

# **Evaluation Of Prolene Mesh As T.O.T. In The Surgical Treatment Of Female Stress Urinary Incontinence**

## **Thesis**

*Submitted for partial fulfillment of the Medical Doctor Degree  
(M.D.)*

*In*  
**Urology**

*By*

**Mohamed Said Elsheemy**  
*(M.Sc, M.B. & B.Ch.)*

*Supervised by*

**Dr. Mohamed Onsi**

*Prof. of Urology  
Faculty of Medicine  
Cairo University*

**Dr. Mohamed Salah**

*Prof. of Urology  
Faculty of Medicine  
Cairo University*

**Dr. Ragheb Elsergany**

*Assistant Prof. of Urology  
Faculty of Medicine  
Cairo University*

**Dr. Mostafa Abdelmohsen**

*Assistant Prof. of Urology  
Faculty of Medicine  
Cairo University*

*Faculty Of Medicine*

*Cairo University*

**2008**

## ACKNOWLEDGEMENT

*All thanks to Allah, glory to Him. Without His help, nothing can be done. I ask Him, glory to Him to purify my intention in this work and to make it just for Him.*

*There are so many people who helped me out with this work, and to each and every single one of them I would like to say thank you.*

*I would like to express my deepest gratitude to Professor Dr. **Mohamed Onsi**, for supervising this work. I also wish to express my sincere appreciations and thanks to Professor Dr. **Mohamed Salah**, Assistant Professor Dr. **Ragheb Elsergany** & Assistant Professor Dr. **Mostafa Abdelmohsen** for their continuous support, sincere assistance, great contributions, valuable guidance and encouragement through out every step of this work. If it was not for them this work would have never been accomplished, and for them, all words of praise are not sufficient.*

*I would like also to thank my family for their help and support.*

*For all of those mentioned, and for the others who unintentionally forgotten, I ask Allah to accept from them their deeds, and to make their help a step to His paradise.*

*Mohammed Said El-Sheemy*

2008

# Abstract

**Objective:** Determination of the short term safety, efficacy and urodynamic effect of the use of Prolene mesh as a midurethral sling for surgical correction of female stress urinary incontinence using trans-obturator vaginal tape inside-out technique as a low cost alternative for available commercial kits in the treatment of female stress urinary incontinence.

**Patients and Methods:** Since June 2006, thirty female patients with stress urinary incontinence (9 with pure ISD (30%), 18 with urethral hypermobility (60%) & 3 (10%) with combined ISD & hypermobility) underwent Prolene mesh midurethral sling in our institution. Preoperative evaluation consisted of history, examination, ultrasonography, ascending cystography, urodynamic studies, and routine laboratory investigations. SUI was evident clinically in all patients. 2 patients underwent anterior colporrhaphy concomitant to the Prolene mesh procedure for correction of symptomatic grade II cystocele. Prolene mesh was cut into a tapes measuring 10x1.5 cm and sterilized by autoclave. The mesh was placed at the mid-urethra and passed through the obturator foramen a by Prolene sutures loaded on specially designed helical passers. The helical passers were passed inside-out. The prolene sutures were anchored to the subcutaneous tissue at the site of exit. Patients were followed up (for a mean of 9 months) by history, examination, urine analysis, pelvic ultrasound to detect residual urine, and urodynamic evaluation at 1, 3, 6, 9 & 12 months post-operatively.

**Results:** All procedures were completed with no intraoperative complications, no failures or recurrences of stress incontinence. All patients were objectively cured but twenty nine patients were subjectively cured (96.7%). One patient (3.3%) developed obstruction but she could complete her voiding without residual urine. She was satisfied with her results. 3 patients (10%) developed vaginal infection, one patient (3.3%) developed wound infection, two patients (6.7%) developed UTI & one patient complained from dyspareunia. Lower limb & groin pain has been developed in 15 patients (50%), but was controlled by analgesics and has disappeared in all patients within the 1<sup>st</sup> post-operative month. Subcutaneous non absorbable sutures were felt in one patient. De novo urgency and erosions have not occurred in any patient.

