Vol. 34 - N. 3
September 2015

Rivista Italiana di Colon-Proctologia
Founded in 1982

ISSN 1973-4905

PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

www.pelviperineology.org

INSTRUCTIONS FOR AUTHORS

The manuscripts including tables and illustrations must be submitted to Pelviperineology only via the Isubmit system **www.isubmit.it**. This enables a rapid and effective peer review. Full upload instructions and support are available online from the submission site.

In **http://www.pelviperineology.org/pelviperineology_authors_instructions.html** please find the updated guidelines for the Authors.

Contents

70 Tissue Fixation System (TFS) neoligament pelvic organ repair procedures - 12 and 24 month results
M. Haverfield

75 Surgeon preference for surgical treatment of stress urinary incontinence among urogynecologic surgeons, comparison after 15 years
G. Rostaminia, S. Pickett, M. Machiorlatti, S. A.s Shobeiri, M. Nihira

79 The TFS minisling restores major pelvic organ prolapse and symptoms in aged Japanese women by repairing damaged suspensory ligaments – 12 - 48 month data
H. Inoue, Y. Kohata, Y. Sekiguchi, T. Kusaka, T. Fukuda, M. Monnma

84 The 3rd International Course on Functional Reconstructive Surgery of Pelvic Floor
M. Frigerio, S. Manodoro

85 Posterior Fornix Syndrome: Comparison of original (2004) and modified (2015) post-PIVS anatomic and symptomatic results: a personal journey
K. Goeschen

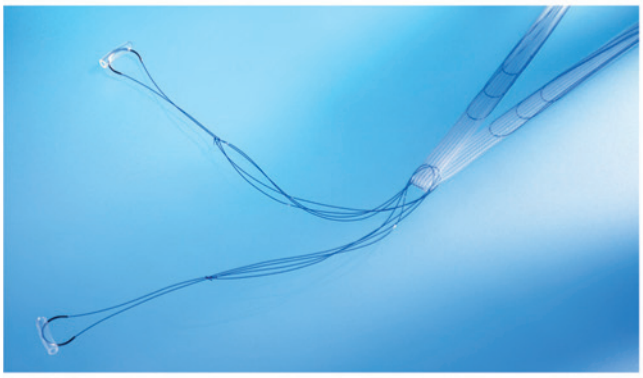
92 Surgical cure of nocturia using 4 different methods based on strengthening the structural supports of the vaginal apex - a short review
P. Richardson

94 Long term results of modified posterior intravaginal slingplasty (P-IVS) in patients with pelvic organ prolapse
A. Caliskan, K. Goeschen, A. E. Zumrutbas

'Taxe Perçue' 'Tassa Riscossa' - Padova C.M.P.
Poste Italiane s.p.a.
Spedizione in Abb. Post. - 70% - DCB Padova

A.M.I. TOA / TVA System
for Female Stress Urinary Incontinence

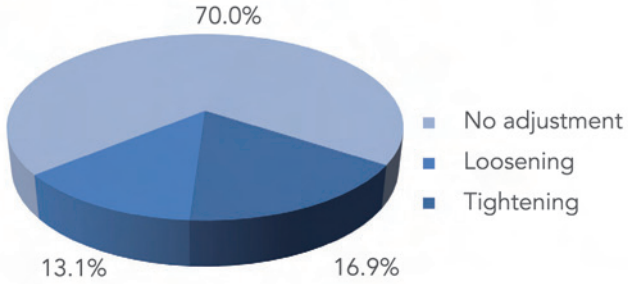
Q.: Who needs an adjustable sling?



If you think adjustability for slings is just a marketing ploy, it might be time to reconsider. The data below is taken from an analysis of **six, peer-reviewed studies** published, comprising a total of **392 patients** treated with either the A.M.I. TVA or TOA System for female stress urinary incontinence.
The results speak for themselves.

A.: About 30% of patients.

% of patients requiring adjustment

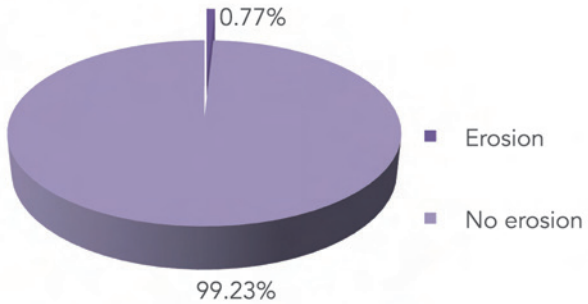


High success rate

90.3% completely dry

6.4% considerably/substantially improved

Low erosion rate



Advantages of Adjustment

Resolves cases of persisting incontinence or urinary retention post-operatively with **no surgical reintervention!**

Effective treatment for **high-risk groups** (e.g. combined SUI and voiding dysfunction), **severe SUI,** or patients with **previous failed treatment.**

A.M.I.®

A.M.I. GmbH . Im Letten 1 . 6800 Feldkirch . Austria . +43 5522 90505-0 . info@ami.at . **www.ami.at**

Vol. 34
N. 3
September 2015

Rivista Italiana di Colon-Proctologia
Founded in 1982

PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

www.pelviperineology.org

Official Journal of the: International Society for Pelviperineology (www.pelviperineology.com)
Pelvic Reconstructive Surgery and Incontinence Association (Turkey)
Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia
Romanian Uro-Gyn Society

Editorial Office: Benito Ferraro, Luisa Marcato
e-mail: benito.ferraro@sanita.padova.it - luisa.marcato@sanita.padova.it
Quarterly journal of scientific information registered at the Tribunale di Padova, Italy n. 741 dated 23-10-1982 and 26-05-2004
Editorial Director: Giuseppe Dodi
Printer "Tipografia Veneta" Via E. Dalla Costa, 6 - 35129 Padova - e-mail: info@tipografiaveneta.it

Original article

Tissue Fixation System (TFS) neoligament pelvic organ repair procedures - 12 and 24 month results

MAX HAVERFIELD

Northern Hospital Melbourne, Australia

Abstract. *Objectives:* To assess the safety and efficacy of the TFS in patients with prolapse and incontinence, with or without uterine preservation and including the learning curve. *Methods:* The Tissue Fixation System (TFS) is an adjustable minisling which uses small lengths of tape to reinforce loose and damaged ligaments and fascial tissue. This is a twenty four month prospective study in a large outer metropolitan Melbourne hospital. Forty women, mean age 60 (50 - 80) years had site-specific TFS repair for grade II to IV urogenital prolapse. Assessment: pre-operative P.O.P.Q, Urodynamics, QOL Questionnaire. Patients with bowel dysfunction had Wexner Score assessment and defecating proctogram. Patients who were sexually active had PISQ-12 assessment. *Results:* The mean surgical time for placement of each device was 12.3 minutes. Improvement rates at 24 months expressed as %, with 12 months in brackets. Prolapse 80% (90%), USI 90% (85%), dragging lower abdominal pain 90% (90%), anal incontinence 70% (70%), nocturia 50% (50%), overactive bladder symptom 50% (50%). There was an average >80% cure rate of urogynaecological prolapse and stress urinary incontinence. There were no tape erosions, anchor slippage or anchor migrations. *Conclusions:* Contrary to the FDA warning on serious complications with transvaginal mesh15 we found TFS neoligament surgery to be safe and minimally invasive, restoring anatomy and function. The unique design which includes a precise one way tensioning system and use of very small amounts of tape is site specific and effective for all pelvic floor reconstruction. Further evaluation is ongoing.

Keywords: Pelvic organ prolapse; Stress urinary incontinence; Adjustable minisling; Tissue Fixation System.

Abbreviations: QOL quality of life questionnaires; *ATFP* arcus tendineus fascia pelvis; *CL* cardinal ligament; *USL* uterosacral ligament; *SUI* stress urinary incontinence; *POP* pelvic organ prolapse; *DTP* deep transverse perinei muscle; *TFS* tissue fixation system.

INTRODUCTION

Anatomical disruptions leading to pathophysiological symptoms of pelvic floor disorders are frequently seen in women. Pelvic Organ Prolapse (POP) encompasses many sub groups, such as anterior compartment prolapse of bladder and urethra, central compartment (uterocervical / apical), central apical descent post hysterectomy, posterior compartment (apical, central and hiatal) and others. POP occurs in up to 50% of parous women.[1] Up to 30% of all females suffer from pelvic floor disruption and dysfunction to a degree that has a negative impact upon their quality of life. The lifetime risk of undergoing prolapse surgery is 1 in 11, moreover up to 30% of those who do undergo native tissue repair surgery will eventually have repeat prolapse surgery. Statistically hysterectomised women presenting with increased POP with the ageing of the population.[2-4] POP symptoms are often described in terms of voiding dysfunction eg urinary urge and urge incontinence, frequency of micturation (Pollakinuria), nocturia enuresis and hesitancy (abnormal bladder emptying). Symptoms also include ano rectal dysfunction such as faecal and flatal incontinence, obstructive bowel disease, rectal loading, pelvic pain, "dragging" sensation and sexual dysfunction. Pelvic dysfunction occurs in 10%-30% of women depending on demographics observed and definitions used. Notoriously the prevalence in women is under reported and undervalued. Sexual dysfunction in women is a very common QOL issue.[5,6] It has been observed in various studies that the anterior and distal parts of the vagina are the most innervated, therefore play an important role in sexual function.[6,7]

Pelvic organ support is maintained by a combination of pelvic musculature, neurovascular bundles and connective tissue. The uterosacral and cardinal ligaments comprise significantly of smooth muscle, vascular elements and loosely organized collagen fibres and are responsible for uterine and apical support. This has been described as Level 1 support by Delancey.[2] Nine main connective tissue structures/ ligaments are said to be critical to organ support and function according to Ulmsten, Petros:[7]

Anterior Zone

Pubo-urethral ligament, external urethral ligament, suburethral vaginal hammock (described by RF Zacharin in 1968[8]).

Middle Zone

Arcus tendineus fascia pelvis, pubocervical fascia, cardinal ligament.

Posterior Zone

Uterosacral ligament, perineal body, rectovaginal fascia.

The upper vertical axis contains suspensory fibres which serve to pull the superior aspect of the vagina, the cervix and the lower uterine segment posteriorly toward the sacrum so they are positioned over the levator plate. Disruption of these structures can cause uterovaginal prolapse.[9]

The rectovaginal septum is a separate endopelvic fascial layer between the vagina and rectum. The rectovaginal septum divides the anterior and central compartment of the pelvis containing the bladder, urethra and vagina from the posterior compartment containing the rectum. Inferiorly the rectovaginal septum is attached to the perineal body. Superiorly it blends with the undersurface of the Pouch of Douglas perineum which during foetal life extends to the perineal body. Superiorly it blends with the undersurface of the Pouch of Douglas and uterosacral ligaments.[10]

As most of the pelvic muscles directly or indirectly contract against these structures, any laxity and/or damage therein will result in weaker muscle contractile force, and therefore, decreased normal pelvic floor and visceral function.[1]

Since pelvic laxity and prolapse and symptoms of excretory and sexual dysfunction are very rarely life threatening, Ostergard[11] in an editorial stated that it is not ethical to impose a life threatening operation for a patient with QOL issues. He went on further to suggests that there should be zero tolerance for any such operation which may have sig-

nificant morbidity. A recent editorial by CW Butrick[12] also highlighted patient selection, particularly those patients with pre-existing myofascial pain. Polypropylene synthetic mesh has been used in urogynaecology since the 1960s to treat stress incontinence. However it was not until Ulmsten and Petros developed the TVT sling with its advantage of same day surgery, less post operative pain and morbidity that the mid urethral sling became the most effective stress incontinence operation performed worldwide. The success of the TVT led to the development of a number of similar slings for SUI and mesh kits for prolapse by many commercial companies.[13] Support of prolapse would be "better served" by using site-specific ligament support within the pelvis. These opinions were reinforced recently by a warning against mesh usage for prolapse surgery by the FDA.[14]

Ideally, the goal of pelvic reconstructive surgery is to address each vaginal compartment separately and provide adequate repair to restore the normal anatomy and functionality of the pelvic floor as a whole. The transvaginal use of the uterosacral-cardinal ligament complex is gaining popularity in the surgical treatment of uterovaginal and post hysterectomy/vault/apical prolapse.[15] The procedure should be easily standardized with reproducible outcomes, have significant improvements on QOL issues, low complication rates and a relatively short surgical learning curve with short hospital admission. This would fit Ostergards criteria.[11] Hence the search for a universally applied, minimally invasive system using site specific neo ligaments to support the pelvic visceral with minimal mesh has been investigated.[1]

In 2005 an innovative minimally invasive universal system - Tissue Fixation System (TFS) was developed, whereby ligamentus and fascial support of all anatomical defects can be addressed and corrected. The tape can be adjusted as required to restore normal pelvic anatomy and function[7] with uterine preservation (an important advantage) as there is no clear evidence that hysterectomy will improve surgical outcomes.[16] Severe post hysterectomy vaginal vault prolapse can be surgically corrected using the TFS.

The principal aim of this study was to assess the safety and efficacy of the Tissue Fixation System (TFS) as treatment for the repair of pelvic organ prolapse as well as urinary and bowel dysfunction. In addition consideration was given to the preservation of the uterus as only 3 patients had concomitant hysterectomy due to associated pathology.

MATERIALS AND METHODS

This 24 month prospective study was conducted at the Department of Obstetrics and Gynaecology of the Northern Hospital in Melbourne. The operations were performed between December 2009 and July 2010 by the senior surgeon or under his direct supervision. Patient demographic (Table 1) consisted of 40 women who had site specific TFS repair for grade II to IV urogenital prolapse.

All women underwent clinical assessment including preoperative POPQ, Urodynamics and a QOL questionnaire. Patients with bowel dysfunction had Wexner Score assessment and defecating proctogram. Patients who were sexually active had PISQ-12 assessment.

As our aim was to assess the safety and efficacy of these procedures as a minimally invasive technique of pelvic floor restoration, no patient was excluded from surgery on BMI, medical co-morbidities or previous pelvic floor surgeries. The only exclusion criterion was an adverse medical or anaesthetic assessment.

For these procedures, the Tissue Fixation System applicator (TFS Surgical, Australia) was used to insert an anchor

TABLE 1. – Patient demographic.

Parameter	Values
Age (years, range)	60 (37-86)
Parity (median, range)	3 (2-7)
Weight (kg, range)	77.9 (57-142)
Previous hysterectomy (No., %)	21 (52.5)
Sexually active (No., %)	22 (55)
Chronic illness* (No., %)	28 (70)

* Diabetes, asthma, hypertension, macro/morbid obesity, COAD, GORD, depression & anxiety.

attached to a non-stretch monofilament macroporous polypropylene tape approx. 7mm wide (Figure 1). Each soft tissue anchor has 4 prongs and is designed to withstand the rigours of pelvic floor function. At the base of the anchor is a one way trapdoor which enables precise tape adjustment. The anchors are totally ensheathed by connective tissue by the 2nd week. The system accurately restores the tension of connective pelvic tissues and the weakened ligaments, the latter providing strong insertion points to restore the strength of the muscle forces and therefore, function.[1] This means that the tape can be adjusted to suit individual anatomy.

The 5 major TFS reconstruction procedures: (Figure 2).

One common method; identify the ligament, hydrodissect where required, create a tunnel adjacent or through the ligament, insert applicator, release anchor, repeat on contralateral side. Adjust and trim tape, close prosthesis tunnel with suture, cover tape with fascia then separately vaginal mucosa. NB No vaginal or fascial excision performed on patient cohort.

TFS Mid Urethral sling procedure: support of pubo urethral ligament:

Check urethral length, create full thickness incision from 1cm below urethral meatus to midurethra (approx 2cms length), insert No. 8 Hegar dilator into urethra to prevent over tensioning, adjust TFS tape to touch urethra without compression. A hammock suture (0 vicryl) as a figure of 8 configuration is placed into external urethral ligament to stabilize distal urethra prior to closure of vaginal mucosa.

TFS Cardinal Ligament procedure: to address level I - apical anterior compartment prolapse:

Create transverse incision (4cm) at versical/cervical junction. Hydrodissect to separate vaginal mucosa from bladder, identify CL; dissect bladder from vaginal mucosa, plicate cystocoele if necessary (2-0 PDS); apply TFS anchor at insertion of CL to ATFP sited approximately 2cms superior and 1cm lateral to the ischial spine. Close tunnel and incision in layers.

Figure 1. – **TFS nchorA 4** pronged polypropylene anchor approximately 11x4mm with a one-way trapdoor at its base sits on a stainless steel applicator. A 7m mm

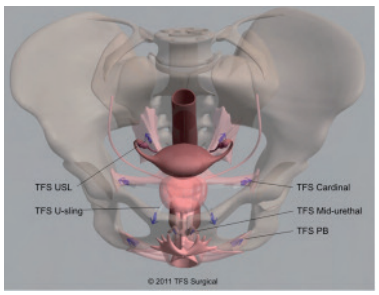


Figure 2. – The TFS re-creates the ligamentous attachments to the pelvic side-wall. USL(uterosacral); cardinal; USling (ATFP); PB (perineal body); mid-urethral (pubourethral).

TFS U Sling procedure - for support of mid/lateral pelvic defects:

Use same incision as for cardinal ligament; dissect toward ATFP at its most medial aspect – 1cm superior to superior notch of obturator foramen. Deploy TFS into position, adjust without tension and close tunnel and incision.

TFS Uterosacral ligament procedure:

Create transverse incision (5-6cm) 1cm above vestibule. With aid of hydro dissection of rectovaginal septum grasp and evert inside of posterior vaginal mucosa with 2 tissue forceps progressively whilst dissecting to posterior apex until USLs are identified. With a finger in rectum palpate lateral border of sacrum at approximately S3 facilitating identification of USL insertion. This also enables the surgeon to protect rectum whilst tunneling and inserting prosthesis.

TFS Deep Transverse Perineii Procedure (perineal body repair):

Using same incision described in USL TFS, the ano rectal junction is separated from perineal body. Under tension, identify DTP with its attachment to lower 1/3 of posteriomedial border of descending pubic ramus. With finger in rectum create a tunnel through DTP to just posterior to ramus in the direction of inferior notch of obturator foramen. Apply TFS prosthesis, tension appropriately, trim tape, close tunnels. Plicate and repair the perineal body if appropriate.

Ethics approval was obtained by the Ethics Committee, The Northern Hospital / Northern Health. Safety of the study was monitored throughout.

Written informed consent was obtained from all patients.

RESULTS

40 women followed up at a minimum of 24 months (Table 2).

70% of cohort suffered from significant medical co-morbidities. 35% had one or more past pelvic organ prolapse procedures.

Perioperative and operative data was predicated on the use of 105 TFS sling applications with the mean of 2.6 slings per patients.

Operative time per sling: 12.5 minutes.

Blood loss average: 50 mls.

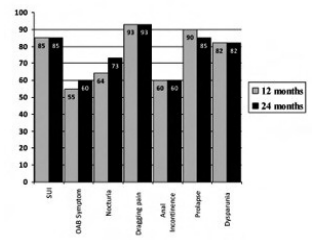


Figure 3. – **12 and 24 month symptom outcomes.**

Hospital stay average: 60 hours, and this was dependent on the extent of surgery ranging from 12 hours to 72 hours.

Postoperative interval before return to normal duties ranged from 72 hours to 2 weeks.

Operative data

Symptomatology of the patient cohort was often multiples of voiding dysfunction, symptoms of prolapse and bowel dysfunction as summarized in table 3.

Operative details: Sub-Urethral TFS 9, U-Sling TFS 15, Cardinal Ligament TFS 25, Utero-sacral TFS 34, Deep Transverse Perinei TFS 22, Vaginal Hysterectomy for Non prolapse reason 3, Cervical amputation (Manchester repair) 2.

Patient outcomes

Improvement rates at 24 months expressed figure 3. There was an average >85% cure rate of urogynaecological prolapse and stress urinary incontinence. Of the patients sexually active (50%), one patient had transient dyspareunia. There were no tape erosions, anchor slippage or anchor migrations noted in our cohort.

Recurrent symptomatic prolapse in 3 out of 4 patients was due to cervical hypertrophy >4cms requiring cervical amputation at 18 - 24 months. This has lead to our conclusion that concomitant cervical amputation should be considered if cervical length >4cms.

85% of patients who complained of stress urinary incontinence as a symptom were cured at follow up. Only half of this group had urodynamic demonstrable stress incontinence, the others complained of SUI but this was not demonstrable on urodynamic studies. The first group had a definitive pubourethral TFS tape, the other group only had anterior compartment repair (Cardinal ligaments/U sling) and yet this group post-operatively had a cure in stress incontinence symptoms not demonstrable with urodynamics.

Complications

One rectal mucosal buttonhole injury sustained at initial dissection was treated successfully with primary repair. One rectal serosal penetration with prosthesis was recognized and removed immediately and successfully (Table 4). Both patients had previous multiple perineal and posterior compartment procedures. No implant was inserted under these

TABLE 2. – Clinical details.

Parameter	Values
Anterior compartment prolapse (POPQ ≥2* No., %)	24 (60)
Posterior compartment prolapse (POPQ ≥2* No., %)	24 (60)
Anterior & Posterior compartment prolapse (POPQ ≥2* No., %)	15 (37.5)
Apical prolapse (POPQ ≥2* No., %)	16 (40)
Anterior &.Posterior & apical prolapse (POPQ ≥2* No., %)	6 (15)
Previous POP reconstructive surgery (No., %)	14 (35)

Accordance with the ICS POP-Q system.

