injury, haematoma and abscess formation were only observed in the RPR group, while vaginal injury only occurred in the TOR group.

References

Sub-Urethral Tape Treatment of Female Urinary Incontinence—Morbidity Assessment of the Trans-Obturator Route and a New Tape (I-STOP®): A Multi-Centre Experiment Involving 604 Cases


Abstract

**Purpose:** To make an assessment of the morbidity related to using the trans-obturator route (TOT): findings after one year for the 140 first cases and preliminary results of short term morbidity after 604 implants.

**Patients and Method:** This retrospective, multi-centre study involves the 604 first procedures with a 1–3 month follow-up. The mean patient age was 57 years. 92% of the patients underwent an isolated urinary incontinence cure and 8% had associated surgery. 47.3% of the cases had pure stress urinary incontinence and 52.7% had mixed incontinence. A 12-month minimum follow-up period was applied to the first 140 cases operated between September 2002 and January 2003. Patient assessment was made by a clinical examination in the first three months and their satisfaction rate expressed after 1 year.

**Results:** Operative complications were very few: 0.5% vesical perforations, 0.3% vaginal perforations, no urethral wounds, 0.8% 200–300 ml haemorrhages, two perineal haematomas (0.33%). The post-operative period was marked by: 1.5% transient retentions, 2.3% transient pain, 2.5% urinary infections, 1.3% transient dysuria.

The 1–3 month follow-up of 572 patients shows a 5.2% rate of de novo symptoms. Patient assessment of 131 subjects after one year revealed an encouraging satisfaction rate of 85.5% with a 1.5% rate of de novo dysuria and urgency. To date there have been no serious or specific complications attributable to the surgical route adopted. The morbidity is not affected by associated surgery.

**Conclusion:** The trans-obturator route combines low morbidity with a low rate of de novo symptoms on a large series. These results will have to be corroborated by further studies.

Keywords: Trans-obturator route; Sub-urethral tape; Stress urinary incontinence; Morbidity

1. Introduction

Stress urinary incontinence surgery has been revolutionised by the arrival of the tension free vaginal tape technique (TVT) first described in 1995 by Ulmsten...
[1]. Follow-up assessments of over 5 years currently make it the "gold standard" technique [2,3].

Delorme's preliminary work on the use of the trans-obturator route for sub-urethral tape implantation (the TOT technique) [4] has opened up an interesting perspective simplifying the surgical procedure and making it more innocuous. The TOT technique appealed to us from the outset and we decided to put it to the test of a multi-centre series trial. For the purpose we chose a new implant, whose characteristics match the ideal specification currently required for prosthetic sling materials [5,6] perfectly.

2. Equipment and method

Six centres and seven surgeons including four gynaecologists and three urologists took part in this multi-centre experiment. The first 140 patients underwent surgery between 1 September 2002 and 15 January 2003. They were then studied retrospectively to assess the morbidity of the technique and the implant. The encouraging results made us enlarge our series. We report the data concerning the 604 first and consecutive procedures performed to date. The aim of this retrospective study is to assess the surgical morbidity of the trans obturator route in the first 3 months following surgery.

2.1. Surgical technique

It is based on Delorme's descriptions [4,7] and primarily differs in the device used. The prosthetic implant is placed under the mid-urethra and passes through the obturator foramen. Surgery commences with an anterior, vertical 15 mm vaginal incision at a point 10 mm below the urethral meatus. Dissection of the para-urethral spaces is then made laterally, with scissors, towards the ischiopubic ramus on either side. The resulting detachment leaves enough room for the index finger to pass. The external needle entry point is made in the genito-femoral fold by a short cutaneous incision made slightly above a horizontal line passing through the clitorial hood. The needle of the device is introduced through this orifice, initially in a direction perpendicular to the cutaneous plane. Once the obturator membrane has been crossed, it is orientated downwards and forwards in an oblique direction to reach the finger inserted in the para-urethral detachment space. It is then wound round the ischiopubic ramus, while the protecting finger remains in contact with the needle until it is exteriorised by the sub-urethral incision. The tape is then "clipped" to the needle tip and exteriorised via the genito-femoral fold after withdrawing the needle. The same procedure is carried out on the opposite side, and then tension-free adjustment is made to the tape under the mid-urethra. Vaginal closure is made with interrupted sutures using slow absorption thread to avoid premature wound dehiscence. Cutaneous closure is made with fast absorption thread. Cystoscopy is hardly ever performed. We feel it is essential to check the vaginal fornices for transition during surgery. During the course of our experiment the incision entry point was modified. At the beginning of the experiment the genito-femoral fold incision was made at the level of a horizontal line running over the urethral meatus. Gradually this point was raised above a horizontal line going through the clitorial hood. This modification became obvious to each surgeon independently, without any consultation. Its effect is to increase the tape angulation to obtain an angle of 45° to the horizontal.