**Conclusion:** Results of our technique showed that midurethral trans-obturator prolene mesh sling is safe, efficient, reproducible and a low cost technique for treatment of stress urinary incontinence. Our technique does not require disposable instrumentation for placement, and is inexpensive as our modified helical passers have the advantage of being resterilizable & each Prolene strip will cost less than 10 EGP. The price of similar incontinence kits in the market ranges from (3000 – 3500 EGP) per set. Long term follow up is required together with prospective randomized studies with the original TVT -O technique to confirm these results.

## Key Words:

Urinary incontinence, stress, Prolene mesh, TVT-O, female.

# TABLE OF CONTENTS

<i>Acknowledgement</i> .....	<i>i</i>
<i>Abstract</i> .....	<i>ii</i>
<i>Table of contents</i> .....	<i>iii</i>
<i>List of tables</i> .....	<i>iv</i>
<i>List of figures</i> .....	<i>vi</i>
<i>List of charts</i> .....	<i>ix</i>
<i>List of abbreviations</i> .....	<i>x</i>
Introduction .....	1
Epidemiology .....	6
Functional anatomy of the female stress continence control system .....	9
Neuroanatomy and neurophysiology .....	25
Pathophysiology of stress incontinence .....	30
Evaluation of urinary incontinence .....	48
Treatment of stress urinary incontinence .....	71
Complications of surgery .....	106
Midurethral slings .....	122
Cystocele repair .....	148
Patients and methods .....	152
Results .....	172
Discussion .....	194
Conclusion .....	219
English summary .....	220
Summary (in Arabic) .....	-225
Abstract (in Arabic) .....	- 228

## LIST OF TABLES

1: <i>Sample voiding diary of an incontinent person</i> .....	50
2: <i>Artificial sling materials used for suburethral slings</i> .....	96
3: <i>Pros and cons of substitution materials depending on their origin</i> .....	99
4: <i>Signs and symptoms of complications after midurethral sling procedures.</i> .....	113
5: <i>Aetiology of midurethral sling-related complications</i> .....	114
6: <i>Complications as reported by large TVT series</i> .....	127
7: <i>Age groups of the patients in years</i> .....	172
8: <i>The parity in the 30 patients</i> .....	172
9: <i>The age and parity in the 30 patients</i> .....	173
10: <i>Relation to menopause</i> .....	173
11: <i>Previous abdominal hysterectomy or vaginal surgery</i> .....	173
12: <i>Type of incontinence</i> .....	174
13: <i>The preoperative grade of SUI</i> .....	174
14: <i>Type of stress urinary incontinence</i> .....	175
15: <i>The preoperative cystocele grade</i> .....	176
16: <i>The preoperative rectocele grade</i> .....	176
17: <i>The preoperative ALPP</i> .....	177
18: <i>The preoperative detrusor overactivity</i> .....	178
19: <i>Intra-operative Complications related to our technique</i> .....	181
20: <i>The post-operative complications</i> .....	181
21: <i>Type of post-operative pain</i> .....	182
22: <i>Time of resolution of post-operative groin pain</i> .....	182
23: <i>Post-operative obstructive symptoms</i> .....	183
24: <i>The cure, improvement and failure rate (subjectively)</i> .....	183
25: <i>Pre &amp; postoperative urgency and urge incontinence</i> .....	184
26: <i>The pre and post-operative <math>Q_{max}</math></i> .....	185
27: <i>The pre and post-operative Maximum cystometric capacity</i> .....	186
28: <i>The pre and post-operative compliance</i> .....	186
29: <i>The pre and post-operative <math>Q_{max}</math></i> .....	188
30: <i>The pre and post-operative detrusor pressure at maximum flow</i> .....	188

31: *The mean pre-operative and 6<sup>th</sup> month post-operative  $Q_{max}$ , capacity, compliance & pressure/flow study including  $Q_{max}$  &  $P_{det}$   $Q_{max}$ ..... 190*

32: *The mean pre-operative and 12<sup>th</sup> month post-operative  $Q_{max}$ , capacity, compliance & pressure/flow study including  $Q_{max}$  &  $P_{det}$   $Q_{max}$ ..... 190*

33: *The mean  $Q_{max}$ , capacity, compliance & pressure/flow study including  $Q_{max}$  &  $P_{det}$   $Q_{max}$  at 3 and 12<sup>th</sup> month post-operatively ..... 190*