TABLE 3. – Operative details.

Parameter	Values
Sub-Urethral TFS (No., %)	9 (22.5)
U-Sling (No., %)	15 (37.5)
Cardinal Ligament TFS (No., %)	25 (62.5)
Utero-sacral TFS (No., %)	34 (85)
Deep Transverse Perinei TFS (No., %)	22 (55)
Vaginal Hysterectomy for Non prolapse reason (No., %)	3 (7.5)
Cervical amputation (Manchester repair) (No., %)	2 (5)

TABLE 4. – Symptom analysis.

Parameter	Values
Stress Urinary Incontinence (No., %)	20 (50)
Urgency (No., %)	22 (55)
Urgency incontinence (No., %)	17 (42.5)
Nocturia (No., %)	11 (27.5)
Frequency (No., %)	13 (32.5)
Presence of Dragging Pain (No., %)	15 (37.5)
Constipation (No., %)	6 (15)
Anal Incontinence (No., %)	15 (37.5)
Dysparunia (No., %)	11 (25)

circumstances. Retention of urine (failed trial of void) x 2 patients after the pubourethral neoligament procedure; both cases were transient and resolved. There was one case of midurethral release after 21 days with 100% resolution of voiding dysfunction at 4 months. There was one case of trigger point pain of the inferior margin of pubic ramus which resolved within 21 days. No haemmorhage, haematoma or tape rejections or infections have been noted.

DISCUSSION:

Many techniques have been devised to address the high failure rates of POP repair using native or biological tissue. Repairs such as sacrospinous fixation have been shown to be anatomically incorrect and have postoperatively caused symptoms such as dyspareunia and other complications including haemmorhage, haematoma, small bowel obstruction and mesh erosion.[18] Implantation of mesh sheets for POP seemed promising initially, but complications, sometimes major, have resulted in FDA warnings about the use of large mesh kits within the pelvic floor. These warnings have revived the question "Are large mesh sheets necessary for POP repair?"[15]

The surgical reconstruction of the anatomy is almost exclusively focused on the restoration of lax pelvic floor ligaments. Exact preoperative identification of the anatomical lesions is necessary to allow for exact anatomical reconstruction with respect to the muscular forces of the pelvic floor.[17]

We have found the TFS procedures to be simpler and more anatomically correct than other procedures. From a structural perspective, the small volume of polypropylene

TABLE 5. – Operative and post operative details.

Parameter	Values
Operative Bladder injury (No., %)	0 (0)
Operative rectal injury (No., %)	2 (5)
Operative bleeding >300ml (No., %)	0 (0)
Operative field infection (No., %)	0 (0)
P/O Haematoma (No., %)	1 (2.5)
P/O Granulation tissue (No., %)	0 (0)
Further mesh segmental resection (No., %)	1 (2.5)
P/O Urinary retention (No., %)	5 (12.5)
P/O overactive bladder symptom at previously 22 OAB patients (No., %)	9 (40.9)
Denovo OAB symptom (No., %)	2 (11.1)
P/O Persistent of Nocturia in 11 patients previously had nocturia (No., %)	3 (27.3)
P/O dragging pain in 15 patients who had dragging pain pre-operatively (No., %)	1 (6.7)
P/O Anal incontinence in 15 patients who had anal incontinence pre-operatively (No., %)	6 (40)
P/O Stress urinary incontinence in 20 patients who had pre-operative SUI (No., %)	3 (15)
P/O Persistence of Prolapse (No., %)	6 (15)

TABLE 6. – Cure rate of symptoms of pelvic organ prolapse treated with TFS sling technology.

Parameter	No. of patients treated	Symptom Cure Rate (No., %)
Stress urinary incontinence	20	17 (85)
Overactive bladder symptom	22	13 (59.1)
Nocturia	11	8 (72.7)
Dragging pain	15	14 (93.3)
Anal incontinence	15	9 (60)
Prolapse	39	33 (84.6)
Dysparunia	11	9 (81.8)

tapes provide excellent support and function for grade IV and the more challenging recurrent POP and visceral incontinence.

In our study 36/40 patients needed multiple anatomical site reconstruction and the with majority requiring apical support. There is evidence that apical repair impacts on anterior vaginal wall prolapse as shown in previous studies comparing sacrospinous ligament fixation and abdominal sacral colpopexy.[18,19]

The procedure of sacrospinous fixation with unilateral retro version of the fixation of the vaginal apex tends to result in the anterior compartment being subjected to unnatural and non physiological forces which may result in cystocoele and enterocoele formation with figures ranging from .1-9%.[20,21]

Our conclusion from our patient cohort is that patients presenting with POPQ (apical) of grade II or more, whether symptomatic or not, had concomitant anterior apical ligament weakness which we supported with an elective TFS cardinal neoligament procedure. Our early assessment is that this reduced de novo anterior wall prolapse to <2% (1 patient). Patients with symptoms of overt SUI in the absence of demonstrable SUI with urodynamics were also cured.

CONCLUSION

We have found the TFS neoligament procedures for restoration of pelvic anatomy and function to be of short duration, minimally invasive, safe and effective with or without uterine preservation. Reproducibility and standardization of the procedure has an acceptable learning curve and safety profile a with a short patient recovery period. Regard should be given to the fact that the results included the patients operated on during the learning curve and there were no exclusions of patients with previous gynaecological, general surgeries or medical co-morbidities and high BMI. We have observed the cohort trend in a further >500 TFS procedures, however longer follow up data and a larger cohort of patients will be important to further ascertain outcomes.

TABLE 7. – Operative and post operative complications.

Parameter	Values
Operative Bladder injury (No., %)	0 (0)
Operative rectal injury (No., %)	2 (5)
Operative bleeding >300ml (No., %)	0 (0)
P/O Haematoma (No., %)	1 (2.5)
P/O Granulation tissue (No., %)	0 (0)
Further mesh segmental resection (No., %)	1 (2.5)
P/O Urinary retention (No., %)	5 (12.5)
Denovo OAB symptom (No., %)	2 (5)
Tape Erosions at 24 months (No., %)	0 (0)
Anchor slippage at 24 months (No., %)	0 (0)
Anchor migration at 24 months (No., %)	0 (0)

ACKNOWLEDGMENTS

The Northern Hospital theatre and nursing staff, continence nurse Andrea McCay.

CONFLICTS

None.

REFERENCES

1. Petros PE The female pelvic floor function, dysfunction and management according to the integral theory Ed 3 Heidelberg & Springer Chapter 4, Surgery pp. 118-218.
2. DeLancey LOL The hidden epidemic of pelvic floor dysfunction: achievable goals for the improved prevention and treatment Am J Obstet Gynaecol 2005; 192: 1448-95.
3. Nygaard I, Barber MD, Burgio KL et al., Prevalence of symptomatic floor disorders in US women. Obstet Gynecol. 2014 Jan; 123 (1): 141-148.
4. Dietz HP The etiology of prolapse. Int Urogynaecol J Pelvic Floor Dysfunction 2008; 19: 1323-9.
5. Pauls RN, Silva WA, Rooney CM et al. Sexual function after vaginal surgery for pelvic organ prolapse and urinary incontinence. Am. J. Obstet. Gynecol. 2007; 197(6), 622-627.
6. Lemack GE, Zimmern PE: Sexual function after vaginal surgery for stress incontinence: results of a mailed questionnaire. Urology. 2000; 56: 223-7.
7. Petros, PE. Surgery. In Petros PE (ed). The female pelvic floor: Function, Dysfunction and Management, According to the Integral Theory, 2nd Edition, Chapter 4. Heidelber: Springer, 2006: 83-167.
8. Zacharin RF The anatomie supports of the female urethra. Obstet Gynae. 1985; 32: 754.
9. DeLancey JOL Anatomic aspects of vaginal eversion after hysterectomy. AMJ Obstet Gynecol 166: 1717, 1992.
10. Uhlenhuth E, Wolfe W, Smith E et al: The rectogenital septum. Surg Gynaecol Obstet 86: 148, 1948.
11. Ostergard DR Editorial The Epochs and Ethics of Incontinence Surgery. Is this direction forward or backward? Int Urogynaecol J. Pelvic Floor Dysfunction 2002; 13: 1-3.
12. Charles W. Butrick Do guns kill people or? The Mesh Dilemma. Int Urogynaecol J 2010; 21: 133-134.
13. Dwyer P Prolapse Surgery and the Mesh Debate 3rd Clinical Epworth Institute of Obstetrics & Gynaecology Symposium September 2012.
14. Dwyer PL Fatton B Bilateral extraperitoneal uterosacral suspension: a new method for apical prolapse repair Int. Urogyn J 2007; 18(1): 109-110.
15. FDA: Public Health Notification - Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence.
16. Neuman M, Lavy Y. Conservation of the prolapsed uterus is a valid option: Medium term results of a prospective comparative study with the posterior intravaginal slingplasty operation. Int Urogynaecol J Pelvic Floor Dysfunction 2007; 18: 889-893.
17. Wagenlehner FME, Bschleipfer T, Liedl B, Gunneman A, Petros P, Weidner W. Surgical Reconstruction of the Pelvic Floor Descent: Anatomic and Functional Aspects Urol Int 2010; 84: 1-9.
18. Paraiso MF, Ballard LA, Walters MD, Lee JC, Mitchinson AR. Pelvic support defects and visceral and sexual function in women treated with sacrospinous ligament suspension and pelvic reconstruction. AmJ Obstet Gynecol 1996; 175:14234-30.
19. Benson JT, Lucente V, McLennan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic floor defects: a prospective randomized study with long term outcome evaluation. AmJ Obstet Gynecol 1996; 175: 1418-21.
20. Nieminen K, Huhtala H, Heinoen PK. Anatomic and functional assessment and risk factors of recurrent prolapse after vaginal sacrospinous fixation. Acta Obste Gynecol Scand 2003; 82: 471-8.
21. Holley RL, Varner RE, Gleason BP, Apffel LA, Scott S. Recurrent pelvic support defects after sacrospinous fixation for vaginal vault prolapse J Am Coll Surg 1995; 180: 444-8.

Correspondence to:

Max Haverfield
Northern Hospital Melbourne Australia
E-mail: Max.Haverfield@nh.org.au

Original article

Surgeon preference for surgical treatment of stress urinary incontinence among urogynecologic surgeons, comparison after 15 years

GHAZALEH ROSTAMINIA[1], STEPHANIE PICKETT[3], MICHAEL MACHIORLATTI[2], S ABBAS SHOBEIRI[1], MIKIO NIHIRA[3]

[1] *Inova FairFax Hospital - Ob&Gyn Department*
[2] *The University of Oklahoma Health Sciences Center, Biostatistics Department*
[3] *The University of Oklahoma Health Sciences Center, FPMRS Department*

Abstract: Innovation in the treatment of stress urinary incontinence (SUI) in the last twenty years has changed practice patterns. The aim of our study was to compare surgeons' preference for surgical treatment for SUI between two surveys collected from American Urogynecologic Society's (AUGS) administered fifteen years apart. This was a cross-sectional study performed at the AUGS annual meeting in 1998 and 2013. Paper survey consisting of nineteen questions was self-administered to all participants at the annual meeting. Simple descriptive and inferential statistics were performed as well as appropriate tests of difference. Database of 136 responders in 1998 and 137 responders in 2013 were available for analysis. Female responders in 1998 and 2013 were 46% and 56%, respectively. The reportedly preferred procedure for treatment of SUI in 1998 was transabdominal retropubic urethropexy consisting of 67.5% of all surgeries performed for SUI. In 2013, the mid-urethral synthetic sling was reported as the most preferred of all surgeries for SUI (89%). Interestingly, open retropubic urethropexy was the preferred surgical approach for primary SUI in 1998 regardless of planned vaginal or abdominal concomitant procedures. In 2013, mid-urethral sling was reportedly the most preferred procedure regardless of need for concomitant surgeries. From 1998 until 2013, there were notable changes in the reported surgical management of stress urinary incontinence. Documentation of this transformation holds important implications as new technologies are constantly introduced and practice patterns continue to evolve. Consideration of these changes in practices should inform curricular development for surgical training.

Keywords: Stress urinary incontinence; Surgeon; Survey.

INTRODUCTION

Surgical treatment is the standard approach for women with stress urinary incontinence (SUI) who have failed conservative management strategies such as lifestyle change, physical therapy, scheduled voiding regimens, behavioral therapy, and pessary.[1] Although many surgical procedures have been reported, the ideal surgical technique would be a procedure that is simple, inexpensive, easy to learn and perform, minimally invasive, with durable efficacy, and without long term morbidity.[2] SUI treatment surgeries traditionally consisted of retropubic urethropexy or pubovaginal sling.[3] Since 1996, when Ulmsten *et al*. published the initial paper about retropubic tension free vaginal tape (TVT), the use of synthetic mid-urethral slings (MUS) has grown to become the most common surgery performed for SUI women.[4-6]

There are seven major types of corrective procedures that have been described for SUI; suburethral fascial plication in anterior colporrhaphy, artificial sphincter, periurethral bulking agent injection, pubovaginal sling procedures (employing a biologic graft and anchored either directly to or above the rectus fascia), transabdominal retropubic urethropexy, transvaginal (needle) retropubic urethropexy, and mid-urethral synthetic sling.

Comparison of the efficacy and safety of these different surgical methods for the treatment of SUI in women exist in the literature, including some randomized control trials.[7-8] In addition, there are a large number of nonrandomized trials of SUI surgery that are often retrospective case series, with short and medium term follow up using outcome parameters.[9-13] Many of these studies researched the efficacy and safety of each procedure in different case scenarios, like concomitant abdominal or vaginal surgeries based on patients' outcome. There is sparse data regarding the individual surgeon's practice patterns and the preferred surgical technique for the treatment of SUI by the individual surgeon especially when concomitant prolapse surgery is indicated. The primary aim of our study was to compare surgeons' preference for surgical treatment for SUI in 2013 to a survey performed on the same surgical society fifteen years prior in 1998. Our secondary aim was to describe the practice pattern of surgeons for treatment of SUI in present time when concomitant prolapse surgery is indicated.

METHODS

This was an anonymous cross-sectional study performed at the American Urogynecologic Society's (AUGS) annual meeting in 1998 and repeated again in 2013. The study was identified as exemption for IRB approval based on 45 CFR 46 IRB exemption categories. AUGS research committee reviewed and approved our study. A self-administered paper-based questionnaire was included in the initial registration packet given to each participant in the meeting. Individual physicians were asked to complete the survey any time during the four days of the meeting and return it to a designated collection box in the meeting area. Registrants who were not surgeons were asked to return the surveys incomplete.

Each questionnaire consisted of nineteen questions requesting both quantitative and qualitative data. The first seven questions documented the demographic data of the responder on age-category, race, gender, the type of practice, training time, proportion of procedures related to SUI, and proportion of procedures to treat urogynecologic/pelvic floor disorders. The remaining questions inquired about the surgical method that the individual surgeon used for SUI treatment in different circumstances. A six point and four point preference scale, choices of procedures, and yes/no responses were employed. See Tables 1-4 below.

All statistical analysis was performed with the SAS V9.2. Chi-Square tests were utilized to test differences in demographic characteristics between the two surveys as well as preferences and proportions for yes/no questions (Table 1 & 4). In questions where no comparison could be made due to the questions being different from 1998 to 2013, counts, proportions and 95% CIs were presented. Although there

were multiple comparisons being assessed, an alpha of 0.05 was deemed to be significant.

RESULTS

A total of 136 participants responded in 1998 and 137 responded in 2013. The demographic data for the survey participants are summarized in Table 1. The majority of the respondents in 1998 were male (54%) compared to 2013 when the majority was female (56%). The age of the respondents shifted over time from ages 41-50 (39%) in 1998 to less than 40 years of age in 2013 (52.6%). There was an increase in the proportion of respondents who had completed a formal, three-year Female Pelvic Medicine and Reconstructive Surgery fellowship after residency, with 1.5% of respondents completing a fellowship in 1998 and 52% of respondents in 2013.

Surgeon's preferred surgical approach for primary SUI treatment and in different concomitant surgery cases:

The preferred surgical techniques based on different concomitant surgical indications are summarized in Table 2. The preferred procedure reported for treatment of primary SUI in 1998 was transabdominal retropubic urethropexy, consisting of 67.5% of all surgeries performed for SUI. In 2013, the MUS was reported as the preferred surgery for the treatment of SUI (89%), while transabdominal urethropexy was only performed 6.2% of the time. In 1998, retropubic urethropexy was reported as the most preferred

Table 1. – Demographic characteristics of survey participants - n (%).

	Survy, fall 1998 n=136	Survey, fall 2013 n=137	P-Value from Chi-Square Test
Gender			
Female	62 (45.6)	77 (56.2)	0.0794
Male	74 (54.4)	60 (43.8)	
Age			
< 40	71 (52.6)	37 (27.2)	0.0001
41-50	43 (31.8)	53 (39.0)	
51-60	16 (11.9)	35 (25.7)	
61-70	4 (3.0)	11 (8.1)	
> 70	1 (0.7)	–	
Type of practice			
Full time university	64 (47.4)	56 (42.1)	
University affiliated	30 (22.2)	34 (25.6)	0.6650
Private practice	41 (30.4)	43 (32.3)	
Formal Urogynecology training beyond Ob/Gyn residency			
None	42 (31.6	26 (19.0)	
six months	21 (15.8)	6 (4.4)	
One year	36 (27.1)	14 (10.2)	<0.0001
Two years	32 (24.1)	21 (15.3)	
Three years	2 (1.5)	70 (51.1)	
Approximate number of procedures to treat SUI in a year			
1-10	3 (2.2)	2 (1.5)	
11-50	60 (44.1)	45 (32.9)	0.0637
51-100	55 (40.4)	56 (40.9)	
>100	18 (13.2)	34 (24.8)	
Proportion of practice strictly related to urogynecology			
<10%	1 (0.7)	1 (0.7)	
11-51%	60 (44.4)	5 (3.7)	<0.0001
>50%	74 (54.8)	131 (95.6)	

Table 2. – Mean and 95% Confidence Intervals for Rankings of Surgeon's preferred surgical approach for primary SUI treatment in different concomitant surgery cases.

Clinical preference	Fall 1998 n=136	Fall 2013 n=137
Average proportion of procedures annually for treatment of primary SUI		
1 - Anterior colporrhaphy	11.7 (8.1, 15.3)	4.9 (2.6, 7.2)
2 - Artificial sphincter	8.3 (1.2, 15.5)	1 (**, **)
3 - Periurethral collagen injection	11.3 (9.7, 12.9)	8.1 (6.6, 9.5)
4 - Sling procedures	26.1 (21.7, 30.5)	7.4 (2.0, 12.8)
5 - Transabdominal retropubic urethropexy	67.5 (63.1, 71.8)	6.2 (4.4, 8.0)
6 - Transvaginal (needle) retropubic urethropexy	16.8 (10.2, 23.4)	5.3 (1.1, 9.6)
7 - Mid-Urethral Synthetic sling	NA	89.0 (86.5, 91.4)
Average rank the following procedures for the treatment of primary genuine stress urinary incontinence		
1 - Anterior colporrhaphy	1.74 (1.59, 1.90)	1.62 (1.45, 1.79)
2 - Artificial sphincter	3.64 (3.31, 3.97)	2.83 (2.54, 3.12)
3 - Periurethral collagen injection	2.80 (2.62, 2.99)	3.27 (3.12, 3.41)
4 - Sling procedures	5.46 (5.34, 5.58)	4.55 (4.33, 4.77)
5 - Transabdominal retropubic urethropexy	5.36 (5.25, 5.47)	4.60 (4.44, 4.76)
6 - Transvaginal (needle) retropubic urethropexy	2.87 (2.70, 3.04)	2.82 (2.59, 3.05)
7 - Mid-Urethral Synthetic sling	NA	5.55 (5.38, 5.71)
Average Rank for the procedure given concomitant need for vaginal hysterectomy		
1 - Anterior colporrhaphy	2.37 (2.11, 2.63)	1.80 (1.59, 2.02)
2 - Artificial sphincter	1.31 (1.13, 1.49)	1.17 (1.04, 1.31)
3 - Periurethral collagen injection	1.88 (1.66, 2.09)	2.50 (2.25, 2.75)
4 - Sling procedures	4.22 (3.91, 4.54)	2.6(2.40, 2.98)
5 - Transabdominal retropubic urethropexy	5.20 (4.98, 5.42)	2.34 (2.08, 2.60)
6 - Transvaginal (needle) retropubic urethropexy	2.61 (2.34, 2.89)	1.78 (1.54, 20.3)
7 - Mid-Urethral Synthetic sling	NA	5.71 (5.52, 5.90)
Average Rank for procedure given concomitant need for abdominal hysterectomy or other transabdominal procedure		
1 - Anterior colporrhaphy	1.50 (1.33, 1.66)	1.40 (1.24, 1.57)
2 - Artificial sphincter	1.28 (1.12, 1.45)	1.19, 1.04, 1.35)
3 - Periurethral collagen injection	1.74 (1.54, 1.94)	2.06 (1.82, 2.30)
4 - Sling procedures	3.75 (3.45, 4.04)	2.49 (2.22, 2.77)
5 - Transabdominal retropubic urethropexy	5.81 (5.71, 5.92)	3.86 (3.58, 4.14)
6 - Transvaginal (needle) retropubic urethropexy	1.77 (1.55, 2.00)	1.71 (1.48, 1.94)
7 - Mid-Urethral Synthetic sling	NA	5.43 (5.22, 5.64)
Average Rank for procedure given concomitant need for pelvic organ prolapse repair that requires a transabdominal approach		
1 - Anterior colporrhaphy	1.67 (1.45, 1.89)	1.49 (1.30, 1.68)
2 - Artificial sphincter	1.27 (1.12, 1.41)	1.18 (1.02, 1.34)
3 - Periurethral collagen injection	1.69 (1.49, 1.89)	2.00 (1.77, 2.23)
4 - Sling procedures	3.93 (3.64, 4.23)	2.38 (2.11, 2.65)
5 - Transabdominal retropubic urethropexy	5.76 (5.64, 5.89)	3.71 (3.42, 4.00)
6 - Transvaginal (needle) retropubic urethropexy	1.82 (1.59, 2.06)	1.65 (1.41, 1.90)
7 - Mid-Urethral Synthetic sling	NA	5.46 (5.24, 5.68)

Note: A 1-6 scale was used for both years; 1 presents the less preferred and 6 presents the most preferred technique, NA =procedure not available in 1998 **= all values were the same so no 95% CI could be calculated.