2.2. Prosthetic implant

The I-STOP® device we are using has been developed in collaboration with a company (CI. Médical) based near Lyon (France). In terms of its structure and current composition, the tape matches the ideal specification currently required [5,6]. It presents the following characteristics:

- Exclusively mono filament polypropylene mesh. Ulmusen [6] has demonstrated it and the use of TVT® has confirmed it. Its material and manufacturing technique provide the highest tolerance to date.
- Arterial structure: macro pores of over 75 microns.
- No rope effect: the tape maintains its integrity right across its width despite sustained traction.
- It is supple and has no shape memory: easy to manipulate, so that it can be adapted in harmony with the patients' anatomy.
- Non-aggressive edges: the tape sticks to the tissues without presenting any irritation.
- No particle release: through a specific cutting-out process.
- Systemic particle migration has been described only during periurethral injections of various materials [8–11]. It has not been possible to link any specific complication to the migration of a polypropylene particle to date. However we consider it important to include this parameter in the specification, to curb a potential risk, as the anatomical area and type of material used are similar in our procedure.
- Low weight per area: specific knit weave, fine thread and little material used.

2.3. Method

All the surgeons had TVT and vaginal surgery experience. In the series, the surgical indications comprised both pure stress urinary incontinence (when stress urinary incontinence is the only symptom) and mixed or complicated urinary incontinence defined as a combination of incontinence symptoms (when another urinary symptom is associated to stress urinary incontinence). Pre-operative urodynamics was not systematically required by the surgeons when faced with typical pure stress urinary incontinence. However it was always performed in cases of mixed or complicated urinary incontinence. The length of hospitalisation, urinary catheterisation and the type of anaesthesia varied according to the individual centre and surgeon. The patients were assessed on the basis of a clinical examination and questioning before their hospital discharge and during the first 3 months following surgery. Patient assessment after 1 year of the 140 first cases was made subjectively by asking them to establish their satisfaction level and describe any persistent or de novo (new) urinary symptoms. Patient satisfaction expresses how well the functional result achieved matched their expectations of the surgical procedure.

2.4. Patients

The total population figure studied for the 1–3 month follow-up is 604. 140 patients had one-year follow-up. The mean patient age was 57 years. 556 patients (92%) had isolated TOT urinary incontinence treatment and 48 (8%) underwent associated surgery (prolapse surgery or hysterectomy) and were studied separately.

Stress urinary incontinence was pure in 47.3% of cases (34.5% of degree 2 and 11% of degree 3) while 52.7% suffered from mixed incontinence (33% of degree 2 and 17.7% of degree 3).
3. Results

3.1. Peri-operative period (Table 1)
Surgery was possible in all cases. The results of the peri-operative period are listed in Table 1.

3.2. Complications
Surgical complications of 604 procedures were very few (about 2%) as shown in Table 2. Our results on surgical morbidity do not reveal any digestive, vascular or urethral wounds. One of the three cases of bladder perforation occurred during a hysterectomy. The haemorrhages were classically treated simply by tamponage, but in one case of an isolated TOT procedure (0.16%) the tape had to be cut during surgery to control perineal venous bleeding. One perineal haematoma (0.16%) in a patient who underwent associated prolapse surgery required immediate revision surgery. We observed no serious or specific complications attributable to the surgical route adopted

Post-operative complications were also moderate (7.5%) (Table 3). Transient pains disappeared after a few days’ treatment with anti-inflammatory drugs and minor analgesics, except in one case (0.16%) with persistent pain 2 months after surgery (isolated TOT). One case (0.16%) of transient dysuria needed revision surgery on Day 1 to lower the tape and one case (0.16%) of retention required section of the tape on Day 3. No patient had to practice self-catheterisation after hospital discharge. Two cicatrisation faults occurred including one premature wound dehiscence and one secondary exposure of the tape after 2 months. They were simply covered over surgically without complication.

572 patients were assessed by clinical examination and questioning in the 3 months following surgery, the immediate failure rate and the urinary symptoms induced (de novo symptoms) are detailed in Tables 4 and 5.

Of the 140 first cases, nine patients (6.4%) were lost to follow-up after 1 year. The assessment was thus made on 131 patients and presented a satisfaction rate of 85.5% (Table 6). Four of the non satisfied patients required repeat surgery and 1.5%, complained of de novo symptoms (urgency and dysuria). No problems of infection on the tape have been noted.