34: *The delayed post-operative complications ..... 191*

35: *Complications Associated With TOT Techniques ..... 199*

36: *Devices, Mesh Materials and Descriptions ..... 204*

37: *Outcomes with Transobturator Techniques ..... 208*

38: *Outcomes with Transobturator Techniques ..... 209*

## LIST OF FIGURES

Fig.1: <i>Normal ureterovesical junction and trigone</i> .....	10
Fig.2: <i>Anatomy of the urethra shown in longitudinal section</i> .....	11
Fig.3: <i>Striated sphincter muscle in women</i> .....	12
Fig.4: <i>The pelvic organs and their relation to the pelvic floor</i> .....	13
Fig.5: <i>Diagram of pelvic organs</i> .....	14
Fig.6: <i>Muscles of the true pelvis</i> .....	15
Fig.7: <i>Photo of the space of Retzius</i> .....	16
Fig.8: <i>The levator muscle fascia viewed from the vaginal side</i> .....	17
Fig.9: <i>Pelvis with organs and connective tissues</i> .....	18
Fig.10: <i>The urethropelvic ligaments</i> .....	19
Fig.11: <i>The pubocervical fascia</i> .....	19
Fig.12: <i>The cardinal and uterosacral ligaments</i> .....	20
Fig.13: <i>Muscles of the perineum</i> .....	22
Fig.14: <i>The “hammock” hypothesis</i> .....	31
Fig.15: <i>Diagrammatic representation of the hammock hypothesis</i> .....	34
Fig.16: <i>Type I sphincteric incontinence</i> .....	37
Fig.17: <i>Type IIA sphincteric incontinence</i> .....	38
Fig.18: <i>Type IIB sphincteric incontinence</i> .....	38
Fig.19: <i>Type III sphincteric incontinence</i> .....	38
Fig.20: <i>A sagittal view of the pelvis with a normal vaginal axis</i> .....	41
Fig.21: <i>MRI of the pelvis in a sagittal plane during straining</i> .....	41
Fig.22: <i>Comparison of pelvic organ prolapse classification systems</i> .....	42
Fig.23: <i>Landmarks for quantitative pelvic examination</i> .....	44
Fig.24: <i>Grid for recording prolapse measurements</i> .....	44
Fig.25: <i>Reference points for POP-Q measurements</i> .....	45
Fig.26: <i>Q-tip test</i> .....	52
Fig.27: <i>Posterior urethrovesical angle &amp; angle of inclination</i> .....	55
Fig.28: <i>Cystogram of type 1 incontinence</i> .....	55
Fig.29: <i>Cystogram of type 2A stress incontinence</i> .....	55

Fig.30: <i>Normal flowmetry curve</i> .....	57
Fig.31: <i>Recording of detrusor pressure</i> .....	58
Fig.32: <i>Normal cystogram</i> .....	59
Fig.33: <i>Pressure flow study</i> .....	63
Fig.34: <i>MRI, sagittal view in a patient with pelvic prolapse</i> .....	65
Fig.35: <i>Dynamic MRI with lateral cystogram</i> .....	66
Fig.36: <i>Raz bladder neck suspension</i> .....	80
Fig.37: <i>Marshall-Marchetti-Krantz procedure</i> .....	82
Fig.38: <i>Burch colposuspension</i> .....	83
Fig.39: <i>Paravaginal fascial repair</i> .....	84
Fig.40: <i>Paravaginal defect repair and Burch urethropexy</i> .....	84
Fig.41: <i>Technique for transurethral injection</i> .....	85
Fig.42: <i>Endoscopic appearance of bladder neck before &amp; after injection</i> .....	86
Fig.43: <i>Technique for periurethral injection</i> .....	86
Fig.44: <i>Artificial urinary sphincter in females</i> .....	89
Fig.45: <i>Bladder neck placement of cuff</i> .....	89
Fig.46: <i>Technique of pubovaginal rectus sheath fascial sling</i> .....	93
Fig.47: <i>In situ anterior vaginal wall sling</i> .....	95
Fig.48: <i>Monofilament &amp; multifilament tapes</i> .....	97
Fig.49: <i>UPP &amp; lateral urethrocytography in a continent female</i> .....	123
Fig.50: <i>Lateral x-ray in the resting closed state</i> .....	124
Fig.51: <i>Lateral x-ray showing urethral closure during effort</i> .....	124
Fig.52: <i>Lateral view showing urethral closure during effort</i> .....	125
Fig.53: <i>TFS applicator</i> .....	128
Fig.54: <i>TFS anchor</i> .....	128
Fig.55: <i>The position of the TVT-O</i> .....	130
Fig.56: <i>The dissected right pelvic sidewall, obturator nerve, artery and vein</i> .....	132
Fig.57: <i>Dissection of the obturator foramen showing TVT-O position tape</i> .....	134
Fig.58: <i>Measurement of distance between TVT-O tape &amp; obturator nerve</i> .....	135
Fig.59: <i>The Retzius' space</i> .....	136
Fig.60: <i>Gynecare TVT-O special device</i> .....	137