TABLE 3. – Surgeon's preferred surgical approach for SUI treatment influenced by patient's situation – n (%).

Clinical preference	Fall 1998 n=136	Fall 2013 n=137	P-Value from Chi-Square Test
Degree to which patient preference for a transvaginal procedure influences your decision to perform a vaginal compared to a transabdominal procedure*			
1	33 (24.8)	30 (22.6)	
2	45 (33.8)	24 (18.1)	<0.0001
3	43 (32.3)	30 (22.6)	
4	12 (9.0)	49 (36.7)	
Do you counsel patients that transvaginal retropubic urethropexies are less efficacious than transabdomonal retropubic urethropexies?			
Yes	115 (87.1)	50 (40.7)	<0.0001
No	17 (12.9)	73 (59.4)	
Does the presence of a large abdominal girth or pannus influence your preference away from abdominal procedure toward vaginal procedure?			
Yes	57 (43.5)	89 (66.4)	<0.0002
No	74 (56.5)	45 (33.6)	
Do you routinely perform complex cystometrics prior to proceeding to anti-incontinence surgery?			
Yes	116 (87.2)	89(66.9)	<0.0001
No	17 (12.8)	44 (33.1)	
Does presence of a chronic cough or other condition that results in habitual increase in intra abdominal pressure influence your choice of surgical procedure?			
Yes	122 (90.4)	85 (63.0)	<0.0001
No	13 (9.6)	50 (37.0)	

surgical approach for incontinence for primary SUI regardless of whether other abdominal or vaginal procedures were planned. In 2013, MUS was reportedly the most preferred procedure regardless of need for concomitant abdominal or vaginal surgeries.

Surgeon's preferred surgical approach for SUI treatment influenced by patient's characteristics:

The degree to which patients' preference for a transvaginal procedure influenced surgeon's decision to perform a vaginal procedure compared to a trans-abdominal procedure increased from 9% to 36.7% in 1998 and 2013, respectively. The approach to the treatment of patients with a large abdominal girth changed over time with 43.5 % of surgeons in 1998 choosing a vaginal approach for incontinence treatment compared to 66.4% of surgeons in 2013. A majority of the time, complex cystometrics was routinely performed prior to an anti-incontinence surgery in both 1998 and 2013 for 87.2% and 66.9%, respectively (Table 3).

Two different case scenarios were described in the survey, one implying low urethral pressure and the other implying low leak point pressure. Participants were asked to suggest their preferred surgical approach. In both cases, pubovaginal sling procedures and mid-urethral sling procedures were the most preferred methods of treatment in 1998 and 2013, respectively (Table 4).

DISCUSSION

Our study documented the notable change in reported surgical management of stress urinary incontinence from 1993 to 2013. Currently, MUS surgery is preferred surgical method for treatment of primary SUI based on the survey results. This technique is also the preferred method by surgeons in cases with indication of concomitant abdominal or vaginal surgeries. Reported current practice relegates transabdominal retropubic urethropexy to only 6.2% of annual surgeries performed for SUI treatment. Even in the case of concomitant abdominal surgery, surgeons preferred to perform MUS.

Based on literature, transabdominal retropubic urethropexy can be as effective as MUS.[3,14,15] Our study showed that over time, surgeons' preferred surgical technique for SUI has dramatically changed. This change has occurred even with recent evidence demonstrating a significant cure rate with the use of abdominal urethropexy, particularly when concomitant abdominal procedure is indicated for the patient.

In 2007 Sivaslioglu et al. performed a randomized comparison of transobturator tape (TOT) and Burch colposuspension in the treatment of female stress urinary incontinence (14). 100 women were recruited in the study with a 24 months follow up period. TOT procedure resulted in similar cure rates of SUI at 1 and 2 years compared to Burch procedure. The TOT procedure had a shorter operative time and length of hospital stay. Foote et al. in a study on 97 women aimed to determine if laparoscopic colposuspension was as effective as vaginal suburethral slingplasty.[15] Upon a follow up of 24 months, the success rates were similar (88.3 vs 81.8%), and they observed that laparoscopic colposuspension is as effective as vaginal suburethral slingplasty after two years' follow-up.

A recently published meta-analysis including ten clinical trials comparing the objective and subjective cure rates between Burch abdominal (open or laparoscopic) urethropexy with MUS operations did not show significant difference for MUS to Burch.[3] Schimpf e*t al*. in this review recruited 10 clinical trials that had compared Burch abdominal (open

TABLE 4. – Surgeon's preferred surgical approach for SUI treatment in two specific case scenarios.

Clinical preference	Fall 1998 n=136	Fall 2013 n=137
Given a patient with a static urethral pressure profile of < 20 cm H2O which procedure do you most favor for treatment?		
1 - Anterior colporrhaphy	0	0
2 - Artificial sphincter	0	1 (0.8)
3 - Periurethral collagen injection	8 (6.11)	9 (6.8)
4 - Sling procedures	110 (84.0)	2 (2.52)
5 - Transabdominal retropubic urethropexy	13 (9.9)	0
6 - Transvaginal (needle) retropubic urethropexy	0	1 (0.8)
7 - Mid-Urethral Synthetic sling	NA	119 (90.2)
Given a patient with a leak point pressure of < 60 cm H2O which procedure do you most favor for treatment?		
1 - Anterior colporrhaphy	1 (0.8)	0
2 - Artificial sphincter	0	1 (0.8)
3 - Periurethral collagen injection	11 (8.4)	4 (3.0)
4 - Sling procedures	99 (75.6)	2 (1.5)
5 - Transabdominal retropubic urethropexy	19 (14.5)	0
6 - Transvaginal (needle) retropubic urethropexy	1 (0.8)	0
7 - Mid-Urethral Synthetic sling	NA	126 (94.7)

or laparoscopic) urethropexy with mid-urethral sling operations.[3] Meta-analysis of objective cure did not show significant difference for MUS to Burch (OR, 1.18; 95% CI, 0.73-1.89). For subjective cure, no significant differences were observed for these two techniques (OR, 1.12; 95% CI, 0.79-1.60). In summary, for women considering MUS or Burch procedures for treatment of SUI, they suggested either intervention for objective and subjective cure, with the decision based on adverse events and other planned concomitant surgeries (vaginal vs abdominal).

Persson *et al*. compared the costs of laparoscopic Burch colposuspension to TVT to the country in a randomized prospective study in 270 women .[16] They showed that laparoscopic Burch colposuspension was less expensive to the country than TVT.

Additionally, a majority of respondents in this survey perform complex cystometrics prior to proceeding to anti-incontinence surgery despite evidence that this may not be necessary for patients with simple SUI. The VALUE trial, published in 2012, suggested that women with uncomplicated SUI might only need a basic office evaluation for a preoperative workup.[17] In the VALUE trial, complex cystometrics did not improve the rate of treatment success compared to those who only underwent an office-based evaluation. While our data shows the rate complex cystometrics has declined from 87% in 1998 to 67% in 2013, this trend will be interesting to watch as the pendulum swings towards cost-effective, efficient delivery of care.

Our study has added valuable information to the practice patterns of surgeons for the surgical treatment of SUI, however certain limitations exist. This was a self-administered questionnaire, and has greater chance of having no response items compared to interviewer-administered questionnaires. Alternately, self-administered questionnaires are less susceptible to information bias and can easily capture a large sample size. Another limitation can be noted in our study population, which included surgeons who participated in AUGS's meeting. This population can generate a selection bias as these surgeons may be from larger academic institution and potentially early adapters of new techniques. However, access to the same study population after 15 years is a definite strong point and makes our results reliable to compare during this period of time to show the existing change in practice patterns and preference on surgical procedures.

This study documents changes in surgical practices in SUI, which directly influences patient care. Surgeons in this cohort prefer to perform mid-urethral sling for surgical treatment of SUI even when concomitant abdominal surgery is indicated, while abdominal urethropexy occupies only 6.2% of annual surgeries performed presently. We suggest a long term follow up clinical trial to evaluate the cost of practice changes and to illustrate its effects on patients' subjective and objective outcomes. Given this reportedly low rate of performance, it is unlikely that trainees in OB/GYN or Urology will be exposed to this effective treatment option in routine clinical practice. If retropubic urethropexy is to remain relevant, other training methods such as simulation should be considered.

CONFLICTS

No conflict of interest of any of the Authors.

REFERENCES

1. Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, et al. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourology and urodynamics. 2010; 29(1): 213-40.
2. Rovner ES, Lebed BD. Stress incontinence surgery: which operation when? Current opinion in urology. 2009 2009 Jul; 19(4): 362-7.
3. Schimpf MO, Rahn DD, Wheeler TL, Patel M, White AB, Orejuela FJ, et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol. 2014 Jan 30.
4 Albo ME, Litman HJ, Richter HE, Lemack GE, Sirls LT, Chai TC, et al. Treatment success of retropubic and transobturator mid urethral slings at 24 months. The Journal of urology. 2012 Dec; 188(6): 2281-7.
5. Thom DH, Nygaard IE, Calhoun EA. Urologic diseases in America project: urinary incontinence in women-national trends in hospitalizations, office visits, treatment and economic impact. The Journal of urology. 2005 Apr; 173(4): 1295-301.
6. Oliphant SS, Wang L, Bunker CH, Lowder JL. Trends in stress urinary incontinence inpatient procedures in the United States, 1979-2004. American journal of obstetrics and gynecology. 2009 May; 200(5): 521 e1-6.
7. Ward KL, Hilton PCINAJOGM, author reply P. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. American Journal of Obstetrics and Gynecology. 2004 2004 Feb; 190(2): 324-31.
8. Paraiso MF, Walters MD, Karram MM, Barber MD. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. Obstetrics and gynecology. 2004 2004 Dec; 104(6): 1249-58.
9. Leach GE. Stress urinary incontinence in women: guidelines for surgical treatment. Journal of women's health / the official publication of the Society for the Advancement of Women's Health Research. 1998 1998 Jun; 7(5): 583-6.
10. Novara G, Artibani W, Barber MD, Chapple CR, Costantini E, Ficarra V, et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. European urology. 2010 2010 Aug; 58(2): 218-38.
11. Ward KL, Hilton PCINNCPUA, Pmid. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG : an international journal of obstetrics and gynaecology. 2008 2008 Jan; 115(2): 226-33.
12. Basok EK, Yildirim A, Atsu N, Basaran A, Tokuc R. Cadaveric fascia lata versus intravaginal slingplasty for the pubovaginal sling: surgical outcome, overall success and patient satisfaction rates. Urologia internationalis. 2008 2008; 80(1): 46-51.
13. Sharifiaghdas F, Mortazavi N. Tension-free vaginal tape and autologous rectus fascia pubovaginal sling for the treatment of urinary stress incontinence: a medium-term follow-up. Medical principles and practice : international journal of the Kuwait University, Health Science Centre. 2008 2008; 17(3): 209-14.
14. Sivaslioglu AA, Caliskan E, Dolen I, Haberal A. A randomized comparison of transobturator tape and Burch colposuspension in the treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Sep; 18(9): 1015-9.
15. Foote AJ, Maughan V, Carne C. Laparoscopic colposuspension versus vaginal suburethral slingplasty: a randomised prospective trial. Aust N Z J Obstet Gynaecol. 2006 2006 Dec; 46(6): 517-20.
16. Persson J, Teleman P, Eten-Bergquist C, Wolner-Hanssen P. Cost-analyzes based on a prospective, randomized study comparing laparoscopic colposuspension with a tension-free vaginal tape procedure. Acta obstetricia et gynecologica Scandinavica. 2002 Nov; 81(11): 1066-73.
17. Nager CW, Brubaker L, Litman HJ, Zyczynski HM, Varner RE, Amundsen C, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. New England Journal of Medicine. 2012 2012 May 24; 366(21): 1987-97.

Correspondence to:

Ghazaleh Rostaminia
3300 Gallows Road - FallsChurch VA - United States
E-mail: ghazaleh.rostaminia@inova.org

Original article

The TFS minisling restores major pelvic organ prolapse and symptoms in aged Japanese women by repairing damaged suspensory ligaments – 12 - 48 month data

HIROMI INOUE[1], YUTAKA KOHATA[1], YUKI SEKIGUCHI[2], TUYOSHI KUSAKA[1], TAKANORI FUKUDA[1], MIKA MONNMA[1]

[1] *Shonan Kamakura General Hospital - Gynecology*
[2] *Yokohama Luna Clinic - Urology*

Background: Ageing of Japan's population has brought increases in pelvic organ prolapse (POP) and symptoms, creating problems for patient QOL, the health system, the community and government cost.
Objective: To assess effectiveness of the Tissue Fixation System (TFS) in curing POP and symptoms of nocturia, urgency, frequency, chronic pelvic pain, fecal incontinence by suspensory ligament repair as predicted by the Integral Theory System.
Design, Setting, and Participants: a tertiary pelvic floor referral centre. Prospective observational study: 278 aged females (mean 69.6years), referred for primary POP repairs January 2009 - December 2012; initial 12 month and 4 year follow-up of original cohort.
Inclusion criteria: 3rd or 4th degree uterine/vaginal prolapse (POPQ classification).
Exclusion criteria: serious comorbid conditions.
Intervention(s): Damaged structures, ATFP, cardinal, uterosacral ligaments and perineal body were identified and repaired by an adjustable TFS tape attached to soft tissue anchors applying the same neoligament principle used in the TVT operation.
Outcome Measurements and Statistical Analysis: Follow-up: 12 months (n = 278), then yearly. 50/68 initial cohort reviewed at 4 years. Statistics: Lower and upper 95% confidence for observed relative frequencies of POP and symptoms were calculated for observed cure rates of 80%, 75% and 60% respectively ($p < 0.05$ Binomial Tests).
Surgical failure: any compartment prolapse for that patient at or beyond stage 2, (POPQ classification).
Results: Mean hospital stay: 0.7 days (0-7); mean return to normal activities: 2.2 days.
Surgical cure rate for POP (n = 278): 91.2% at 12 months, with a 10% fall at 48 months for original cohort (n = 68) to 84% (n = 50).
Symptom cure rate at 12 months 278 patients: nocturia (n = 86) 72.1%; daytime frequency (n = 132) 90.1%; urgency (n = 133) 93.2%; chronic pelvic pain (n = 56) 93%; fecal incontinence (n = 52) 88.5%. *Complications* There were two early cases of ileus because of intraperitoneal placement of the tape, attributed to incorrect technique. Erosion rate (all TFS placements) 3.0% Excluding the perineal body tapes, the erosion rate was 9/989 = 1.1%.
Limitations 18 absent patients from the 4 year follow-up.
Conclusions: The minimal nature and high cure rate of bladder and bowel symptoms may offer hope for reduction of admissions to Nursing Homes in the future. However, large multicenter more robust comparative studies will be required to more fully assess this method before such hopes can be justified.

Key words: TFS; POP; Nursing homes; Cystocele repair; Perineal body repair; Rectocele repair; Uterine prolapse repair; Adjustable minisling.

INTRODUCTION

The Japanese female population is ageing rapidly. In September 2013, there were 17.59 million women aged 65 and older, an increase of 7.6% in 4 years.[1] Consequently, more Japanese women are developing pelvic organ prolapse (POP) and troubling symptoms such as urgency, nocturia, chronic pelvic pain, bladder emptying problems, causing major problems for patient QOL, the health system the community and government cost. Collateral health problems create a concomitant demand for minimally invasive operations to safely correct the prolapses. The TFS (Tissue Fixation System),[2-4] fig. 1, is a less invasive evolution of the TVT operation;[5] like the TVT, a short narrow strip of tape provokes the host tissues to create an artificial collagenous neoligament,[6] to reinforce the 5 supporting structures of the pelvic organs, pubourethral, arcus tendineus fascia pelvis (ATFP), cardinal (CL), uterosacral ligaments (USL) and perineal body (PB).

The TFS was introduced to Japan in 2006 at the 13th Annual Meeting of the Neurogenic Bladder Society of Japan and the first live surgery of TFS in Japan was performed in September 2006 under the aegis of the Japanese Society for Pelvic Floor Medicine.

In a previous work,[7] we described our preliminary assessment of this method, including initial POP and symptom cure, analysis of the learning curve (short) and surgical complications (few).

The primary aim of this work was to report our experience of using TFS for POP over 4 years and 278 patients. A secondary aim was to track the fate of pelvic symptoms, urgency, frequency, nocturia, chronic pelvic pain and fecal incontinence.

MATERIALS AND METHODS

This was a prospective observational study. We used validated questionnaires[8] and ICIQ SF to assess symptoms, vaginal examination to directly identify the sites of ligament repair, according to specific anatomical criteria set down for clinical diagnosis of damaged ligaments.[9]

The TFS (TFS Surgical, Adelaide South Australia) consists of an applicator, a non-stretch tape attached to two soft tissue anchors with an adjustable mechanism at the base, fig1. A non-stretch lightweight non-stretch type 1 macropore monofilament polypropylene mesh tape was used. The TFS sling operations were variously applied at up to 5 main sites, figures 2-4. We calculate that the total length of implant was 5-8cm for each tape.

Anterior wall support for cystocele repair, fig. 2 The U-Sling supports the distal vaginal wall; it repairs the lateral defect by re-attaching the prolapsed vaginal wall to the ATFP near its origin behind the pubic bone immediately above the pubourethral ligament and there is growing evidence that it may restore dislocated pubovisceral muscles also (9a). The cardinal ligament repairs the high or trans-

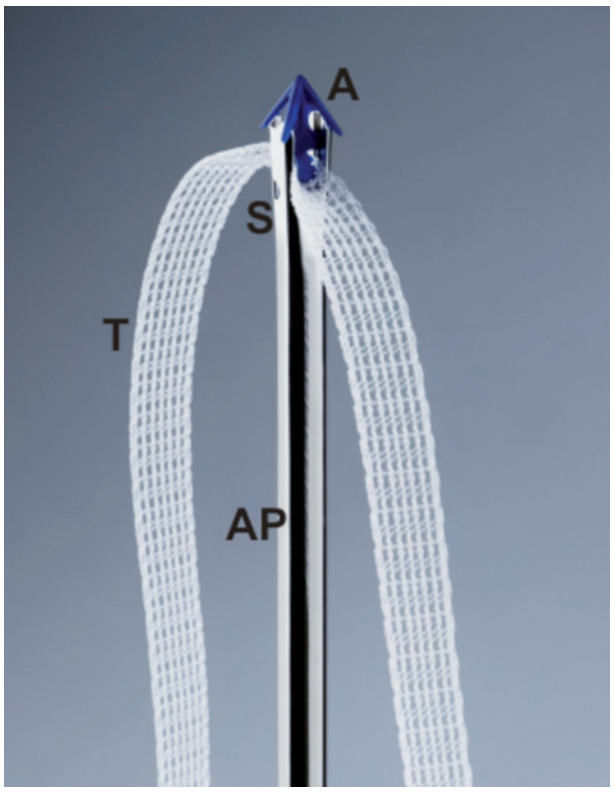


Figure 1. – The TFS system for creation of artificial collagenous neoligaments for POP and USI cure. Applicator (AP) and anchor (A). T=lightweight macropore monofilament tape. At the base of 'A' is a system which allows one-way directional tensioning of the tape. (Reproduced with the permission of TFS Surgical)

verse defect. It re-attaches the prolapsed pubocervical fascia to the cervical ring, shortens the cardinal ligament and re-attaches the displaced ATFP onto the side wall.

Apical support for uterine/apical prolapse, fig. 2. The cardinal TFS sling re-attaches the uterus or apex laterally to the fascia of the side wall skeleton. The uterosacral TFS attaches it posteriorly to the pre-sacral fascia at S3 level.

Posterior vaginal and anterior rectal wall support, figures 2&3

The uterosacral TFS attaches the posterior cervical ring posteriorly to the pre-sacral fascia at S3 level. Because it passes by the lateral wall of the rectum, it, too, is re-attached, constituting a transvaginal rectopexy. At the level of the introitus, the reconstituted perineal body supports 50% of the posterior vaginal wall[10] and the anus.[11,12]

Urinary stress incontinence It is the policy of our department not to perform USI surgery concomitantly with POP surgery. There were 6 exceptions made in this study.