Table 1
Peri-operative period

<table>
<thead>
<tr>
<th>Anaesthesia</th>
<th>Length of operation</th>
<th>Hospitalisation</th>
<th>Urinary catheterisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>Loco-regional</td>
<td>&lt;15 min &lt;30 min</td>
<td>&lt;24 h &lt;48 h</td>
</tr>
<tr>
<td>432 (71.5%)</td>
<td>172 (28.5%)</td>
<td>452 (75%) 545 (90%)</td>
<td>407 (67.4%) 558 (92.4%)</td>
</tr>
<tr>
<td>432 (71.5%)</td>
<td>172 (28.5%)</td>
<td>452 (75%) 545 (90%)</td>
<td>407 (67.4%) 558 (92.4%)</td>
</tr>
</tbody>
</table>

Table 2
Surgical complications

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Bladder perforation</th>
<th>Vaginal perforation</th>
<th>Haemorrhage</th>
<th>Haematoma</th>
<th>Immediate section of tape</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated TOT</td>
<td>556</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>–</td>
</tr>
<tr>
<td>Associated surgery</td>
<td>48</td>
<td>1</td>
<td>–</td>
<td>1</td>
<td>1</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Total</td>
<td>604</td>
<td>3 (0.5%)</td>
<td>2 (0.33%)</td>
<td>5 (0.83%)</td>
<td>2 (0.33%)</td>
<td>1 (0.16%)</td>
<td>–</td>
</tr>
</tbody>
</table>

Table 3
Post-operative complications

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Transient retention</th>
<th>Transient perineal pain</th>
<th>Transient dysuria</th>
<th>Urinary infection</th>
<th>Cicatrisation faults</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated TOT</td>
<td>556</td>
<td>8</td>
<td>14</td>
<td>8</td>
<td>10</td>
<td>2</td>
<td>–</td>
</tr>
<tr>
<td>Associated surgery</td>
<td>48</td>
<td>1</td>
<td>–</td>
<td>–</td>
<td>5</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Total</td>
<td>604</td>
<td>9 (1.5%)</td>
<td>14 (2.3%)</td>
<td>8 (1.3%)</td>
<td>15 (2.5%)</td>
<td>2 (0.3%)</td>
<td>–</td>
</tr>
</tbody>
</table>
Table 5
Details of de novo symptoms after 1–3 months

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Isolated TOT</th>
<th>Associated surgery</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dysuria and urinary urgency</td>
<td>2</td>
<td>–</td>
<td>2 (0.35%)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>15</td>
<td>1</td>
<td>16 (2.8%)</td>
</tr>
<tr>
<td>Urinary urgency</td>
<td>9</td>
<td>–</td>
<td>9 (1.6%)</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>1</td>
<td>1</td>
<td>2 (0.3%)</td>
</tr>
<tr>
<td>Perineal pain</td>
<td>1</td>
<td>–</td>
<td>1 (0.2%)</td>
</tr>
</tbody>
</table>

Table 6
Assessment after one year

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>Patients</th>
<th>Satisfied</th>
<th>Not satisfied</th>
<th>De novo dysuria and urinary urgency</th>
<th>Re-operated patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year</td>
<td>131</td>
<td>85.5%</td>
<td>14.5%</td>
<td>2 (1.5%)</td>
<td>4 (3%)</td>
</tr>
</tbody>
</table>

4. Discussion

With the benefit of scientific literature and several years’ experience of practising TVT we recorded certain points that could lead improving this technique [3,12–17]. This extends to: post-operative dysuria and retention rates, the risk of visceral wounds, de novo symptoms rates and the tape-dependent “rope” effect. The trans-obturator route technique was put forward by Delorme as a useful alternative to the retropubic route. It retains the urethral support principle whose role in stress urinary incontinence treatment is clearly explained by de Lancer’s theory [18]. Moreover it enables the pre-vesical space to be preserved as it avoids intra-pelvic and retropubic passage, and consequently seems to limit the risks of not only visceral and vesical wounds, but more importantly digestive and vascular wounds. Anatomic studies rule out the risk of lesion to the obturator pedicle in theory [4]. We were able to observe low surgical morbidity on our first 140 cases. No visceral wounds or serious complications or haemorrhages occurred. This observation enabled us, like others [19], to continue our series in total safety without practising per-operative cystoscopy as a matter of course. The results after 604 procedures confirm the low morbidity. We recall that vesical perforation rate has been assessed at 0–7% as against the French national ANAES report [3] on TVT, which can rise to as much as 21% according to some exhaustive TVT reviews [13,14]. We report two cases of bladder perforation during an isolated TOT procedure. They both occurred in cases of associated major cystocele and were immediately noticed by the surgeon. The first tape was removed and a second tape was placed without any consequences. A cystoscopy was performed at the end of both procedures.