Fig.61: <i>Vaginal &amp; skin incisions in TVT-O</i> .....	138
Fig.62: <i>Introduction of dissection scissors towards the ischio-pubic ramus</i> .....	139
Fig.63: <i>Specifically designed instruments for TVT-O</i> .....	140
Fig.64: <i>The introducer perforates the obturator membrane</i> .....	141
Fig.65: <i>Introduction and removal of the helical passers</i> .....	142
Fig.66: <i>The proposed continence mechanism of the TVT device</i> .....	143
Fig.67: <i>Polypropylene mesh with polygalactyne -0 thread fixed to the extremities</i> .....	144
Fig.68: <i>Technique of anterior colporrhaphy</i> .....	148
Fig.69: <i>The urodynamic system (Andromeda, Ellipse 4)</i> .....	156
Fig.70: <i>Pressure flow study &amp; schaffer nomogram</i> .....	159
Fig.71: <i>The modified helical passers</i> .....	161
Fig.72: <i>Handly prepared polypropylene strip</i> .....	162
Fig.73: <i>The polypropylene suture is inserted into the 'eye' at the end of the passer</i> ..	163
Fig.74: <i>Exposure of the field</i> .....	163
Fig.75: <i>The anterior vaginal wall is suspended with two Allis clamps</i> .....	164
Fig.76: <i>Hydrodissection</i> .....	164
Fig.77: <i>Incision of the vaginal wall</i> .....	164
Fig.78: <i>Dissection scissors are introduced towards the ischio -pubic ramus</i> .....	165
Fig.79: <i>Introduction of the helical passers</i> .....	166
Fig.80: <i>Skin incision</i> .....	166
Fig.81: <i>The Prolene sutures are extracted from the passer</i> .....	166
Fig.82: <i>Cystoscopy</i> .....	166
Fig.83: <i>The tape is aligned under the urethra &amp; adjusted</i> .....	167
Fig.84: <i>Tension is set by passing a clamp between the tape and urethra</i> .....	167
Fig.85: <i>The Prolene sutures attached to the tape are fixed to the deep fascia</i> .....	167
Fig.86: <i>Closure of the anterior vaginal wall and skin</i> .....	168
Fig.87: <i>A vaginal pack soaked with betadine is used for 24 hours</i> .....	168

# LIST OF CHARTS

1: <i>Type of incontinence</i> .....	174
2: <i>The preoperative grade of SUI</i> .....	175
3: <i>Type of stress urinary incontinence</i> .....	175
4: <i>The preoperative cystocele grade</i> .....	176
5: <i>The preoperative rectocele grade</i> .....	177
6: <i>The preoperative ALPP</i> .....	177
7: <i>The type of intervention</i> .....	179
8: <i>The mean operative time (minutes)</i> .....	180
9: <i>The mean intra-operative bleeding</i> .....	180
10: <i>Pre &amp; postoperative urgency and urge incontinence (UI)</i> .....	184
11: <i>The pre and post-operative <math>Q_{max}</math> (ml/sec)</i> .....	185
12: <i>Pre &amp; postoperative detrusor over activity (DO)</i> .....	187
13: <i>The pre and post-operative <math>Q_{max}</math> &amp; <math>P_{det} Q_{max}</math> at 6 months (ml/sec)</i> .....	189
14: <i>The pre and post-operative <math>Q_{max}</math> &amp; <math>P_{det} Q_{max}</math> at 12 months (ml/sec)</i> .....	189
15: <i>The post-operative complications</i> .....	192