TFS SURGICAL TECHNIQUE

The surgical technique uses the same technique for all the TFS operations. The vagina is incised. Bladder, enterocele or rectum are dissected as required. The ligament is identified. A tunnel is made with Metzenbaum scissors. The applicator is inserted into the tunnel. The anchor is released. The application is repeated on the contralateral side and the tape is adjusted until a resistance is felt. This indicates return of muscle tone in the muscles which act on that ligament. The tape is cut and the vagina is closed.

The prolapse was staged according to the ICS POPQ classification.[13,14]

This study was approved by the Ethics Committees of the Kamakura General Hospital in 2006. Written informed consent was obtained from all patients. The principles of the Helsinki Declaration (2008) were followed.

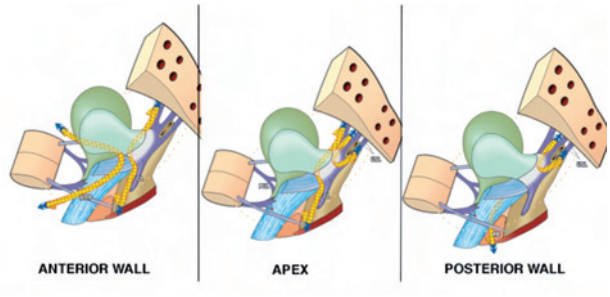


Figure 2. – TFS Surgery for POP The anchor is positioned along the ligament and tape adjusted to remove looseness. This lifts the organ back into its non-prolapsed position. The tape reinforces the ligaments and stretches the anterior and posterior vaginal wall like ropes stretching a tent. By strengthening the ligaments, the TFS also restores the muscle forces which support, open and close the organs, on the basis that the ligaments are the effective insertion points of the pelvic muscles. (Reproduced with the permission of Professor Peter Petros)

RESULTS

Operations using the TFS anchor system were performed on 278 women, mean age 69.6 years (36-89), between January 2009 to December 2012 inclusive. Mean parity was 2.2 (range 0-6). Mean body index was 24.2 (range 15.1-39.8). All patients had stage 3 or 4 pelvic organ prolapse according to the Pelvic Organ Prolapse Quantification (POPQ) standard scoring system. The results are summarized in Tables 1&2.

A total of 989 tapes were used in 278 patients (mean 3.5 tapes per patient).

There were 272 U slings for lateral/central anterior vaginal wall defects, 243 posterior slings (USL-sling) of the uterosacral ligaments, 264 Cervical slings for cardinal ligament defects, 204 perineal body slings for defect of the perineal body and 6 pubourethral slings for SUI (ISD) were performed.

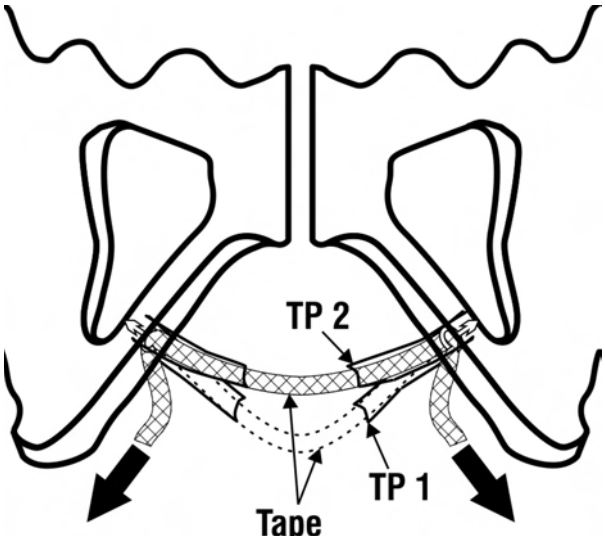


Figure 3. – Perineal body (PB) TFS sling
The anchors penetrate the deep transversus perinei which inserts exactly at the junction of the upper 2/3 and lower 1/3 and the tape is tightened. In patients with descending perineal syndrome, this action elevates the prolapsed perineal body from position TP1 to TP2. (Reproduced with the permission of Professor Peter Petros)

Mean operation time was 89.4 minutes (range 39-190). The time for insertion of a TFS sling varied between 15-25 minutes per ligament. Mean estimated total blood loss per patient was 74ml (range 5-378ml). Mean hospitalization after operation was 0.7 days (range 4 hours to 3 days), with 42% of patients discharged on the same day. Mean days return to usual life was 2.2 days (range 1-10 days). Mean no of tapes per patient 3.5 (range 1-5).

We defined surgical failure as any prolapse *in any compartment* of the patient at or beyond stage 2 according to the ICS POPQ classification, even, if in patients undergoing multiple TFS surgeries, other compartments remained intact. On this basis, surgical cure rate for POP was 91.2% at 12 months. The 12 month cure rate for the original cohort was largely maintained, with only a 10% fall at 48 months, from 91.2% (n = 68) to 84% (n = 50).

There were no intraoperative complications and no bladder or bowel perforations. However, there were two longer term post-operative complication, ileus due to tape in abdominal cavity and adhesion of the mesentery and USL mesh tape, 3 and 15 months after operation and treated operatively by laparotomy and adhesiolysis. In case 1, omentum was dissected from the tape. In case 2, between small bowel and tape. Both patients recovered well without prolapse recurrence. This complication occurred in the 1st cohort of patients. It was attributed to faulty surgical technique and resulted in change in technique, ensuring the tape was extraperitoneal at all times. There have been no further episodes of this complication in the subsequent 209 patients.

Of 989 tapes inserted over a 12-48 month period (2009-2012) , 30 tapes of 29 patients were rejected or eroded and partial excision of meshes was performed in all patients as an outpatient procedure. However, this figure included a disproportionate number of perineal body slings. Including the 1st cohort, the rate of tape rejection or erosions was 0.4% in the ATFP U-slings (1/272), 1.5% in Cardinal/Cervical ring slings (4/264), 1.6% in posterior slings (USL-sling) (4/243), and 10.3% in perineal body (PB) slings (21/204), respectively. Rejection rates for PB slings were 21.6% in 2009, 4.3% in 2010-11 and 2.6 % in 2012. There was no rejection of midurethral slings (n = 6) and all 6 patients were cured. The total rate of rejection or erosions in 989 tapes including the perineal body tapes was 30/989 (3.0%). Excluding the perineal body tapes, the erosion rate for the other tapes was 9/785 = 1.1%.

TABLE 1. – Lower and upper 95 % confidence intervals for the observed relative frequencies of Prolapse, Urgency, Nocturia, Day time frequency, Dragging pain and Fecal incontinence. Parallelly the results of testing the hypothesis Ho: P ≤ p0 vs H1: p > p0 have entered.

Variable	N	No of cured	observed cure rate (%)	95 %-lower CI	96 %-upper CI	Test results Ho: $p \leq p_0$ vs. H1: $p > p_0$
Prolapse	278	257	92.10	0.891	0.952	*
Urgency	133	124	93.20	0.879	0.971	*
Nocturia	86	62	72.10	0.597	0.809	/
Day time frequency	132	120	90.10	0.935	0.999	*
Dragging pain	56	52	92.90	0.862	0.998	*
Fecal incontinence	52	46	88.50	0.798	0.977	#

'*', '#' and '/' means significant p-values when p0 is setting equal to 0.80, 0.75 and 0.60, respectively.
With other words these symbols depict that the observed cure rates are significantly higher than 0.80, 0.75 and 0.60 respectively ($p < 0.05$; Binomial Tests)

TABLE 2. – Lower and upper 95% confidence intervals for the observed relative frequencies of Prolapse, Urgency, Nocturia, Day time frequency, Dragging pain and Fecal incontinence after certain time intervals with the test results by testing Ho: Ps p0 vs H2: p > p0.

Time after TFS	Cure of prolapse	Cure of urgency	Cure of nocturia	Cure of day time frequency	Cure of dragging pain	Cure of dysuria	Cure of fecal incontinence
12mths	62/68	30/31	17/18	30/32	13/14	35/38	16/18
observed cure rate (in %)	91.2%	96.8%	94.4%	93.8%	92.9%	92.1%	88.9%
95 % (lower CI; upper CI)	0.877 0.946	0.936 0.999	0.890 0.998	0.895 0.980	0.860 0.997	0.877 0.965	0.815 0.963
Test results of Ho: p ≤ 0.80 vs. H1: p > 0.80	*	*	#	*	/	*	/
24mths	57/65	25/30	11/17	26/29	14/15	26/28	12/15
observed cure rate (in %)	87.7%	82.3%	64.7%	89.7%	93.3%	92.9%	80%
95 % (lower CI; upper CI)	0.836 0.918	0.765 0.901	0.531 0.763	0.840 0.953	0.869 0.998	0.880 0.977	0.697 0.903
Test results of Ho: p ≤ 0.80 vs. H1: p > 0.80	*	/	ns	/	/	#	ns
36mths	48/58	23/24	14/23	27/30	9/10	25/26	6/7
observed cure rate (in %)	82.7%	95.8%	60.9%	0.900	0.900	96.2%	85.7%
95 % (lower CI; upper CI)	0.778 0.877	0.918 0.999	0.507 0.710	0.845 0.955	0.805 0.995	0.924 0.999	0.725 0.969
Test results of Ho: p ≤ 0.80 vs. H1: p > 0.80	/	*	ns	#	/	*	ns (?)
48mths	42/50	18/20	8/17	13/19	6/6	22/23	5/5
observed cure rate (in %)	84%	90.0%	47.1%	68.4%	1.000	95/6%	100%
95 % (lower CI; upper CI)	0.788 0.892	0.833 0.967	0.350 0.592	0.578 0.791	1.000 1.000	0.914 0.999	1.000 1.000
Test results of Ho: p ≤ 0.80 vs. H1: p > 0.80	/	/	ns	ns	/(?)	*	ns (?)

'*', '#' and '/' means significant p-values when p0 is setting equal to 0.80, 0.75 and 0.60, respectively.
With other words these symbols depict that the observed cure rates are significantly higher than 0.80, 0.75 and 0.60 respectively ($p < 0.05$; Binomial Tests)
Note: Yellow marked field in table 2 means that we have to pay attention in the interpretation of significances, because for these fields the corresponding sample sizes are too small.

DISCUSSION

This is the first longer term study of a minisling system applied to POP. Our opinion, based on 12 and 48 month data, mean age of the patients (69.6 years), is that the TFS is a safe and effective method for POP reconstruction especially applicable to the old and frail because of its minimal invasiveness. It is known that urinary and fecal incontinence are responsible for more than 50% of female admissions to Nursing Homes. The continued effectiveness of the TFS as regards POP, bladder and bowel symptom cure at 4 years encourages us to predict that this method may well be the key to solving the looming societal, health and economic problems associated with caring for older populations.

The TFS is a very different technique to the large POP mesh kits inserted behind the vagina in DeLancey level 2. Large mesh sheets inserted at level 2 glue the organs to the vagina, inhibiting independent organ movement, thus facilitating erosion, dyspareunia and perhaps organ dysfunction. The TFS is a direct evolution of the TVT, works much like the TVT and has similar erosion rates. It is applied directly onto damaged ligaments which lie outside the vaginal wall at DeLancey levels 1&3. The one-way sling tightens lax ligaments and fascia. Our experience is that if the anchors are correctly positioned, this method has a low incidence of erosion and causes minimal organ adherence. The anteroposterior elasticity required for normal organ function and symptom cure at Level 2 is largely maintained.

The TFS method allows 'real-time' visualization as the restitution of the pelvic floor anatomy proceeds. For example, there is a sudden deepening of the sulcus after the TFS cardinal tape is tightened, rapid elevation of a prolapsed uterus with the USL sling, elevation of distal vagina on tightening the ATFP U-Sling, disappearance of low rectocele and perineocele on tightening the perineal body sling, with concomitant correction of the "descending perineal syndrome".

Based on operating time and blood loss, we estimated the learning curve in a previous publication[7] to be 5 cases. The 4 year data which was inclusive of learning curve, appears to substantiate this view. However, there are important subtleties in the technique which may lead to problems, for example, two cases of ileus and high initial erosion rates with the perineal body TFS.

The two patients who presented with ileus-type symptoms post-operatively were from the 1st cohort. We attributed this to a fault in technique: we did not take sufficient care to dissect and close the enterocele, or to angle the applicator from medial to lateral during the tape insertion, so as to avoid the peritoneal cavity. We have not experienced any further ileus complications.

The first improvement in erosion rate followed when we changed the position of the anchors from inside the perineal body to behind the insertion point of deep transverse perinei at the junction of the upper 2/3 and lower 1/3 of the descending pubic ramus. The 2nd improvement was changing from one layer closure to a two layer closure and washing with sterile normal saline 100ml before closure. Following this, the rate of tape rejection or erosions in perineal body slings was improved, from 21.6% in 2009, to 4.3% in 2010 and 2011 to 2.6% in 2012.

We have not experienced any of the problems reported by Atherton *et al*.,[15] 5 case reports out of 1012 inserted tapes.[16] The complications were mainly anchor slippage consequent upon excessive tissue reaction to the multifilament tape in use at the time.[16] No such problems have occurred in 989 implants using the lightweight macropore type 1 tape.

The high improvement rate in symptoms of nocturia, urgency chronic pelvic pain and fecal were consistent with the predictions of the diagnostic system we used to place the tapes.[9] We consider this to be an important finding, as the estimated annual cost of hospitalizations for hip fracture in the EU-15 countries due to severe nocturia alone is approximately □ billion p.a.[17] Chronic pelvic pain is another disabling condition which occurs in up to 20% of women[18] and is considered incurable.[19] Furthermore, it is generally acknowledged that >50% of admissions to Nursing Homes is due to urinary or fecal incontinence. This method offers hope that some of these admissions may, in the future, be prevented with major benefits for patient QOL and the public purse.

Cure of non-sphincteric fecal incontinence (FI) was an affirmation of a previous study by Abendstein *et al*.,[20] who attributed their FI cure to restoration of competent PUL and USL ligaments.

The perineal body data supports the study of Wagenlehner for cure of patients who require manually assisted defecation[12] for descending perineal syndrome. The laterally displaced perineal bodies are elevated and positioned medially, thereby preventing extrusion of the rectocele, fig. 3, and restoring normal defecation.

We are uncertain as to the final mechanisms for restoration of such widely diverse symptoms. According to,[9] the one-way sling tightens lax ligaments and fascia, thereby restoring the action of muscles which contract against these structures to open and close the urethra and anorectum and to support nerve bundles in the uterosacral ligaments in patients with chronic pain.

CONCLUSIONS

The TFS procedures apply the same neoligament method as the TVT to repair other ligaments besides the pubourethral. This method appears to deliver good results for POP and symptoms, with low mesh reactions once the technique is properly learnt. It has the potential to provide at least a partial answer to the twin dilemmas confronting POP repair today, poor results from native tissue repair and problems using large mesh sheets. The minimal nature and high cure rate of bladder and bowel symptoms may offer hope for reduction of admissions to Nursing Homes in the future. However, large multicenter more robust comparative studies will be required to more fully assess this method before such hopes can be justified.

REFERENCES

1. http://www.stat.go.jp/index.htm Ministry of Internal Affairs and Communications
2. Petros PEP, Richardson PA The TFS posterior sling for repair of uterine/vault prolapse-a preliminary report. Aust N Z J Obstet Gynaecol, 2005; 45: 372-375.
3. Petros PEP, Richardson PA The TFS posterior sling for repair of uterine/vault prolapse-a preliminary report. Aust N Z J Obstet Gynaecol, 2005; 45: 376-379.
4. Petros PEP, Richardson PA, Goeschen K and Abendstein B, The Tissue Fixation System (TFS) provides a new structural method for cystocoele repair- a preliminary report. Aust N Z J Obstet Gynaecol, 2006; 46: 474-478.
5. Ulmsten U, Henriksson L, Johnson P, and Varhos G An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence, Int Urogynecol J Pelvic Floor Dysfunct..; 1996; 7: 81-86.
6. Petros PE & Ulmsten U, Papadimitriou J, The Autogenic Neoligament procedure: A technique for planned formation of an artificial neo-ligament. Acta Obstetricia et Gynecologica Scandinavica, Supplement 1990; 153, 69, 43-51.
7. Inoue H, Sekiguchi Y, Kohata Y *et al*. Tissue Fixation System (TFS) to repair uterovaginal prolapse with uterine preservation: a preliminary report on perioperative complications and safety. J Obstet Gynaecol Res 2009; 35 (2): 346-353.

8. Wagenlehner FM, Fröhlich O, Bschleipfer T, Weidner W, Perletti G: The Integral Theory system Questionnaire: An anatomically directed questionnaire to determine pelvic floor dsyfunctions in women. World J Urol 2013; 31: 747-753.
9. Petros PEP, Chapter 3 Diagnosis of Connective Tissue Damage, in The Female Pelvic Floor, Function, Dysfunction and Management According to the Integral Theory, Petros PEP, Springer Heidelberg, 2008; 77-117.

9a A hypothesis for urinary stream divergence in the female: unilateral dislocation of the pubovisceral muscle Kay U. Scheffler, Peter E. Petros, Oliver W. Hakenberg Pelviperineology 2014; 33: 10-13.

10. Abendstein B, Petros P. E. P, Richardson P. A. Goeschen K, Dodero D. The surgical anatomy of rectocele and anterior rectal wall intussusception. Int Urogynecol J 2008.19, 5; 513-7.
11. Wagenlehner F. M. E., Del Amo E, G. A. Santoro GA and P. Petros, Live anatomy of the perineal body in patients with third- degree rectocele. Colorectal Disease, 2013; 15; 1416-1422.
12. Wagenlehner[1], F. M. E, Del Amo[2], E., Santoro[3,*] G. A, Petros[4] P., Perineal body repair in patients with third degree rectocele: a critical analysis of the tissue fixation system**,** Colorectal Disease, Article first published online: 2013; 21 NOV DOI: 10.1111/codi.12453.
13. Bump RC, Mattiasson A, Bo K *et al*. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol 1996; 175: 10-17.
14. Gin-Den ChenMD, Soo-Cheen NgMD Updated definition of female pelvic organ prolapse. Incont Pelvic Floor Dysfunct 2007; 1 (4): 121-124.
15. Atherton MJ, Daborn JP, Tsokos N *et al*.; Complications associated with tissue anchor migration after vaginal surgeryusing the tissue fixation system – a case series. Aust N Z J Obstet Gynaecol 2012; 52 (1): 83-86.
16. Petros PEP and Richardson PA The basic science of TFS minisling complications. Aust N Z J Obstet Gynaecol, 2012; 52 (1): 83-86.
17. Holm-Larsen T. The economic impact of nocturia Neurourol. Urodynam. 2014; 33: S15-S18.
18. Breivik H[1], Collett B, Ventafridda V, Cohen R, Gallacher D., Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. Eur J Pain. 2006; 10: 287-333. Epub 2005 Aug 10.
19. Stones W, Cheong YC, Howard FM Interventions for treating chronic pelvic pain in women, Cochrane review, 2007.
20. Abendstein B, Petros PE, Richardson PA Ligamentous repair using the Tissue Fixation System confirms a causal link between damaged suspensory ligaments and urinary and fecal incontinence. J. Pelviperineology, 2008; 27; 114-117.

No conflict of interest for any of the Authors.

Correspondence to:
Hiromi Inoue
E-mail: inoue@shonan.kamakuza.or.jp

ERRATA CORRIGE

In the article published by in Pelviperineology 2014; 33: 90-92 (P. Petros. Non-linearity, a dilemma and opportunity for clinical research in urogynecology) the correct Figure 2 and its legend are as follows:

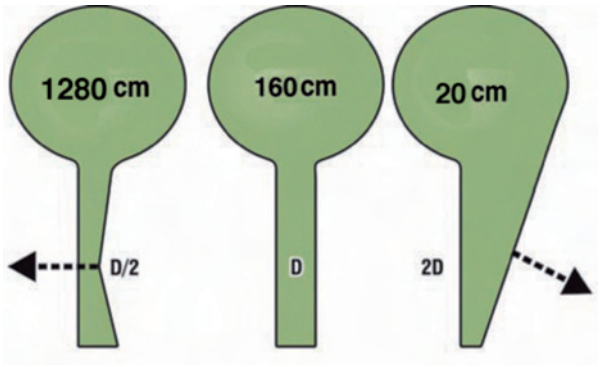


Figure 2. - The non-linear relationship of urethral resistance to continence and micturition (for non-laminar flow).
Resting closed (middle figure): 160cm H2O is a nominal pressure for leakage at diameter D. For closure (continence) (left figure); if the forward vector can close the diameter to D/2, resistance to flow increases by the 5th power of the radius. The head of pressure required for leakage increases almost to 1280 cm H2O. For opening (micturition) (right figure); if the backward vectors can open the diameter to 2D, resistance to flow decreases by the 5th power of the radius. The head of pressure required for leakage decreases to almost 20cm H2O.

The 3rd International Course on Functional Reconstructive Surgery of Pelvic Floor

University Milano Bicocca, San Gerardo Hospital Monza, June 4-6, 2015

M. FRIGERIO, S. MANODORO

Dipartimento di Ginecologia e Ostetricia, A.O. San Gerardo, Università degli Studi Milano Bicocca, Monza, Italy

Last 4-5-6 June, the 3rd International Course on Functional Reconstructive Surgery of Pelvic Floor has taken place at San Gerardo Hospital in Monza. Several international pelvic floor specialists have been hosted by Prof. Rodolfo Milani (course president) and Dr. Federico Spelzini (course director). Among the others: prof. J. DeLancey, prof. B. Shull, prof. P. Dwyer, prof. S. Athanasiou, prof. L. Cardozo, Dr. D. Robinson, prof J.B. Dubuisson, Dr. G. Giraudet.