There were also very few post-operative complications in comparison with the literature on TVT. The immediate retention rate, between 2.3 and 27% in scientific literature [13,14] was 1.5% in our series and required section of the tape in one case (0.16%). The cases of immediate post-operative dysuria improved rapidly and no patient needed to practice self-catheterisation after being discharged. The 2.3% of transient perineal pains rapidly receded except in one case in which pain was still present but improving after 2 months. They do not amount to obturator nerve trauma. The cicatrization fault rate of 0.3% falls within the mean of the publications studied, which give a range of 0.8–2% [3]. In our series premature separation of the cicatrix and secondary exposure occurred. In both cases, the incision was simply closed up and the tape covered. These two cases further bolstered our choice of tape which did not present any infectious development. Probably the most interesting result is the rate of de novo symptoms (urgency and dysuria), which is only 4.7% for the 572 patients assessed after 3 months and 1.5% for the 131 patients assessed after one year. We recall that the literature on TVT records 5–38% of de novo dysuria cases and 1–36% of de novo instability cases [13,14]. Another point is that morbidity does not seem to be affected by associated surgery (prolapse treatment, hysterectomy).

Our results obtained after one year, demonstrate an encouraging satisfaction rate of 85.5%. We chose to assess the patients subjectively by asking them to express their satisfaction level and any urinary symptoms. Our series has not been objectively assessed as the pre-operative and post-operative urodynamic were not systematic and the quality of life was not taken into account.

Our results must be interpreted in the light of the fact that 52.7% of the patients operated presented mixed urinary incontinence sometimes combined with sphincter insufficiency. These operative indications are the same as those retained by surgeons practising TVT, which now extend beyond the treatment of pure stress urinary incontinence.

Our group is quite heterogeneous, firstly in terms of the specialities (urologists and gynecologists) and the sector of activity (public and private health). The series includes each surgeon’s learning curve. These observations enhance the good feasibility and safety results of the trans-obturator technique even more. However the way each centre is run and the practices of each individual surgeon give rise to differences in the type of anaesthetic, the length of the hospitalisation and indwelling catheterisation.
These results are really encouraging in confirming the usefulness of the trans-obturator technique and the quality of the tape used. This study is currently being pursued prospectively, as it is vital that these first results are substantiated on a greater number of cases over a longer post-operative period.

5. Conclusion

Our approach is part and parcel of our determination to improve a technique and product that have already been giving very good results. Stress urinary incontinence surgery must meet the demands of functional surgery with low operative risk and low de novo morbidity. The trans-obturator route appears to achieve gains in terms of morbidity and safety combined with a low rate of de novo symptoms. In our view this result is due to combining a pertinent surgical technique with an implant that matches the specific constraints of this surgery. Corroboration on the basis of a larger series is required. This calls for further studies to make an objective and prospective assessment of patients and a comparison with the “gold standard” technique (TVT).

References


Editorial Comment

C. Saussine, Strasbourg, France
Christian.Saussine@chru-strasbourg.fr

The authors described the morbidity after three months follow-up in a large series of 604 patients with stress urinary incontinence who have been operated by a sub-urethral tape using the trans-obturator route. Hopefully the 48 patients who had associated procedures have been separated from those with isolated procedures. This data confirms that trans-obturator route avoids digestive or iliac vessels lesions and dramatically limits bladder perforation. But trans-obturator route also considerably limits de novo symptoms including acute retention, chronic retention, dysuria or urgency. Why is it so? One explanation is the following. Both procedures are tension-free ones. But experience has proven that some TVT could be placed anyway with too much tension and needed to be secondarily released. In trans-obturator route, as the tape is placed horizontally between the two ischiopubic rami the urethra is sustained and no more tension is
CL-Medical supplies many different kits and also I-STOP mesh for custom cutting in shape.

In the UK Genesis Medical carries a stock of the three most commonly used kits:

**Code: IS-1**
The IS-1 kit contains 2 Emmett needles and a pair of retropubic (TVT) needles shaped slightly differently to the preferred shape in the UK. In the UK this is the kit preferred for vaginal vault prolapse repair.

**Code: IS-6**
The IS-6 kit contains 2 helical needles and guide for the TOT inside-out (TVT-O) approach.

**Code: IS-10**
The IS-10 kit contains 2 TOT (outside-in) and 2 retropubic (TVT) needles with the shape preferred in the UK.

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