# LIST OF ABBREVIATIONS

ALPP:	Abdominal leak point pressure
ATLA:	Arcus tendineus of the levator ani.
ATFP:	Arcus tendineus fascia pelvis.
AUA:	American urological association
AUS:	Artificial urinary sphincter.
AVWS:	Anterior vaginal wall sling
BOO:	Bladder outlet obstruction
BOOI:	Bladder outlet obstruction index
CaHA:	Calcium hydroxylapatite.
CBC:	Complete blood picture.
CIC:	Clean intermittent catheterization
CMG:	Cystometrogram.
CNS:	Central nervous system
CS:	Caesarian section.
DSD:	Detrusor sphincter dyssynergia
DLPP:	Detrusor leak point pressure
EMG:	Electromyography
EUS:	External urethral sphincter.
F:	French
FDA:	Food and drug administration.
GAX:	Gautaraldehyde cross-linked bovine collagen.
Gh:	Genital hiatus
ICS:	International Continence Society
ISD:	Intrinsic sphincter deficiency
IVS:	Intravaginal slingplasty
LBNS:	Laparoscopic bladder neck suspension.
linPURR:	Linear partial urethral resistance relation
LMA:	Longitudinal muscle of the anus
LP:	Levator plate
LUTS:	Lower urinary tract symptoms.
MMK:	Marshal-Marchetti-Krantz-cystourethropexy.
MRI:	Magnetic resonance imaging.
MUCP:	Maximum urethral closure pressure
MUI:	Mixed urinary incontinence
NE:	Nor-Epinephrine.
Pabd:	Abdominal pressure.
Pb:	Perineal body
PCM:	Pubococcygeus muscle
Pdet:	Detrusor pressure.
PFES:	Pelvic floor exercises.
PFS:	Pressure flow study.
PMC:	Pontine micturition center
POPQ:	Pelvic organ prolapse quantification.
PPA:	Phenylproparolamine
PTFE:	Polytetrafluoroethylene
PUL:	Pubourethral ligaments.
PUV:	Posterior urethro vesical

Pves:	Intravesical pressure.
PVS:	Pubovaginal sling
Qmax:	Maximum flow rate.
SD:	Standard deviation
SUI:	Stress urinary incontinence
TFS:	Tissue fixation system
TOT:	Trans-obturator tape
T.O.T:	Trans-obturator tape outside-in
TVL:	Total vaginal length
TVNS:	Transvaginal needle suspension
TVT:	Tension free vaginal tape.
TVT-O:	Tension-free vaginal tape-outside (inside-out trans-obturator tape)
UCP:	Urethral closure pressure.
UI:	Urinary incontinence
UPP:	Urethral pressure profile
USL:	Uterosacral ligament
UTI:	Urinary tract infection.
UUI:	Urge urinary incontinence
VLPP:	Valsalva leak point pressure
VUDS:	Videourodynamics
VUR:	Vesicoureteric reflux

## INTRODUCTION

Urinary disorders in women are common place . Among the most distressing of these are the various forms of incontinence. <sup>1&2</sup>

Urinary incontinence is a significant health problem worldwide with considerable social and economic impact on individuals and society. It was estimated that urinary incontinence in women was the primary cause for more than 1.1 million office visits in 2000 in the United States. The total direct and indirect cost of incontinence in the United States in the year 2000 was estimated to be approximately \$19.5 billion.<sup>3</sup> It accounts for approximately 2% of health care costs in USA.<sup>4</sup> Despite its prevalence, morbidity and cost, incontinence remains largely neglected.<sup>5</sup> Furthermore urinary incontinence is with wide spread human and social implications, causing discomfort, shame and loss of self-confidence, and may negatively affect the quality of life. It can result in a loss of self-esteem and decreased ability to maintain an independent life style. In elderly women, urinary incontinence may lead to possible rejection on the part of a relative and may be an important factor in the decision on whether to institutionalize an elderly person. <sup>4&6</sup>

Stress incontinence is the involuntary loss of urine during maneuvers that increase intra-abdominal pressure (for example coughing), and reflects urethral hypermobility or intrinsic sphincter weakness.<sup>7</sup> Stress urinary incontinence (SUI) is considered one of the most common types of urinary incontinence accounting for about 50% of all cases. <sup>8&9</sup>