This year the course focused on pelvic organ prolapse. Prof. Bob Shull had two interesting lectures about risk factors for prolapse and prolapse recurrence focusing on prevention. He stated that some degree of prolapse is nearly ubiquitous in older women and risk factors for prolapse differ depending on which definition of prolapse is considered. He also proposed six reasons for prolapse surgery failure: wrong diagnosis, poor surgical skills, iatrogenic defects, poor wound healing, insufficient patient compliance, and genetics. A magistral lecture by Prof. DeLancey focused on biomechanical aspects of pelvic prolapse pathophysiology. He showed experiments of his group related to dynamic characteristics of pelvic supports in patients with different stages of prolapse and also proposed an interesting theoretical biomechanical model based on MRI studies. He concluded that much still has to be learned about biomechanics applications to anatomy of pelvic floor defects. Different procedures have been discussed in theoretical view with analysis of the techniques and results. Prof. Cardozo made and historical review on evolution of surgical procedures with links to nowadays situation. She concluded that knowledge of the pelvic floor and its supports is essential to make the correct diagnosis leading to appropriate management. However surgery should only be undertaken when necessary and in accordance with the patients' wishes; moreover native tissue repair is preferable to reduce complications associated with foreign body materials. Much time was dedicated to the functional anatomy of pelvic supporting mechanisms as well as surgical anatomy both by vaginal and laparoscopic route. Fascial vaginal surgery has been compared to laparoscopic and prosthetic surgery thanks to contributes of eminent surgeons in these fields. Prof. Milani analyzed theoretical and rational aspects of vaginal fascial reconstructive surgery. Accurate intraoperative identification of each defect and tailored specific repair of each fascial and muscular defect are mandatory to achieve a total reconstruction of the pelvic supporting mechanisms in every vaginal compartment. The analysis of anatomical pelvic support was based on DeLancey's three levels theory and great importance was given to the role of the first level (apical support) and its continuity to the second level. Apical suspension can be successfully achieved through Shull's repair using uterosacral ligaments. As confirmation, Prof Milani showed the records of his clinical experience with this technique that reaches optimal results in terms of anatomical and functional outcomes. Prof. Dubuisson showed the laparoscopic view of pelvic support with particular attention to the surgical aspect of this approach. He made a video demonstration of his peculiar technique of lateral uterine suspension: the body of T-shaped mesh is fixed on the uterus and the long branches of the mesh are carried out of the pelvis through bilateral extraperitoneal tunnels made by a grasper. Great interest was addressed to live surgery sessions in which prof. Milani performed three different prolapse repairs in three patients representative of the main clinical scenarios. The first case was a uterovaginal prolapse corrected through hysterectomy followed by fascial repair with uterosacral suspension and traditional fascial duplication for cystocele repair. The second one was a conservative management of a uterovaginal prolapse in a young woman through uterosacral hysteropexy. This procedure could be an effective alternative to conservative prosthetic surgery in order to preserve the uterus and reduce graft related complications at the same time. The last surgical case was a vault prolapse - a traditional challenge for the urogynecological surgery - managed by a combination of uterosacral suspension and iliococcygeus fixation. During round table discussion, after every surgical session, the faculty proposed video of surgical alternatives to the performed techniques. Discussion focused on pros and cons to different techniques. Not only the faculty but every attendant was free to bring his/her own experience and feelings about surgical situations giving place to deep and interesting debate. The result was a healthy discussion leading to a cultural enrichment about many aspects of pelvic floor surgery. The common feeling was the need of institutional education and constant international update about these topics.

Correspondence to: frigerio86@gmail.com

Original article

Posterior Fornix Syndrome: Comparison of original (2004) and modified (2015) post-PIVS anatomic and symptomatic results- a personal journey

KLAUS GOESCHEN

European Center of Excellence for Reconstructive Pelvic Surgery, Hannover, Germany

Background: Posterior Fornix Syndrome (PFS) surgery was first reported by Petros in 1993. Farnsworth 2001 and Goeschen 2004 confirmed the reliability of his strategy. *Aim:* 2009 we started a second prospective observational study with a modified infracoccygeal sling procedure (PIVS). The purpose of this second study was to find out, whether in comparison to the technique 1997 the cure rates for symptoms and/or prolapse recurrence improved. *Methods:* 198 patients with symptomatic pelvic organ prolapse (POP) in various grades underwent P-IVS operation between Jannuary 2009 and December 2012. In contrast to 2004 additionally the PIVS tape was fixed to the sacrospinous ligament on both sides. 66 patients with stress urinary incontinence obtained a concomitant suburethral transobturator sling (TOT), 96 patients an anterior transobturator 4-arm mesh (ATOM). These procedures were not performed in 2004. Furthermore, not only patients with previous hysterectomy as in 2004, but also with existing uterus are included in this study. All patients had follow-up for at least 1 year. *Results:* Compared with our data from 2004 there was no further improvement in functional or symptomatic cure rates such as frequency, nocturia, urgency with or without incontinence, pelvic pain, abnormal bladder emptying, stress incontinence, stool outlet obstruction and/or fecal incontinence. The success rate was still in the same high level. However, modified surgery lead to a statistical significant decrease of POP recurrence. At 1 year follow up 99% of patients presented a normal anatomy, whereas in 2004 only 90% were cured. Regarding the complication rate no significant difference was observed. *Conclusions:* The results from 2015 demonstrate that total pelvic reconstruction with bilateral SSLF of P-IVS tape in combination with ATOM and TOT, if necessary, reduces the POP recurrence rate significantly, whereas the high cure rate of symptoms remains at the same level.

Keywords: Posterior fornix syndrome; POP; Pelvic pain; Urinary and faecal incontinence; LUTS; Uterosacral ligaments; Pelvic ligaments; Posterior IVS; Integral theory.

INTRODUCTION

Since decades it has been described in the German literature that various typical bladder and rectum problems can be caused by damaged suspension or support of the pelvic organs. 1946 Heinrich Martius[1] published in the first edition of his gynecological Textbook, that "*there is a strong correlation between pelvic organ prolapse and symptoms like bladder emptying problems with residual urine, urge, frequency, nocturia, stool-outlet-obstruction, bladder and fecal incontinence and chronic dragging pelvic pain*". In 1960 he pointed out in his Textbook "Gynecological Operations", "*that after birth nearly every woman has at least a slight descent of her pelvic organs. Some have major, some minor prolapse; however, there is no relationship between the quantum of prolapse and the experiencing of symptoms*". He concluded that "*This problem can only be solved by a sufficient operation enabling restoration of the natural anatomy*".

Unfortunately, Martius's concepts have incomprehensibly been forgotten in Europe and have remained totally unknown in the English literature. Independently from Martius, Petros and Ulmsten, as part of their 1993 Integral Theory[2] which introduced the midurethral sling operation, also described the "Posterior Fornix Syndrome" (PFS) with symptoms comprising pelvic pain, nocturia, urgency, frequency and abnormal emptying. They reported a significant cure rate of posterior fornix symptoms following repair of the uterosacral ligaments.[2] Between 1993 and 1997, still ignorant of Martius's work in the German literature, Petros substantiated Martius´s statements by scientific research as part of his ongoing development of the Integral Theory.[3-8] The Integral Theory differed from Martius's work in that it was a universal theory which described the role of ligaments in the causation of POP, pain, bladder and bowel symptoms and described the mechanisms thereof.[3-8]

The author of the present article was trained by Gerhard Martius, the son of Heinrich Martius, and later by Peter Petros both in the theory and the use of polyproylene slings to repair damaged suspensory ligaments according to the Theory.[3-5]

The reaction to my initial results with these surgical methods[3-5] from "leading opinion leaders" is best described in the words of the famous American Economist, John Kenneth Galbraith who described how "intellectual dissenters become the object of witch hunts pursued with medieval fury". These "leading opinion leaders" who since decades falsely imposed their views on patients, that they must live with their problems or could only get help from drugs, physical or psychotherapeutical therapy - vehemently attacked my attempts to cure what they considered was incurable. In 2001 for example one, Hansjörg Melchior, President of the Medical Society of Incontinence Help Germany was quoted in a famous, widely read German Newspaper (Süddeutsche Zeitung Nr. 138, Tuesday 19. June 2001) with these headlines:

> *Title: Knife against bladder weakness: In case of urge incontinence most experts rail against surgical intervention and recommend the application of drugs. However, Goeschen is convinced that most patients can benefit from new operation techniques.*
>
> *"Bullshit" denounced Hansjörg Melchior, President of the Medical Society of Incontinence Help Germany. "It is even a medical **malpractice** to operate in case of urge incontinence. The operation may increase the suffering. Every surgeon needs something new to boost his profile".*

On the other side of the world, in 2002 Farnsworth[10] published his first data from patients with "PFS" after surgical repair of posthysterectomy vaginal vault prolapse. During 1998 and 2000, he performed the posterior intravaginal slingplasty (PIVS), first reported by Petros 1997,[5] in 93 pa-

tients with evident vault prolapse (grade 2 or 3) and associated symptoms, including urgency, nocturia and pelvic pain. The one year follow up of his prospective observational study showed a symptomatic cure rate for prolapse of 91%, urgency 79%, nocturia 82% and pelvic pain 78%.

In 2001 myself et al performed a prospective PIVS observational study, published in 2004.[10] This study was based on 83 patients with prior hysterectomy and at least grade 2 vault prolapse with posterior fornix symptoms. At follow up 1 year after the operation, the symptomatic cure rates for urgency were 78%, nocturia 78%, pelvic pain 71%, emptying problems of the bladder 81% and quality of life 86%, with 10% anatomical failure.

In order to improve the anatomical results we changed our surgical technique in 2005. In case of concomitant anterior wall prolapse we combined the posterior IVS with insertion of an anterior transobturator 4-arm mesh (ATOM4). From 2007 onwards, using a special instrument, we additionally fixed the posterior tape and the posterior ATOM-arms to the sacrospinous ligaments on both sides.

After establishing the new surgical strategy in more than 300 patients during 2007 and 2008 we started a second prospective observational study in 2009. The purpose of this second PFS study was to find out, whether in comparison to the technique 2001 the cure rates 1) for symptoms and/or 2) prolapse recurrence have changed and 3) to compare our findings with the data of the recent literature.

PATIENTS AND METHODS

This study is based on 198 patients with symptomatic POP suffering from posterior fornix symptoms such as frequency, nocturia, urgency with or without incontinence, pelvic pain, abnormal bladder emptying, stress incontinence, stool outlet obstruction and/or fecal incontinence during Jan 2009 and Dec 2012 (Table 1).

The grade of prolapse was assessed using the Halfway Classification System according to Baden-Walker.[12] Grade 1 was defined as prolapse to the mid-vagina, grade 2 prolapse extending to the introitus, grade 3 everting beyond the introitus, and grade 4 total protrusion.

All patients presented a clinically evident fornix prolapse: 15 patients grade 1, 39 patients grade 2, 107 patients grade 3 and 37 patients grade 4 (Table 2).

TABLE 1. – Distribution of symptoms in the two groups: Patients after „hysterectomy =HX“ and with „no hysterectomy = NoHX“.

	No HX n=132 (100%)	**HX n=66 (100%)**
Frequency, urge	N=81 (61%)	N=46 (70%)
nocturia	N=42 (32%)	N=21 (32%)
Pelvic pain	N=132 (100%)	N=66 (100%)
Bladder emptying problem	N=40 (30%)	N=28 (42%)
Urge incontinence	N=25 (19%)	N=30 (45%)
Stress incontinence	N=40 (30%)	N=26 (39%)
Stool outlet problems	N=35 (35%)	N=26 (40%)
Fecal incontinence	N=31 (23%)	N=25 (38%)

TABLE 2. – Distribution of prolapse grades in all patients n = 198 (100%).

	Grade 1	**Grade 2**	**Grade 3**	**Grade 4**
Pre-op n=198	n=15 (7,5%)	n=39 (19,5%)	n=107 (54%)	n=37 (19%)

The following definitions for symptoms and its cure rates have been used:

Frequency, Urge: Micturition more than 8 times per day, **Cure:** 1-8 per day

Nocturia: Micturition two or more times per night (ICS[13]), **Cure:** less than 2 times.

Bladder emptying difficulty: Presence of at least one of these symptoms[14]

- Do you feel that your bladder isn't emptying properly?
- Do you ever have difficulty starting off your stream?
- Is it a slow stream?
- Does it stop and start involuntarily?

Cure: no symptoms., **Improved:** more than 50% better, **Unchanged:** same or less than 51% better

Residual urine: Cure: less than 10ml. **Improved:** 10 – 50ml. **Unchanged:** more than 50ml

Urge incontinence: At least one episode per day of wetting prior to arrival at the toilet. **Cure:** no wet episodes. **Improved:** less than 50% wed episodes per week. **Unchanged:** same frequency or more than 50%.

Stress urinary incontinence: Complaint of involuntary leakage on effort, sneezing, coughing. **Cure:** continent at any time. **Improved:** few drops leakage. **Unchanged:** more than few drops

Stool outlet obstruction: Feeling of incomplete emptying, constipation (less than 3 stools per week), hard pellety stools, straining at stool, pain during evacuation, assisted digital evacuation. **Cure:** normal defecation **Improved:** more than 50% better **Unchanged:** less than 50% better

Fecal incontinence: Loss of liquid or solid faeces more than once per week. **Cure:** continent **Improved:** more than 50% better **Unchanged:** less than 50% better

Pelvic pain:

- Low abdominal dragging pain
- Low sacral pain
- Deep dyspareunia ache

Cure: no pain **Improved:** more than 50% better **Unchanged:** less than 50% better

Quality of life: How much is your quality of life influenced by your problems?

1 = no restrictions
2 = mild restrictions
3 = clearly restrictions
4 = It has a strong influence on my quality of life
5 = I cannot leave the house

Tremendous improvement: 1 and 2, **Little or no effect:** 3 to 5.

The mean patient age was 62 years (range 43-93), the mean weight 68kg (range 52-113kg). All patients were examined and operated personally by the author. In all cases a cystotonometry including measuring the residual urine followed by an ultrasound check was performed by the author one day before the operation. The amount of residual urine was calculated by ultrasound according to Fischer and Kölbl 1995.[15]

Surgery In all 198 patients a posterior intravaginal slingplasty (pIVS) according to Peter Petros[5] was performed with repair of all 3 DeLancey levels[16] following the surgical principles described by Petros.[17] Additionally the tape was fixed to the sacrospinous ligament on both sides with a prolene suture using a special minimally invasive instrument. Levels 2 ('bridge' repair) and 3 (approximation of perineal bodies) were repaired as required. Patients with stress urinary incontinence (n=66) had a suburethral transobturator sling. In cases of concomitant anterior wall prolapse (n=96) the posterior IVS was combined with insertion of an anterior transobturator 4-arm mesh (ATOM4). The posterior ATOM-arms were attached to the sacrospinous ligaments bilaterally as well.

In contrast to our first study 2004[6] we incorporated patients with (n=66 group "HX") and without previous hys-

terectomy (n=132 group "NO HX"), in order to compare the results.

Inclusion criteria were POP in combination with at least two of the above mentioned symptoms (Table 1) and a follow up of at least one year.

Exclusion criteria were patients with endometriosis, proven organ infection or other obvious pathology explaining symptoms.

Follow up including vaginal examination and ultrasound was performed 5-7 days, 4-6 month and 1 year after the operation, again by the author. At any time the above mentioned associated symptoms were recorded using a standardized questionnaire.

Statistics Pearson chi-square test, Fisher's exact test and Wilcoxon signed rank tests were used to analyze categorical variables and functional results. A p value less than 0.01 was considered to be statistically significant.

RESULTS

The mean operating time entirely for pIVS was 65 minutes (range 51-105 min), in cases with concomitant ATOM4 89 minutes (range 75-115 min). Intra- and postoperatively no serious bleeding was observed. No patient required a blood transfusion. Other severe complications such as rectal perforation, embolic problems, pyrexia did not occur.

The mean hospital stay was 5 days (range 3-9 days). All patients were treated with 600mg Ibuprofen postoperatively every 6 hours, and the following days on demand. One urinary tract infection was observed, within the first week after surgery. This patient was treated with broad-spectrum antibiotics and recovered soon and completely. In 6 patients (3 with and 3 without) TOT a permanent catheter was reinserted for 2-5 days. After at least 5 days the micturition was normal in all cases. Two extraperitoneal haematomas in the cranial rectovaginal space evacuated spontanously. No second surgical intervention was necessary.

Frequency

Table 3 shows that 81% NOHX- and 79% HX-patients had a normal micturition frequency one year after the operation ($p < 0,001$).

TABLE 3. – Daily micturition frequency before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

		< 9	9 to 12	>12
NOHX n=81	pre OP		30 (37%)	51 (63%)
NOHX	one year after OP	66 (81%) *	11 (14%)	4 (5%)
HX n=46	pre OP		18 (39%)	28 (61%)
HX	one year after OP	36 (79%) *	7 (14%)	3 (7%)

Nocturia

One year after surgery only 19% HX- and 21% NOHX-patients had to go to the toilette more than once per night, whereas in 81% (HX) and 79% (NOHX) the situation was normal p<0,001 (Table 4).

TABLE 4. – Micturition frequency during the night before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

		< 2	2 to 4	>4
NOHX n=42	pre OP		24 (56%)	18 (44%)
NOHX	one year after OP	33 (79%) *	6 (14%)	3 (7%)
HX n=46	pre OP		18 (86%)	3 (14%)
HX	one year after OP	17 (81%) *	3 (14%)	1 (5%)

Bladder emptying problems

One year after surgery 80% NOHX and 79% HX patients were cured (Table 5), 12,5% respectively 11% improved and only 7,5% respectively 10% unchanged ($p < 0,001$).

TABLE 5. – Bladder emptying problems before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		normal	improved	unchanged
NOHX n=40	one year after OP	32 (80%) *	5 (12,5%)	3 (7,5%)
HX	one year after OP	22 (79%) *	3 (11%)	3 (10%)

Residual urine

Ultrasound examination selected 23 NOHX and 21 HX patients with more than 50ml residual urine (median = 71ml, range 52 until 210ml) (Table 6). One year after surgery 65% NOHX and 60% HX patients were cured, 26% respectively 30% improved and only 9% respectively 10% unchanged ($p < 0,001$).

TABLE 6. – Residual urine before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		<10 ml	11-50 ml	51-150 ml
NOHX n=23	one year after OP	15 (65%) *	6 (26%)	2 (9%)
HX	one year after OP	13 (60%) *	6 (30%)	2 (10%)

Urge incontinence

One year after surgery 80% NOHX and 80% HX patients were cured (Table 7), 12% respectively 10% improved and only 8% respectively 10% unchanged ($p < 0,001$).

TABLE 7. – Urge incontinence before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		normal	improved	unchanged
NOHX n=25	one year after OP	20 (80%) *	3 (12%)	2 (8%)
HX n=30	one year after OP	24 (80%) *	3 (10%)	3 (10%)

Stress urinary incontinence

One year after surgery 95% NOHX and 92% HX patients were continent (Table 8), 5% respectively 8% improved and no patient unchanged ($p < 0,001$).

TABLE 8. – Stress urinary incontinence before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		normal	improved	unchanged
NOHX n=40	one year after OP	38 (95%) *	2 (5%)	
HX n=30	one year after OP	24 (92%) *	2 (8%)	

Stool outlet obstruction

One year after surgery in 79% NOHX and 81% HX patients the evacuation was normal (Table 9), in 15% respectively 16% improved and in only 6% respectively 3% unchanged ($p < 0,001$).

TABLE 9. – Stool outlet obstruction before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		normal	improved	unchanged
NOHX n=33	one year after OP	26 (79%) *	5 (15%) *	2 (6%) *
HX n=26	one year after OP	21 (81%) *	4 (16%) *	1 (3%) *

Faecal incontinence

One year after surgery 81% NOHX and 79% HX patients were continent (Table 10), 13% respectively 16% improved and only 6%) respectively 5% unchanged ($p < 0,001$).

TABLE 10. – Fecal incontinence before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		normal	improved	unchanged
NOHX n=31	one year after OP	25 (81%) *	4 (13%) *	2 (6%) *
HX n=25	one year after OP	20 (79%) *	4 (16%) *	1 (5%) *

Pelvic pain

One year after surgery 81% NOHX and 79% HX patients were cured (Table 11), 12% respectively 15% improved and only 7% respectively 6% unchanged ($p < 0,001$).

TABLE 11. – Chronic pelvic pain before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		cured	improved	unchanged
NOHX n=132	one year after OP	107 (81%) *	16 (12%) *	9 (7%)*
HX n=66	one year after OP	52 (79%) *	10 (15%) *	4 (6%)*

Quality of life

In 86% NOHX- and 85% HX-patients quality of live has improved tremendously one year after surgery (Table 12). Only 14% respectively 15% reported little or no effect ($p < 0,001$).

TABLE 12. – Quality of life before and 1 year after operation in patients without (NOHX) and with (HX) previous hysterectomy. * difference statistically significant p<0,001.

post op		Tremendous improved	Little or no effect
NOHX n=132	one year after OP	113 (86%) *	19 (14%) *
HX n=66	one year after OP	56 (85%) *	10 (15%) *

Anatomical results

Alltogether 196 out of 198 patients (99%) had a normal vaginal anatomy one year after the operation. 2 out of 132 NOHX-patients (1,5%) with grade 3 posterior wall prolapse and without reconstruction of the anterior wall developed de novo a high grade 2 cystocele postoperatively. Repair of the cystocele one year after the first operation lead to normal results. Compared to the HX-group this result was not statistical significant.

No TOT tape erosion was observed. 2 (1%) small mesh erosions at the anterior wall could be repaired in local anaestesia.

DISCUSSION

In 1946 Martius[1] already pointed out, that "*in 30% of women who had given birth, a POP emerge and that there is no relationship between the quantum of prolapse and the experiencing of symptoms*". Recent observational studies indicate that the prevalence of menopausal patients with POP has increased over the years and ranges now from 31 to 41.1%[18, 19] and lifetime risk of undergoing POP between 11 and 19%[20, 21] because of increased life expectancy.

In the past most POP studies concentrated mainly on altered anatomy. However, we all know patients with major POP, but absence of symptoms and no desire for therapy. Unfortunately the older and current generation of urogynecologists learned from their teachers to recommend an operation to all women with at least grade 2 prolapse. As they had no preoperative symptoms and no eversion of the prolapse, this practice frequently leads to complications so the women feel much worse than before. This practice has to be a thing of the past.

Therefore, in the present study entirely patients with symptomatic POP and a follow up of at least one year are included.

Regarding the symptoms: frequency, nocturia, urge and pelvic pain about 80% of the patients were cured one year after the operation. Concerning dysfunction of bladder and rectum such as stress urinary and fecal incontinence, bladder emptying problems with residual urine, obstructive defecation sugery lead to complete restitution in a range of 60% to 95%. The difference before and after treatment was statistically highly significant. Compared with our data from 2004[10] there was no difference in symptomatic and functional cure rates (Table 13). This is a very important result, because according to the Integral Theory the rationale for the posterior tape is not only the renewal of USL, but also reattachment of the uterus or vagina to the levator plate in order to allow the backward force to open and close bladder and rectum. If the tape is fixed to SSL, this mechanism could be blocked. However, the results show, that Integral Theory still works and the function of the levator plate is not negatively affected by our modified procedure.

In contrast to our first study 2004[10] we incorporated patients with and without previous hysterectomy, in order to compare the results. In literature conflicting data still exist regarding the effectiveness of POP surgery with and without uterine preservation.[22-27] Dietz et al. report that uterine preservation is associated with more apical prolapse recurrences than vaginal hysterectomy at the time of POP-repair.[22] These results conflict with data by Maher et al., who found vaginal sacrospinous hysteropexy to be equally effective for vaginal hysterectomy combined with sacrospinous fixation.[23]

In our study no patient underwent concomitant hysterectomy. However, if the hypothesis is valid that uterus preservation deteriorates the outcome, we would expect better anatomical results in the group with no uterus. However, this was not the fact. We had no recurrence in both groups. Only 2 of the uterus- and none of the no-uterus-group developed a de novo cystocele.

Complications and recurrences are more likely in patients with higher POP grades. A complete protrusion of all pelvic organs, an "enteroptosis", is surgically the greatest challenge. Therefore, when comparing success rates, it is important to take the distribution of POP severity into consideration. According to Swift[28] and Nygaard et al.[29] in normal population only 2-2,5% women provide a grade III and none grade IV prolapse.

By contrast, patients planned for POP surgery present an everting grade III or IV prolapse in 25,5%[30] up to 63%.[31] The distribution in our study for grade III and IV was 62% 2004 and 73% 2015 (Table 13). Despite the high quantity of grade III and IV patients in our recent study the anatomical results are significantly better than 2004.[10] What is the explanation for that?

TABLE 13. – Comparison of symptomatic cure rates 2004 and 2015 for frequency, nocturia, pelvic pain, emptying problems of the bladder and quality of life.

Cure rate	frequency	nocturia	emptying	pelvic pain	quality of life
2004	78%	78%	81%	71%	86%
2015	81%	81%	79%	79%	85%

Our strategy is to reconstruct, on the base of Petros Integral Theory[32] and DeLancey´s three level repair,[16] all damaged compartments simultanously using artificial mesh for damaged ligaments or fascia. This can only be done vaginally.

Bojahr[30] fixed the vaginal or uterine prolapse laparoscopically to the promontorium. His relatively high recurrence or de novo rate is probably due to the fact, that abdominal procedures only allow the repair of the suspension system. In most POP cases, this is not enough, because the supporting base normally is insuffient as well.[33]

Therefore, it is not surprising that Sivaslioglu[34] in a retrospective study comparing vaginal PIVS with abdominal sacrocolpopexy, came to the conclusion that PIVS causes significantly better anatomical and symptomatic results. Moreover, the recent literature shows, that isolated defects in the anterior, apical or posterior compartments are very rare.[20, 35, 36] That means, if in case of complex pelvic floor defects entirely one part undergoes reconstruction, a shifting of pressure occurs causing a prolapse at another place.

As complex reconstruction can only be done vaginally, the next question is: Which vaginal technique is the best?

A multicenter randomized trial, published 2013 by Barber,[31] demonstrates that surgical success rates after sacrospinous ligament fixation (SSLF)[37, 38] or uterosacral ligament vaginal vault suspension (ULS)[39] ranged between 60.5% and 59.2% respectively. In our opinion, these not convincing data are mainly due to to the fact, that damaged tissue was approximated to damaged tissue and not reinforced by artifical mesh. However, recurrence of POP is not only caused by weakness of tissue, but also by disruption of the wound before it has cross-bonded sufficiently. Therefore, in the first few weeks the healing wound has little strength and will give way again without reinforcement. Furthermore, unilateral SSLF pulls the vagina to one side. This potentionally weakens the contralateral side, creating the possibility for enterocele formation.

Our good anatomical results are the consequence of mesh usage with fixation at the SSL bilaterally.

It is well known since decades, that the anterior vaginal compartment is mainly exposed to the abdominal pressure and gravity. Therefore, according to the recent literature, the recurrence rate in this area is the highest among all compartments.[31] Weber et al.[40] and Sand et al.[41] reported anterior colporrhaphy to be successful in the management of cystocele in only 30% and 57% respectively. Thus, an isolated anterior colporrhaphy cannot be recommended any longer. Barber et al.[31] found an anterior recurrence rate of 13,7% after SSLF without mesh-reinforcement. The 2011 Cochrane meta-analysis[42] indicates that the use of transobturator mesh had a significant lower recurrence rate compared with anterior colporrhaphy alone, however is still in a level of 14% vs. 49%.

TABLE 13. – Distribution of prolapse grade in a normal population (Swift, Nygaard) and in prolapse patients with problems (Bojahr, Barber et al, Goeschen).

	grade I (%)	grade II (%)	grade III (%)	grade IV (%)	Normal >1 year after OP (%)
Swift[23]	51	46,5	2,5	0	
Nygaard[24]	34	64	2	0	
Bojahr[25]	23,5	51	24,5	1	77,6
Barber[26]					
USL		37,3	59	3,7	59,2
SSLF		39,3	54,8	5,9	60,5
Goeschen[6] 2004		38	52	10	90
Goeschen 2015 n=198	7,5	19,5	54	19	99

TABLE 14. – Distribution of POP grade in patients with anterior wall deficiency (AWP) n = 96 (100%).

	grade I (%)	grade II (%)	grade III (%)	grade IV (%)
Goeschen 2015 AWP n=96	0	16 (16,5)	61 (63,5)	19 (20)

This means: Mesh support without SSLF and SSLF without mesh lead to better results in the anterior compartment than traditional colporrhaphy. It follows that a combination of both must be the best.

Of our patients 96 (49%) presented a concomitant anterior wall prolapse (AWP) (Table 14), in 83,5% the anterior wall was beyond the hymen. In these patients we reconstructed the posterior wall as already described and inserted aditionally a transobturator 4-arm-mesh, girdled the posterior arms around the cervix or vault and sutured the arms bilaterally to the sacrospinous ligaments. Compared to the recent literature this procedure lead to excellent anatomical results. After 1 year we had no apical or posterior recurrence and only 2 de novo cases anteriorly. In comparison to 2004 we cured 99% in 2015, an improvement of 9% points. This difference is statistically significant and seems to be the logical consequence of synergistic effects.

Still controversial in literature is, whether concomitant incontinence surgery in POP patients is recommendable or not. In the cochrane review 2011 Maher et al. (42) concluded, that the value of a continence procedure in addition to a prolapse operation in women who are continent pre-operatively remains uncertain. On the other hand, studies from Schierlitz (43) and Meschia (44) show, that adding TVT to prolapse operation this group was far more likely to be continent.

Our concept was and is to check all POP patients preoperatively for occult or obvious SUI using cystotonometry and so called simulated operations (45). We recruited 33% POP patients with SUI, in which we performed a concomitant paraurethral TOT.

In comparison to the recent literature with cure rates of 87% on average after TOT (46) we obtained excellent continence rates of 95% for NOHX and 92% for HX patients. No serious complications emerged.

CONCLUSION

In comparison with 2004 our recent data demonstrate, that symptomatic cure rates due to PFS remained at the same high level, even though patients were included

- with almost twice as much major prolapse grade 3-4,
- with and without previous hysterectomy
- and with modified surgical technique.

These variables had no negative effect on functional or symptomatic cure rates. However, the modified surgery, meanwhile confirmed by Caliskan et al.,[47] lead to a statistically significant improvement of the anatomy and decrease of recurrence rate.

REFERENCES

1. Martius H, Lehrbuch der Gynäkologie. Thieme, Stuttgart 1946.
2. Petros PE, Ulmsten U. The posterior fornix syndrome: a multiple symptom complex of pelvic pain and abnormal urinary symptoms deriving from laxity in the posterior fornix. Scandinavian Journal of Urology and Nephrology 1993; 27 Supplement No 153 - part IV: 89-93.

3. Petros PE. Severe chronic pelvic pain in women may be caused by ligamentous laxity in the posterior fornix of the vagina, Aust NZ J Obstet Gynaecol. 1996; 36:3: 351-354.
4. Petros PE. New ambulatory surgical methods using an anatomical classification of urinary dysfunction improve stress, urge, and abnormal emptying. Int J Urogynecol 1997; 8: 270-278.
5. Petros PE & Ulmsten U. Bladder instability in women: A premature activation of the micturition reflex. Neurourology and Urodynamics 1993; 12, 235-239.
6. Petros PE & Ulmsten U. Urethral pressure increase on effort originates from within the urethra, and continence from musculo-vaginal closure. Neurourology and Urodynamics, 1995;14: 337-350.
7. Petros PE and Ulmsten U Role of the pelvic floor in bladder neck opening and closure: I muscle forces. Int J Urogynecol and Pelvic Floor, (997; 8, 74-80.
8. Petros PE and Ulmsten U Role of the pelvic floor in bladder neck opening and closure: II vagina. Int J Urogynecol and Pelvic Floor, (1997) vol 8, 69-73.
9. Farnsworth BN. Posterior intravaginal slingplasty (infracoccygeal Sacropexy) for severe posthysterectomy vaginal vault prolapse - a preliminary report on efficacy and safety. Int J Urogynecol 2001, 12: 304-308.
10. Goeschen K, Gent H-J Das posteriore Fornixsyndrom. Frauenarzt 2004, 45: 104-112.
11. Baden WF, Walker TA. Genesis of the vaginal profile: a correlated classification of vaginal relaxation. Clin Obstet Gynecol. 1972; 15: 1048-54.
12. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van Kerrebroeck P, Victor A, Wein A The standardisation of terminology of lower urinary tract function: Report from the standardisation sub-committee of the International Continence Society Neurourology and Urodynamics, 2002, 21; 2 167-178.
13. Wagenlehner FM, Fröhlich O, Bschleipfer T, Weidner W, Perletti G. The Integral Theory System Questionnaire: an anatomically directed questionnaire to determine pelvic floor dysfunctions in women. World J Urol. 2013 Aug 25 [Epub ahead of print].
14. Fischer W, Kölbl H Urogynäkologie in Praxis und Klinik. De Gruyter, Berlin - New York 1995.
15. DeLancey JO Structural anatomy of the posterior pelvic compartment as it relates to rectocele. Am J Obstet Gynecol 1999; 180(4): 815-823.
16. Petros P. The Female Pelvic Floor, Function, Dysfunction and Management according to the Integral Theory. Springer, Heidelberg, 3rd Ed. 2010, 1-330.
17. Handa VL, Garrett E, Hendrix S, Gold E, Robbins J Progression and remission of pelvic organ prolapse: a longitudinal study of menopausal women. Am J Obstet Gynecol 2004; 190(1): 27-32.
18. Hendrix SL, Clark A, Nygaard I, Aragaki A, Barnabei V, McTiernan A Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol 2002; 186(6): 1160-1166.
19. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL (Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol 1997; 89(4): 501-506.
20. Smith FJ, Holman CD, Moorin RE, Tsokos N. Lifetime risk of undergoing surgery for pelvic organ prolapse.Obstet Gynecol. Nov 2010;116(5):1096-100. [Medline].
21. Dietz V, van der Vaart CH, van der Graaf Y, Heintz P, Schraffordt Koops SE. One- year follow-up after sacrospinous hysteropexy and vaginal hysterectomy for uterine descent: a randomized study. Int Urogynecol J 2009;21(Feb (2)):209–16. http://dx.doi.org/10.1007/s00192-009-1014-7. Epub/10/17.eng.
22. Maher CF, Cary MP, Slack MC, Murray CJ, Milligan M, Schluter P. Uterine preservation or hysterectomy at sacrospinous colpopexy for uterovaginal prolapse? Int Urogynecol J Pelvic Floor Dysfunct 2001;12(6): 381-4 (Discussion 4-5. PubMed PMID: 11795641. Epub 2002/01/25.eng).
23. HefniM, El ToukhyT, BhaumikJ, Katsimanis E. Sacrospinous-cervicocolpopexy with uterine conservation for uterovaginal prolapse in elderly women: an evolving concept. Am J Obstet Gynecol 2003; 188 (Mar (3)):645-50 (PubMed PMID: 12634635. Epub 2003/03/14.eng).
25. Diwan A, Rardin CR, Kohli N. Uterine preservation during surgery for uterova- ginal prolapse: a review. Int Urogynecol J Pelvic Floor Dysfunct 2004;15(Jul-Aug (4)): 286-92 (PubMed PMID: 15517676. Epub 2004/11/02.eng).
26. Carramao S, Auge AP, Pacetta AM, et al. A randomized comparison of two vaginal procedures for the treatment of uterine prolapse using polypropyl- ene mesh: hysteropexy versus hysterectomy. Rev Col Bras Cir 2009;36(Feb (1)): 65-72 (PubMed PMID: 20076870. Epub 2010/01/16. Estudo randomico da correcao cirurgica do prolapso uterino atraves de tela sintetica de polipropileno tipo I comparando histerectomia versus preservacao uter- ina. por).
27. Roovers JP, van der Vaart CH, van der Bom JG, van Leeuwen JH, Scholten PC, Heintz AP. A randomised controlled trial comparing abdominal and vaginal prolapse surgery: effects on urogenital function. BJOG 2004;111(Jan (1)): 50-6 (PubMed PMID: 14687052. Epub 2003/12/23.eng).
28. Swift S, Woodman P, O'Boyle A, Kahn M, Valley M, Bland D, et al. (2005) Pelvic Organ Support Study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. Am J Obstet Gynecol. Mar 2005;192(3): 795-806. [Medline].
29. Nygaard I, Bradley C, Brandt D. Pelvic organ prolapse in older women: prevalence and risk factors. Obstet Gynecol. Sep 2004;104(3): 489-97. [Medline].
30. Bojahr B, Tchartchian G, Waldschmidt M, Ohlinger R, De Wilde RL. "Laparoscopic Sacropexy: A Retrospective Analysis of the Subjective Outcome in 310 Cases," Obstetrics and Gynecology International 2012, Article ID 538426, 6 pages, 2012. doi: 10.1155/2012/538426.
31. Barber MD, Brubaker L, Burgio KL, Richter HE, Nygaard I, Weidner AC, Menefee SA, Lukacz ES, Norton P, Schaffer J, Nguyen JN, Borello-France D, Goode PS, Jakus-Waldman S, Spino C, Klein Warren L, Gantz MG, Meikle SF. Comparison of 2 Transvaginal Surgical Approaches and Perioperative Behavioral Therapy for Apical Vaginal Prolapse The OPTIMAL Randomized Trial. JAMA. 2014; 311(10): 1023-1034. doi:10.1001/jama. 2014.1719.
32. Petros PE, Ulmsten U. An Integral Theory and its Method, for the Diagnosis and Management of female urinary incontinence. Scandinavian Journal of Urology and Nephrology 1993; 27: Suppl. No 153, 1-93.
33. Goeschen K. Review: Role of Uterosacral Ligaments in the Causation and Cure of Chronic Pelvic Pain Syndrome J Pelviperineology. 2015; 34: 02-20.
34. Sivaslioglu AA, Ilhan TT, Aydogmus S, Uzun M, Dolen I. The comparison of the anatomical and symptomatic outcomes of sacrocolpopexy and posterior intravaginal slingoplasty. Int Urogynecol J. 2011; 22: 1363-8.
35. Boyles SH, Weber AM, Meyn L Procedures for pelvic organ prolapse in the United States, 1979-1997. Am J Obstet Gynecol 2003; 188(1): 108-115.
36. Whiteside JL, Weber AM, Meyn LA, Walters MD Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol 2004; 191(5): 1533-1538.
37. MorleyGW,DeLanceyJO.Sacrospinous ligament fixation for eversion of the vagina. Am J Obstet Gynecol. 1988; 158(4): 872-881.
38. DeLanceyJO,MorleyGW,HowardD. Sacrospinous suspension. Obstet Gynecol Manage. 2001; 13(3).
39. ShullBL,BachofenC,CoatesKW,KuehlTJ.A transvaginal approach to repair of apical and other associated sites of pelvic organ prolapse with uterosacral ligaments. Am J Obstet Gynecol. 2000; 183(6): 1365-1373.
40. Weber AM, Walters MD, Piedmonte MR, Ballard LA Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol 2001; 185(6): 1299-1304.
41. Sand PK, Koduri S, Lobel RW et al Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol 2001; 184(7): 1357-1362.
42. Maher CM , Feiner B, Baessler K, CMA Glazener. Surgical management of pelvic organ prolapse in women: the updated summary version Cochrane review. The International Urogynecological Association 2011.10.1007/s00192-011-1542-9.

43. Schierlitz L, Dwyer P, Rosamilia A, Murray C, Thomas E, Taylor N et al A prospective randomised controlled study comparing vaginal prolapse repair with and without tension free vaginal tape (TVT) in women with severe pelvic organ prolapse and occult stress incontinence (Abstract number 114). Neurourol Urodyn 2007; 26: 743-744.
44. Meschia M, Pifarotti P, Spennacchio M, Buonaguidi A, Gattei U, Somigliana E . A randomized comparison of tension-free vaginal tape and endopelvic fascia plication in women with genital prolapse and occult stress urinary incontinence. Am J Obstet Gynecol 2004;190: 609-613.
45. Goeschen K, Petros P. Der weibliche Beckenboden. Springer, Heidelberg-New York 2008.
46. LatthePM,FoonR,Toozs-HobsonP. Trans- obturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007;114: 522-531.
47. A Caliskan, K Goeschen, AE Zumrutbas. Long term results of modified posterior intravaginal slingplasty (P-IVS) in patients with pelvic organ prolapse. Pelviperineology in press.

Correspondence to:
Prof. Dr. Klaus Goeschen, KVINNO Center Hannover, Germany
University of Hannover, Hildesheimer Str. 34-40,
30169 Hannover, Germany - E-mail: goeschen@carpe-vitam.info

Multidisciplinary UroGyneProcto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in *Pelviperineology* are commented on by **Urologists, Gynecologists, Proctologists/Colo Rectal Surgeons** or **other Specialists**, with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

THE COLORECTAL SURGEON'S OPINION

Goeschen's article describes the results of the posterior fornix syndrome treatment by a modified posterior IVS pelvic reconstruction. It reported a significant reduction in recurrence of POP at one year compared with posterior IVS only, while maintaining similar cure rates of pelvic pain and urological and proctological symptoms (nocturia, urgency, difficult bladder emptying, obstructed defecation, fecal incontinence). This paper is quite intriguing for the proctologist's traditional opinions on the posterior compartment dysfunctions.

Fecal incontinence has a 38% incidence in patients following hysterectomy, significantly higher than those with their uterus intact (23%), while fecal outlet obstruction presents roughly similar percentages, 35% vs 40% respectively. This confirms, according to the *Integral Theory*, that preservation of the uterus is of the outmost importance to support fibro-muscular vaginal structures in the posterior compartment, and therefore in the long-term to prevent vaginal prolapse, urinary and faecal incontinence. Other factors, in addition to the musculo-fascial weakening, could however contribute to obstructed defecation as various degrees of rectal mucous prolapse, intussusception, symptomatic rectocele, enterocele. The percentages of success as far as the posterior compartment, appear to be significant. For fecal incontinence success rate in patients with or without prior hysterectomy was 79% vs 81%, in obstructed defecation 81 vs. 79%. The study does not show clearly what kind of functional and morphological assessments were performed at the anorectal level, such as scores for incontinence and constipation, proctoscopy, endoanal ultrasound, anorectal manometry, defecography to highlight the extent of any prolapse and intussusception and to assess the integrity of the sphincters. These conditions in the long-term may lead to relapse and supposedly to complete rectal prolapse.