There are two main types of sphincter abnormality: urethral hypermobility & intrinsic sphincter deficiency (ISD).<sup>10</sup> However, both conditions may co-exist, especially when subjective loss of urine is high.<sup>11</sup> Urethral hypermobility occurs when there is a defect in the pelvic support of the bladder neck, while intrinsic sphincter deficiency is defined as loss of bladder outlet closure potential.<sup>12</sup>

As more women seek for SUI, the demand for safe, effective, minimally invasive and durable form of therapy has increased.<sup>13</sup>

Understanding of the physiopathological concepts of female stress urinary incontinence (SUI) has consistently improved over the past decades and their application has lead to the development of numerous surgical techniques aimed at curing this disorder.<sup>14</sup>

The surgical treatment of female stress urinary incontinence caused by urethral hypermobility was drastically changed in 1995 by the description of a new concept, the mid-urethral support without tension, by *Ulmsten and Petros*.<sup>15</sup> Among the numerous surgical techniques aimed at curing female stress urinary incontinence (SUI), retro-pubic tension-free vaginal tape (TVT) has probably been the most revolutionary.<sup>16-22</sup>

The wide use of retro-pubic TVT has been associated with various peri- and post-operative complications, including bladder perforation, temporary or persistent retention, pain, urinary infection, and de novo instability.<sup>19</sup> Other rare but severe—and possibly under-estimated—complications have been reported with this approach. Indeed, the blind passage of the needle in the retro-pubic space can result in injuries to other organs than the bladder, in particular the urethra, vessels, nerves and bowel.<sup>23&24</sup>

A new surgical approach has been introduced maintaining the position under the mid-urethra of the tension-free vaginal tape but reducing or even eliminating complications related to the penetration of the retro-pubic space by placing the tape between the two obturator foramina.<sup>25</sup> Anatomic studies ruled out the risk of lesion to the obturator pedicle in theory.<sup>26</sup> The alternate approaches with a trans-obturator passage of the tape have continence rates roughly similar to those after the 'classic' retro-pubic TVT at least on the short term.<sup>26-28</sup>

The original design of this new technique described by *Delorme* in 2001, called trans-obturator tape (T.O.T.), was to place the tape between the two obturator foramina, from outside to inside.<sup>26</sup> The reported results are very close to those reported in most of the observational series of tension-free vaginal tape.<sup>29,30,31&32</sup> No vascular, nerve or bowel injuries have been reported, justifying the interest in the trans-obturator route.<sup>25</sup> At the end of 2003, a novel surgical technique was described by *de Leval*, with the passage of the tape through the obturator foramina from inside to outside, which was called tension-free vaginal tape-outside (TVT-O).<sup>33</sup> Clinicians, who have been convinced that the trans-obturator approach is safer than the retro-pubic approach, now have the possibility to choose between outside in TOT and inside out TVT-O. Results obtained in a series of 107 consecutive patients in that study indicate that this surgical procedure is feasible, accurate, quick, and simple. In addition, this technique avoids damage to the urethra and bladder and, for this reason, makes cystoscopy not necessary.<sup>33</sup>

Various materials were used in the slings, from autogenous tissues to synthetic materials, and the choices were based upon well-defined criteria, in which the cost was one of the most important factors for the selection of materials, mainly in countries with limited public health resources.<sup>34</sup>

Studies confirmed that the choice of a tension free polypropylene mesh allows high success rates and simplified the SUI therapy. The TVT and the TOT are becoming one of the most common options for the treatment of this disease. Thus, the industry has offered different kits to make the slings, but most of the time the costs are prohibitive for public health systems with few financial resources.

**The aim of this article** is to evaluate the safety & efficacy of Prolene mesh for surgical correction of female stress urinary incontinence (SUI) using trans-obturator vaginal tape inside-out technique as a low cost alternative for available commercial kits in the treatment of female stress urinary incontinence (SUI). The principal difference lies in the cost of the material used, since in this study the polypropylene mesh (PROLENE© Polypropylene Mesh; Ethicon Ltd UK) was used, however it was prepared, instead of the specific commercialized material for this procedure.