According to the *Integral System* proposed by Petros, the connective tissue plays a role in the ano-rectal opening and closure, and consequently in idiopathic fecal incontinence. The pubococcygeal muscle and the perineal body anchor the anterior wall of the rectum during defecation, while both the pubo-urethral ligaments (PUL) do the same with the levator plate (LP) during muscle contraction, and similarly, during the anorectal closure, the utero-sacral ligaments (USL) with the longitudinal muscle of the anus (LMA). When PUL and USL are damaged, LP and LMA respectively lack structural support at the insertion points, and dysfunction of opening and closing of the anus may occur. When forces directed inferiorly do not form the anorectal angle, fecal incontinence may result. Lax ligaments can also weaken the force directed posteriorly required during the contraction of the muscles for opening the anorectal canal, so causing obstructed defecation. In some way these concepts could clarify many aspects of the etiology and pathogenesis of the so called idiopathic constipation.

Therefore, according to the *Integral System*, symptoms of the posterior compartment such as obstructed defecation and fecal incontinence can be treated by reinforcing the anchoring points of the LP and LMA to the USL and PUL. With regard to fecal incontinence the impact of damage to the pelvic musculature and the external anal sphincter would seem to be smaller since just the reinforcement of the USL results in an improvement of symptoms in 80% of cases. The complex lesions of the pelvic floor rarely involve a single compartment, and therefore it appears consistent with the principles of the *Integral System* to correct all the defects, in order to avoid the onset of problems in the areas not covered. The *Integral System* emphasizes the role of connective tissue as the most vulnerable element in the pelvic floor, and the need of its involvement in issues related to any surgical corrections.

Also in the past, theories were developed trying to unify the pelvic floor dysfunctions. According to the "Unifying concept of pelvic floor disorders and incontinence"[1] the central problem was varying degrees of denervation of the pelvic floor muscles, triggered by predisposing factors such as childbirth and chronic straining, as documented with biopsies of muscle tissue and electrophysiological studies. Shafik was the first author to realize the functional interactions among the pelvic organs, starting from research on the phyisioanatomy of the pelvic floor muscles. He demonstrated the important role of the longitudinal muscle in the mechanism of defecation, as was later taken over by the *Integral Theory*.[2-4]

Pelvic floor anatomy and function are still difficult to interpret. As well, it is not easy to formulate guidelines for a diagnostic-therapeutic orientation shared and accepted by all surgeons. Short-term results of total reconstruction of the pelvic floor in the treatment of POP are encouraging, with percentages around 80% for FI and ODS correction. It will be interesting also to see the long-term results. For the colorectal surgeon transabdominal (LS or LT) recto- and colpo-pexies seem to have a lower morbidity and a lower incidence of recurrence, so the practical application of the principles of the *Integral System* need to be encouraged in the proctologic field, where, at the moment the role of conservative treatment (rehabilitation, SNS) is highly regarded both in constipation and in fecal incontinence.

REFERENCES

1 M Swash; SJ Snooks; MM Henry. Sir Alan Parks Physiology Unit; St. Mark's Hospital, London- J Roy Soc Med. 1985; 78:906-911
2 A Shafick A new concept of the anatomy of the anal sphincter mechanism and the phisiology of defecation.III. The Longitudinal anal muscle anatomy and role in anal sphincter mechanism. Invest Urol 1976;13:271-7.
3 A Shafick Atti IX Giornate Internazionali di Chirurgia E. Malan, Colorno-Parma, 26-28/9/1996; Seminari Clinici, Periodico semestrale di scienze e cultura, Anno XVII n° 27, 1997
4 A Shafick A new concept of the anatomy of the anal sphincter mechanism and the physiology of defecation: mass contraction of the pelvic floor muscles. Int. Urogynecol J Pelvic Floor Dysfunct 1998; 9:28-32

Benito Ferraro
S. Antonio Hospital, Padova, Italy
Colorectal Surgeon
benito.ferraro@sanita.padova.it0

Original article

Surgical cure of nocturia using 4 different methods based on strengthening the structural supports of the vaginal apex - a short review

PETER RICHARDSON

Central Queensland, Univrsity Rockhampton, Australia

Abstract: Data is presented indicating that nocturia and other "posterior fornix" symptoms such as urgency, abnormal emptying and chronic pelvic pan can be cure/improved in up to 86% of patients using 4 different surgical operations, all of which suspend the vaginal apex: uterosacral ligament plication, infracoccygeal sacropexy sling, posterior TFS (Tissue Fixation System) sling and abdominal sacrocolpopexy. Besides nocturia, other symptoms such as urgency and chronic pelvic pain were also improved by all methods. An anatomical hypothesis for cure of nocturia is presented: a vaginal apex competently supported by the posterior ligaments of vagina prevents activation of the bladder base stretch receptors. A simple test for this hypothesis is to insert a large tampon into the apex overnight to support it; many patients report relief of their nocturia.

Keywords: Nocturia; Urgency; Chronic pelvic pain; Abnormal bladder emptying; Apical laxity; Uterosacral ligaments.

INTRODUCTION

Nocturia increases linearly with age, occurring in more than 50% of women ≥80 years old.[1] A recent supplement in Neurourology and Urodynamics more extensively investigated this problem, summarizing current thoughts on etiology,[2] renal physiology[3] economic impact,[4] effect on patient Quality of Life,[5] Role of pharmacotherapy[6] and future research.[7] The conclusions were that nocturia has a major effect on quality of life,[5] costs the community up to 62 billion dollars p.a.[5] The authors of the nocturia supplement concluded there was no effective treatment to date.

Not mentioned was the Integral Theory paradigm which describes nocturia in women as part of a complex of symptoms caused by laxity in the apical supports of the vagina, "Posterior Fornix Syndrome": nocturia, chronic pelvic pain, urgency and abnormal emptying.[8] The ultimate pathogenesis of all these symptoms relates to inability of the three directional vector forces to stretch the vaginal membrane sufficiently to support the bladder base stretch receptors because the vector insertion point, the uterosacral ligament, is loose.[9] Cure in up to 80% of nocturia cases has been reported in the literature for almost 20 years using operations which mechanically support the posterior vaginal fornix.[10-18]

The purpose of this submission is to open a scientific debate by presenting peer review data of nocturia cured by strengthening the uterosacral ligaments.

Simple uterosacral ligament plication, figure 1

This simple operation, plicating lax uterosacral ligaments (USL) under LA (local anesthesia) gave good initial cure rates for Posterior Fornix symptoms,[9] but was abandoned by 1994 in favour of the posterior sling (Infracoccygeal Sacropexy or Posterior IVS)[10] because of diminishing longer term cure rates. However, in the context of nocturia being an "incurable disease",[1-6] given that the more effective sling operations are not widely available, a simple posterior fornix repair, fig1, will give significant relief in >50% of patients[8] if improvement is seen on inserting a large tampon in the apex overnight .

Infracoccygeal sacropexy (Posterior IVS)

This operation attaches the vaginal apex to the fascia of the sacropinous ligament using thin strips of polypropylene mesh tape.[10] Nocturia was cured in 80% of patients, with varying cure rates for the other posterior fornix symptoms: frequency 85% (n = 42), urge incontinence 86% (n = 74), emptying symptoms 50% (n = 65), mean residual urine >50 ml from 110 ml to 63 ml. Equal numbers of patients had 1st or 2nd degree apical prolapse (Baden Walker classification).

In 2002 Farnsworth reported cure rates for urgency 79%, nocturia 82% and pelvic pain 78%.[11] In 2005, Sivaslioglu reported cure rates for pelvic pain 82%, urgency 75%, nocturia 86%, 'obstructed' micturition 93%.[12] In 2007, Abendstein reported cure rates for urge incontinence 76%, pelvic pain 79%, nocturia 86%.[13]

Sacrocolpopexy (SCP)

A 4-5cm wide mesh suspends vaginal apex to the sacral promontory. In 1999, Pilsgaard et al reported cure of urge incontinence, frequency, nocturia and voiding problems in 75%, 80%, 50% and 100% of patients after abdominal sacrocolpopexy.[14] In an RCT between Posterior IVS and SCP in 2011 for apical prolapse, Sivaslioglu reported statistically significant cure rates for nocturia and chronic pelvic pain for the PIVS posterior sling, but no change with abdominal sacrocolpopexy.[15]

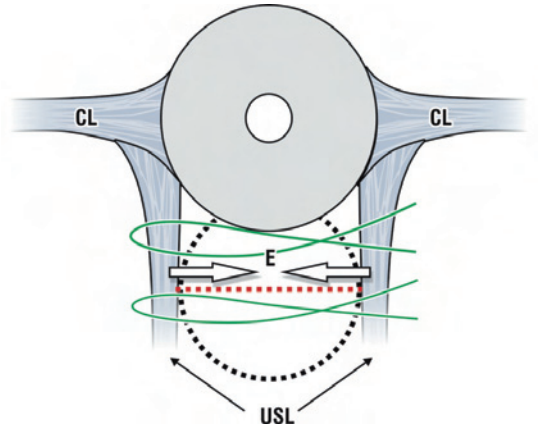


Figure 1. – Simple posterior fornix repair. A transverse incision is made in the posterior fornix 3-4cm below the cervix,. A large No1 needle is inserted widely laterally below the vaginal skin and the loose uterosacral ligaments (USL) are approximated (arrows) with a strong Vicryl or polypropylene sutures. CX= cervix; CL=cardinal ligament; E=enterocele.

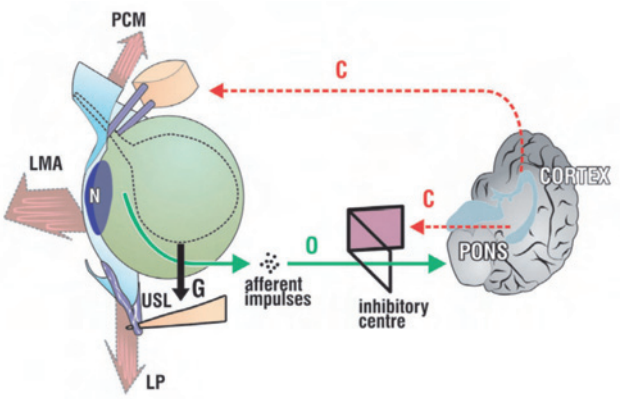


Figure 2. – **A mechanical hypothesis for nocturia causation** - patient asleep, supine Pelvic muscles (arrows) are partly relaxed. As the bladder (broken outline) fills, it is distended downwards by gravity G. If the uterosacral ligaments (USL) are loose, the bladder base continues to descend until the stretch receptors 'N' are stimulated, activating the micturition reflex. Once the closure reflex 'C' has been overcome, the afferent impulses reach the pons and activate the micturition reflex.

TFS (Tissue Fixation System)

Thin 0.7 mm wide polypropylene tapes attached to a 4x11mm soft tissue reinforced the uterosacral ligaments using the TVT neoligament principle.[16] Cure rates reported after posterior TFS (Tissue Fixation System) sling[16] in 67 patients were: frequency>10/day 63% (n=27); nocturia >2/night 83% (n=47); urge-incontinence >2/day 78% (n=36); abnormal emptying, 73% (n=54); pelvic pain, 86%(n=46) fecal incontinence, 87% (n=23). One third of patients had only 1st degree apical prolapse (Baden-Walker classification).

In 2013,[17] Inoue published TFS data in 337 patients with the following cure rates, incidence in brackets, 82.7% (n=52), frequency> 10/Day 84.9% (n=179), nocturia > 2/night, 60.5% (n=129), urge incontinence >2/day, 91.2% (n=171), chronic pelvic pain 71.1% (n=76). These findings were more recently confirmed by Sekiguchi who repaired cardinal and USL ligaments under LA.[18] All patients[17-19] had either 3rd or 4th degree POP (POPQ).

Hypothesis for nocturia causation

Loose uterosacral ligaments cannot support the anterior vaginal wall which is stretched downwards by the force of gravity. This activates the bladder base stretch receptors to send afferent signals to the brain arouse the patient from her sleep- nocturia, figure 2.

Tampon test

A simple test for this hypothesis is to insert a large tampon into the apex overnight to support it; many patients report relief of their nocturia and other posterior fornix symptoms.

CONCLUSIONS

Surgical cure of nocturia and other "posterior fornix" symptoms by 4 distinctly different operations all of which surgically correct deficient apical support seem to validate the concept that nocturia is largely caused by laxity in the structural supports of the vaginal apex.

The simplest surgical method is uterosacral ligament plication. It gives acceptable results in the shorter term. Prediction of surgical cure of nocturia can often be achieved by inserting a large tampon to support the apex and observing change in symptoms, nocturia, urgency and chronic pelvic pain.

REFERENCES

Petros PEP, Chapter 2: The Anatomy and Dynamics of Pelvic Floor Function and Dysfunction, in textbook The Female Pelvic Floor, Function, Dysfunction and Management according to the Integral Theory, 3rd Ed., 2010, Springer, Heidelberg, 17-76.

1. Lose G, Alling-Moller, Jennum P, Nocturia in women. Am J Obstet Gynecol 2001; 185:514-21.
2. Van Kerrebroeck P, Andersson K-A , Terminology, epidemiology, etiology, and pathophysiology of nocturia Neurourology and Urodynamics,2014; 33: S1, S2-5.
3. Verbalis JG Renal physiology of nocturia Neurourology and Urodynamics,2014:33;S1, S6-9.
4. Holm-Larsen T. The economic impact of nocturia Neurourology and Urodynamics, 2014; 33: S1, S10-14.
5. Bliwise DL, Rosen RCBaum N Impact of nocturia on sleep and quality of life: A brief, selected review for the International Consultation on Incontinence Research Society (ICI-RS) nocturia think tank Neurourology and Urodynamics, 2014; 33; S1, S15-18.
6. Weiss JP, Juul KV, Wein AJ, Management of Nocturia: The Role of Antidiuretic Pharmacotherapy, Neurourology and Urodynamics, 2014: 33; S1, S19-24.
7. Weiss JP, Wein AJ, Van Kerrebroeck P , Future Research Guidance for Nocturia, Neurourology and Urodynamics, 2014; 33; S1, S25.
8. Petros PE & Ulmsten U. The posterior fornix syndrome: a multiple symptom complex of pelvic pain and abnormal urinary symptoms deriving from laxity in the posterior fornix. Scandinavian Journal of Urology and Nephrology 1993 ; 27 Supplement 153: PART IV: 89-93
9. Petros PE & Ulmsten U. An Integral Theory and its Method, for the Diagnosis and Management of female urinary incontinence. Scandinavian Journal of Urology and Nephrology 1993; 27 Supplement 153-1-93.
10. Petros PE New ambulatory surgical methods using an anatomical classification of urinary dysfunction improve stress, urge, and abnormal emptying. Int J Urogynecology 1997; 8, 5: 270-278.
11. Farnsworth BN. Posterior intravaginal slingplasty (infracoccygeal sacropexy) for severe posthysterectomy vaginal vault prolapse, a preliminary report on efficacy and safety Int. Urogynecol J. 2002; 13: 4-8.
12. Sivaslioglu AA, Gelisen O, Dolen I et al. Posterior sling (infracoccygeal sacropexy): an alternative procedure for vaginal vault prolapse. Aust N Z J Obstet Gynaecol 2005; 45: 159-160.
13. Abendstein B, Letter to the editor, Posterior IVS, American Journal of Obstetrics & Gynecology 2007; 196;3 e18-e19.
14. Pilsgaard K. Mouritsen L. Follow-up after repair of vaginal vault prolapse with abdominal colposacropexy, Acta Obstet Gynecol Scand. 1999; 78:66-70.
15. Sivaslioglu AA, İlhan TT, Aydogmus S, Uzun M,Dolen I, The comparison of the anatomical and symptomatic outcomes of sacrocolpopexy and posterior intravaginal slingoplasty Int Urogynecol J , 2011; 22:1363–1368, DOI 10.1007/s00192-011-1442-5.
16. Petros P, Richardson P. TFS posterior sling improves overactive bladder, pelvic pain and abnormal emptying, even with minor prolapse. A prospective urodynamic study. Pelviperineology 2010; 29: 52–55.
17. Petros PEP, Inoue H Letter - Pelvic pain may be caused by laxity in the uterosacral ligaments as part of the "Posterior Fornix Syndrome". ANZJOG 2013; 53(3):325-6. DOI:10.1111.
18. Sekiguchi Y1, Kinjo M, Maeda Y, Kubota Y. Int Urogynecol J. Reinforcement of suspensory ligaments under local anesthesia cures pelvic organ prolapse: 12-month results. 2013: Dec 7. DOI 10.1007/s00192-013-2281-x [Epub ahead of print].
19. Petros PEP, Richardson PA TFS posterior sling improves overactive bladder, pelvic pain and abnormal . Int Urogynecol J 2014; 25: 465-470.

Correspondence to:

Peter Richardson

E-mail: ozappa@bigpond.com

Original article

Long term results of modified posterior intravaginal slingplasty (P-IVS) in patients with pelvic organ prolapse

ALPASLAN CALISKAN[1], KLAUS GOESCHEN[2], ALI ERSIN ZUMRUTBAS[3]

[1] *Denizli State Hospital, Obstetrics and Gynecology Clinic, Denizli, Turkey*
[2] *European Center Of Excellence for Reconstructive Pelvic Surgery, Hannover, Germany*
[3] *Pamukkale University School of Medicine, Department of Urology, Denizli, Turkey*

Background: Existing POP surgery methods repair vagina and ignore ligaments. The 1993 Integral Theory created a new strategy for pelvic floor surgery, site specific ligament repair. *Aim:* The objective of this study was to evaluate the anatomical and symptomatic success rates of a modified infracoccygeal sling procedure (P-IVS) for apical prolapse. *Methods:* 267 patients with symptomatic POP in various grades, underwent P-IVS operation between October 2009 and January 2014 modified by suturing each side of the tape to the sacrospinous ligament. Where required a modified anterior transobturator mesh (ATOM) procedure was performed for cystocele. All had follow-up for at least 1 year. *Results:* Mean age was 54.9 (28-88) years, mean operation time 149.8 (95-225) minutes, mean hospital stay 2.9 (1-10) days and mean follow up time 28.7 (12-63) months. Preoperatively 86.5% of the patients had anterior, 99% had posterior and 100% had apical prolapse. When surgical success was defined as grade 0 or grade 1 according to Baden-Walker, success rates for anterior, posterior and apical compartments at 3rd month were 92.1%, 98.1% and 97.3%; and 82.4%, 96.2% and 95.4% after ≥1 year, respectively. There was a statistically high improvement ($p<0001$) in all symptoms, such as urinary stress and urge incontinence, nocturia, urgency, pad use, fecal incontinence, difficulty in defecation, pelvic pain and quality of life. *Conclusions:* Total pelvic reconstruction with bilateral SSLF of P-IVS tape in combination with ATOM and TOT, if necessary, has a high success and low complication rate. Experience and strict attention to surgical principles are important for good symptomatic and anatomical results.

Keywords: Integral theory; Pelvic organ prolapse (POP); Posterior intravaginal slingplasty (P-IVS); Rectocele; Sacrospinous ligament fixation (SSLF); Cystocele.

INTRODUCTION

Pelvic Organ Prolapse (POP) is characterized by a descent of the pelvic organs: uterus, vagina, bladder, rectum and small bowel. In most cases concomitant urinary, defecation, sexual problems or pelvic pain are present. POP increases with age and causes great impact on quality of life.

In the past many different techniques have been described about POP surgery, but the search for the ideal technique still is going on. Due to the fact that deficient connective tissue is mainly responsible for prolapse and pelvic floor dysfunction,[1] an isolated damage of ligaments represents an exception.[2] In the majority of cases, a descent of pelvic organs is the consequence of both, insufficient support and suspension.[2] Traditional methods are still being used for surgical treatment of POP and stress urinary incontinence,[3] which are unphysiological in most cases and thus not able to cure symptoms or the exact anatomy in a proper way. A new dimension of understanding POP formation arose in 1992, when De Lancey[4] demonstrated the significance of connective tissue structures for organ suspension by specifying three levels of vaginal support; Level I, or the upper vagina, is supported by the cardinal-uterosacral ligament complex, Level II, or the mid-vagina, is supported by its attachments of the vaginal muscularis laterally to the fascia of the levator ani muscles, Level III support, being the most distal portion of the vagina, is provided by the perineal membrane and the rectovaginal septum.

Furthermore, conflicting data still exist regarding; the best approach (abdominally or vaginally) the effectiveness of POP surgery with and without hysterectomy, the use of artificial or autologous material to reinforce lax tissue, the best place to fix the apex/uterus (promontorium or sacrospinous ligaments) and the most effective combination of reconstruction.

In order to find an answer to these important questions in 1993 Petros et al. created a new vaginal strategy of pelvic floor surgery based on the Integral Theory,[5,6] which regards symptoms and organ prolapse as being both caused by lax suspensory ligaments. As, in our experience, this procedure was not sufficient enough to bring the apex far back, resulting in a normal vaginal length, we modified the PIVS by suturing the polypropylene tapes to the sacrospinous ligaments with a special instrument. Furthermore, in case of concomitant anterior wall prolapse we combined the posterior IVS with insertion of an anterior transobturator 4-arm mesh (ATOM4), whereas the posterior ATOM arms were sutured to the sacrospinous ligaments on both sides as well. After establishing our new surgical strategy by combining two procedures we performed a prospective observational study.

The objective of this study was to find an answer to the above mentioned important questions and to evaluate the anatomical and symptomatic success rates obtained by our procedure in comparison to the data from the literature.

The study was approved by the local ethics committee. Informed patient consent was obtained. There was no conflict of interest.

PATIENTS AND METHODS

This study is based on 267 patients, who had symptomatic POP of any degree and underwent P-IVS in combination with SSLF between October 2009 and January 2014 in Denizli State Hospital. Patients who were not admitted with POP, but with urinary and defecation problems resistant to conservative and medical treatment, were also included, if POP was detected whilst preoperative vaginal examination.

At the first consultation, all patients completed a questionnaire indicating age, body mass index (BMI), menopause status, parity, systemic diseases, medications, past gynecologic and urogynecologic history, previous operations, urinary symptoms, defecation symptoms, pelvic symptoms and sexual problems (Table 1). Preoperative and postoperative data were recruited retrospectively from the patient files, which had been prospectively recorded for each patient. Included were only patients with long term follow-up for at least one year and with at least two or more posterior fornix syndrome symptoms according to Petros and Ulmsten[7] such as abnormal emptying of the bladder,

TABLE 1. – Patient demographics (n = 267).

	Mean ± SD / n (%)	Range
Age	54.9 ± 11.4	28 - 88
Body Mass Index	28.1 ± 4.2	21 - 49
Parity	3.7 ± 1.7	1 - 10
Patients with menopause	169 (63.3%)	
Years in menopause	8.3 ± 9.1	0 – 40
Ongoing sexual activity	106 (39.7%)	
Previous surgery		
Hysterectomy	25 (9.4%)	
POP surgery	17 (6.4%)	
Incontinence surgery	6 (2.2%)	
Abdominal surgery	24 (9.0%)	
Operation time (minutes)	149.8 ± 26.3	95 - 225
Hospitalization (days)	2.9 ± 1.3	1 - 10
Follow-up (months)	28.7 ± 14.9	12 - 63

frequency, urgency, nocturia, fecal incontinence, obstructed defecation or pelvic pain.

Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) form and International Urogynecological Association (IUGA) and International Continence Society (ICS) definitions were also included in the questionnaire.[8] For the evaluation of stress urinary incontinence a stress test was performed. Fecal incontinence was defined as involuntary loss of solid or liquid feces. Defecation problems were also recorded.

Physical examination was always performed by the first author with a full bladder and POP grade was evaluated and graded according to Baden Walker halfway system between grade I and IV. Valsalva maneuver was used to evaluate the extent of POP. Specific anatomical defects were also recorded according to integral theory diagnostic algorithm and diagnosis was supported by simulated operation when needed. Stress test was performed after replacement of prolapse with a speculum in patients with grade III-IV POP. The patients were classified into 3 groups for vaginal compartments, 86.5% of the patients had anterior prolapse (Baden-Walker Stages; 1:20.3%, 2:17.7%, 3:38.5% and 4:23.4%), 99% had posterior prolapse (Baden-Walker Stages; 1:12.8%, 2:38.5%, 3:26.7% and 4:20.9%) and 100% had apical prolapse (Baden-Walker Stages; 1:25.8%, 2:25.1%, 3:28.5% and 4:20.6%).

Only 2 (0.7%) patients underwent PIVS + SSLF without further surgery. In 265 (99.3%) patients at least one of the following concomitant surgical procedures was performed: ATOM in 163 (61%), posterior bridge repair in 226 (84.6%) and TOT in 199 (74.5%) patients (Figure 1). None

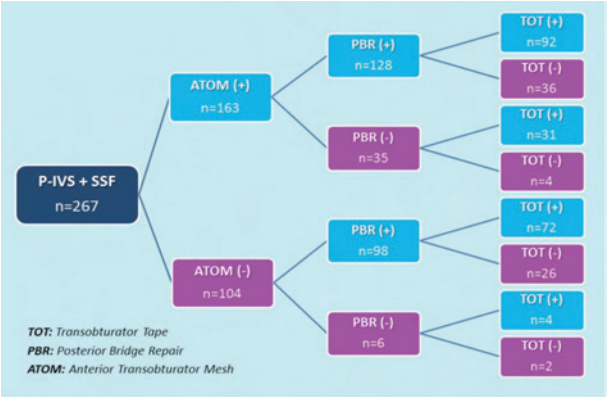


Figure 1. – Surgical algorithm.

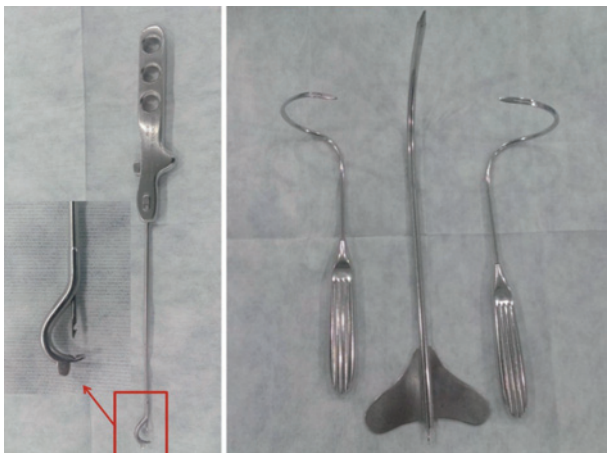


Figure 2. – Surgical instruments.

of the patients had concomitant hysterectomy. 237 cases were operated by the first and 30 by the second author.

Postoperative Follow-up

Postoperative follow-up visits were performed after 3 months, 1 year and yearly thereafter. All 267 patients had a 3 months control. 128 patients came for next check-up after one year, 54 after 13 to 24 months, 47 after 25 to 36 months and 38 after 37 to 48 months. These 267 patients with a long term follow-up for at least 1 year represent our pre- and postoperatively evaluated study group.

For the symptomatic relief of prolapse, the responses to the 2nd and 3rd questions of the POPDI-6 form and the results of a visual analogue scale were recorded. All patients were asked about the changes in life quality, satisfaction and if they would recommend this operation to others.

Postoperatively, patients were examined during Valsalva maneuver and anatomical success was defined as "no prolapse" (Baden-Walker grade 0) or "minimal prolapse" (Baden-Walker grade I).

Preoperative evaluation and surgical technique in details

All menopause patients were treated with local estrogen, single dose Ceftriaxone (2 gr) and thrombosis prophylaxis.

Level I repair:

After aquadissection a transverse incision was made in the posterior vaginal wall 1,5 cm below the cervix or cuff line and opened out antero-posteriorly. With a digital blunt preparation the sacrospinous ligament was freed from adherent tissue and two 2-0 prolene sutures were inserted into the ligament on both sides with a sacrofix device according to Goeschen (HandkeMedizintechnikGmbh Germany) (Figure 2). Bilateral 0.5 cm long incisions were made in the perianal skin at 4 and 8 o'clock, halfway between the coccyx and the external anal sphincter (EAS) in a line 2 cm lateral to the EAS. The tip of the IVS tunneller was gently pushed through the levator plate and placed into the ischiorectal fossa (Figure 3a). Then it was brought approximately 2 cm medially from the ischial spine, the tape was turned around the rectum and reached the transverse incision. One prolene suture from each side was stiched through the middle of the tape leaving a distance of 4 cm between each other (Figures 3b and 3c).

The procedure was repeated on the contralateral side and the tape was secured to the vaginal vault and also to the remnants of the uterosacral ligaments and the cervix with interrupted No.1 Vicryl (Figure 3d). In all procedures, self-tailored 1 cm wide polypropylene monofilament meshes (Atrium®) were used.

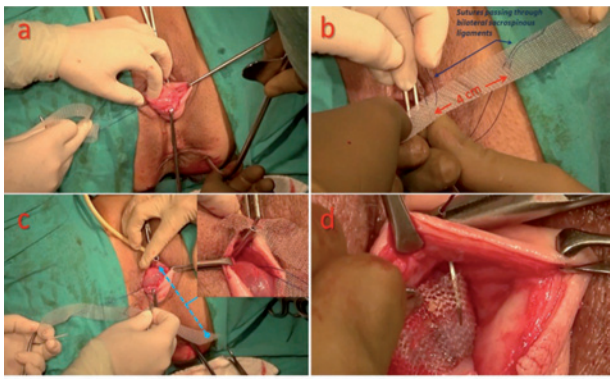


Figure 3. – IVS Tunneler was placed into the ischiorectal fossa (a); one prolene suture from each side was stiched through the middle of the tape leaving a distance of 4 cm between each other (b); one end of the mesh is brought into the tip of the inner piece of tunneler (c) and, the tape was secured to the apex (d).

Level II and III repairs:

Repair of the anterior vaginal wall:

After aquadissection, a full thickness elliptical incision, 1-3 cm wide, over the herniation of the cystocele was made, extending from 2 cm distal of the bladder neck to the cervix or vaginal cuff. The space between bladder and vaginal wall was opened out with a scissors and blunt dissection up to the arcus tendineus fasciae pelvis (ATFP). Extensive diathermy was used to destroy the superficial vaginal epithelium overlying the bridge. The anterior part of the bridge was anchored by burrowing 0.5 cm below the anterior border of the incision, the posterior part into the cervix or vaginal cuff.

A polypropylene mesh (Atrium®) 4-5 cm wide, 30 cm long was cut in a figure with two arms on each side. The anterior two arms of both sides were pulled out transobturatorially (Figure 2). The posterior two arms were placed around the cervix subepithelially and then connected with the remaining sacrospinous sutures, one right and one left. The pubocervical fascia was narrowed with U-sutures to cover the mesh. The skin incision was closed. The remaining sacrospinal sutures on both sides were fixed to the free lower two ends of the meshes and tied at the end of the procedure.

Table 2. – Distribution of prolapse grades in patients with anterior, apical and posterior POP before, 3 months and at least 12 months postoperatively.

	Grade 1	Grade 2	Grade 3	Grade 4
Anterior POP Pre-op n= 231 (100%)	47 (20.3%)	41 (17.7%)	89 (38.5%)	54 (23.4%)
Anterior POP 3m Post-op n= 231 (100%)	22 (9.5%)	18 (7.8%)	3 (1.3%)	0 (0%)
Anterior POP ≥12m Post-op n= 231 (100%)	44 (19.0%)	36 (15.6%)	10 (4.3%)	0 (0%)
Apical POP Pre-op n= 267 (100%)	69 (25.8%)	67 (25.1%)	76 (28.5%)	55 (20.6%)
Apical POP 3m Post-op n= 267 (100%)	14 (5.2%)	6 (2.2%)	1 (0.4%)	0 (0%)
Apical POP ≥12m Post-op n= 267 (100%)	10 (3.7%)	9 (3.4%)	3 (1.1%)	0 (0%)
Posterior POP Pre-op n= 264 (100%)	37 (14.0%)	103 (39.0%)	69 (26.1%)	55 (20.8%)
Posterior POP 3m Post-op n= 264 (100%)	16 (6.1%)	5 (1.9%)	0 (0%)	0 (0%)
Posterior POP ≥12m Post-op n= 264 (100%)	23 (8.7%)	9 (3.4%)	1 (0.4%)	0 (0%)

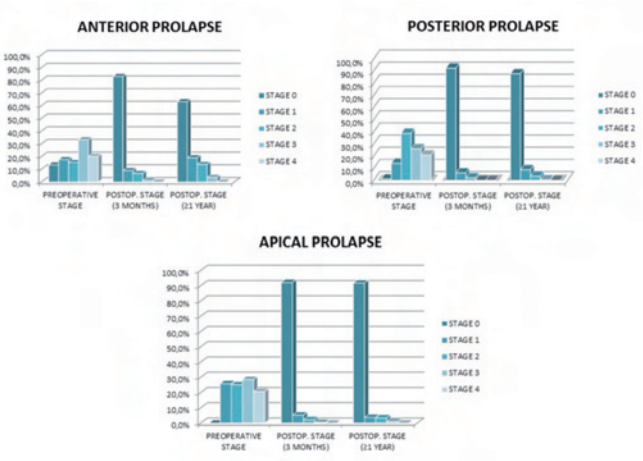


Figure 4. – Preoperative and postoperative prolapse grades.

Repair of the posterior vaginal wall:

After aquadissection, two full-thickness parallel longitudinal incisions were made along the posterior vaginal wall, extending from the transverse incision to 1 cm distal to the introitus. Extensive diathermy was used to destroy the superficial vaginal epithelium overlying the bridge. Adherent rectum was freed from the vaginal wall and perineal body (PB) over the distal 3-4 cm of vagina. The rectocele was reduced by using laterally placed horizontal mattress sutures which run subepithelially as a horizontal mattress suture through the bridge. The bridge was anchored separately to the tape above and the perineal body below. The sacrospinous and the PDS sutures were tied only with smooth tension to bring all pelvic organs in normal position. Finally 1 Vicryl unlocked running suture was placed which approximated the lateral cut edges.

Statistical analysis

Descriptive statistics were used to analyze the data of the patients. Pearson chi-square test, Fisher's exact test and Wilcoxon signed rank tests were used to analyze categorical variables and functional results. All analyses were performed using SPSS 17.0 software (SPSS; Chicago, IL, USA). A p-value less than 0.05 was considered to be statistically significant.

RESULTS

Preoperative and postoperative prolapse grades are given in Table 2 and Figure 4. Anatomical success rates for apical, anterior and posterior compartments were 95.5%, 82.7% and 96.3% in a mean follow-up of 29 months. In contrast to the first 2 years success rates for anterior and posterior prolapse were significantly better in the last two years. Regarding apical prolapse the difference did not reach statistical significance, although we observed a 4.6% points improvement.

Postoperative changes in symptoms after 3 and ≥12 months are listed in Table 3. Surgery caused a significant improvement of the symptoms: urine incontinence, nocturia, urgency, pad use, defecation problems, pelvic pain and quality of life.

Intraoperative, early and late postoperative complications are summarized in Table 4. Only one patient needed postoperative blood transfusion, another one, admitted with vaginal bleeding after 10 days, was cured by some stitches under general anesthesia. Two patients had mesh erosion in 3 months follow-up and 5 later on. In these patients only the protruded mesh was removed and covered by vaginal

TABLE 3. – Symptoms before and after the surgery.

Preoperative n. (% of total)	Cured after 3 months	*P Value**	Cured after ≥12 months	*P Value**
Urinary incontinence n=195 (73)				
Stress UI n=125 (46.8)	121 (96.8%)	0.0001	113 (90.4%)	0.0001
Urge UI n=70 (26.2)	1 (87.1%)	0.0001	49 (70%)	0.0001
Stress test negative n=130 (48.7)	126 (96.9%)	0.0001	122 (93.8%)	0.0001
Nocturia n=65 (24.3)	61 (93.8%)	0.0001	27 (41.5%)	0.001
Urgency n=95 (35.7)	79 (83.1%)	0.0001	70 (73.7%)	0.0001
Pad Use (Daily)				
1-2 n=44 (16.6)	34 (77.3%)		N/A	
3-4 n=65 (24.5)	65 (100%)	0.0001	N/A	N/Ap
≥5 n=47 (17.7)	47 (100%)		N/A	
Fecal incontinence n=3 (1.1)	3 (100%)	0.083	3 (100%)	0.083
Difficulty in defecation n=59 (22.1)	55 (93.2%)	0.0001	50 (84.7%)	0.0001
Pelvic pain n=70 (26.2)	44 (62.9%)	0.0001	58 (82.9%)	0.0001
Quality of life				
Severely affected n=211 (79.0)	2 (0.7%)		12 (4.5%)	
Moderately affected n=56 (21.0)	14 (5.2%)	0.0001	26 (9.7%)	0.0001
Minimally affected n=0	13 (4.9%)		20 (7.5%)	
Not affected n=0	238 (89.1%)		209 (78.3%)	
Visual analogue scale**				
8-10	250 (93.6%)		233 (87.3%)	
4-7	15 (5.6%)	N/Ap	21 (7.8%)	N/Ap
1-3	2 (0.8%)		13 (4.8%)	

N/A: Not available, N/Ap: Not applicable
*Data were compared to the preoperative status.
**Patient's satisfaction from the surgical treatment (1 to 10)

skin followed by local estrogen application. In the long term follow up the most frequent complication was dyspareunia. However, this symptom was reduced from 33,8% before to 10,1% after the operation.

In the long term follow-up (≥1 year) 93.6% of the patients responded "No" to POPDI-6 2nd and 3rd questions. 78.2% of the patients pointed out, that POP symptoms did not affect their quality of life any longer after ≥1 year. 7.5% were affected minimally, 9.8% moderately and 4.5% severely. In the postoperative satisfaction visual analogue scale (from 1 to 10) mean score was 9.1 ± 2.1. 92.5% of the patients would recommend this surgery to others with similar symptoms. Even 82.6% patients with anterior wall recurrence (n=46), responded "No" to POPDI-6 2nd and 3rd questions and 85% recommended this surgery to others.

Twenty-five patients (9.4%) without any anatomical or functional problem after 3 months rejected further follow-up visits. These patients were contacted by telephone yearly. All remained happy with their situation.

DISCUSSION

In 1990 Petros et al.[9] created a new vaginal procedure for pelvic floor surgery based on the Integral Theory and DeLancey's 3-level-classification.[4] Using Petros new treatment high cure rates for widely varied symptoms such as USI, urgency, nocturia, chronic pelvic pain were reported by Farnsworth[10] in 2002 and confirmed by Goeschen[11] 2004. In more recent publications anatomical success rates ranged from 37% to 100%.[12-18]

Our vaginal procedure combines the principles of Integral Theory based on DeLancey's suggestions and traditional proven surgery. The key pillar performed in all patients was bilateral fixation of the P-IVS tape to the sacrospinous ligament, a surgical evaluated for the first time. As in our series only 2 out of 267 patients presented an isolated apical prolapse, exclusively these patients got P-IVS+SSLF without any concomitant surgery. All other cases obtained a simultaneous reconstruction of all damaged compartments. The rationale behind our strategy was to benefit the advantages of proven procedures by reinforcing deficient ligaments and supporting structures at the same time.

Recent data from the United States also demonstrate, that in approximately 225,000 POP operations performed every year, in 40 to 85% a combination was necessary.[19-21] This shows, that a defect in only one compartment is an exception, as POP is a multifactorial condition, mainly caused by lax connective tissue, requiring a complex repair in most cases.

In order to compare our postoperative anatomical results with the literature, anatomical success rates have been evaluated separately for each compartment using the Baden-Walker classification system.[22] This system has proven his worth for a long time.[23] Anatomic cure is defined as POP stage 0 or 1.[24] In 1996 another score, the POP-Q system was created as a scientific method for determining anatomic success before and after prolapse surgery.[25] As this classification has not been successful in daily routine, in our study we used the Baden-Walker system and defined success as POP grade 0 and 1. In case of converting our results in the POP-Q system, half of the patients with postoperative grade 2 prolapse would be Stage 1 and considered as successful. Nevertheless, our anatomical success rates range amongst the highest reported in the literature. The best success rate was obtained in the posterior (96,2%) and apical compartment (95,4%), whereas anteriorly only 82,4% had good anatomical results. Is there an explanation for these differences?

In order to replace the everted uterus or vaginal vault and reconstruct the posterior vaginal wall as physiological as possible we combined traditional surgery with Petros strategy based on DeLancey's recommendations. Meanwhile this idea got support by Karram and Maher.[42] In 2012 they

pointed out, that especially in cases of advanced posterior vaginal wall prolapse a combination of techniques is commonly required.

For Level I, the upper vagina repair, we inserted a tape along the uterosacral ligaments, connecting uterus or vault with the levator plate. The cardinal ligament complex was renewed by the posterior two arms of a mesh or a tape around the cervix. Both tapes and mesh arms were bilaterally sutured to the sacrospinous ligaments. SSLF was firstly described by Amreich in 1951 for cases with vaginal vault prolapse fixation[26] and later on for replacement of the uterus and the fornix. The success rates of SSLF range between 64% and 97%.[17,27-30] In contrast to the classical SSLF we used a minimal invasive instrument, which allows a digital blunt preparation to pass sutures through the ligament in a few minutes. We fixed the P-IVS tape with 2 sutures and, if necessary, two more for the posterior arms of the mesh or cervical tape. This combination provides an excellent apical support and still connects the levator plate with uterus and vagina.[1]

Posterior Level II or mid-vagina repair was performed with homologous tissue instead of mesh and with transvaginal holding sutures in order to reinforce the rectovaginal fascia. The aim of this procedure was to preserve the rectovaginal space and to prevent adhesions or mesh erosions.

Anteriorly the pubocervical fascia was renewed with mesh and two transobturator and two sacrospinous arms around the cervix or vaginal vault. The perineal body in Level III was reconstructed by horizontal mattress sutures.

Karram and Maher reported 2012 success rates for posterior wall repair between 76-96% with a mean of 83%, Barber et al 2013 92,8% for SSLF.[31] Our complex vaginal reconstruction resulted in an anatomical success rate of 96.2% for the posterior and 95,4% for the apical compartment, compared with the literature one of the highest.

It is well known since decades, that the anterior vaginal compartment is mainly exposed to the abdominal pressure and gravity. Therefore, according to the recent literature, the recurrence rate in this area is the highest among all compartments[17] and still at least two times higher than posteriorly.[31] Weber et al.[32] and Sand et al.[33] reported anterior colporrhaphy to be successful in the management of cystocele in only 30% and 57%, respectively. Thus, an isolated anterior colporrhaphy can not be recommended any longer.[34]

The 2012 Cochrane meta-analysis indicates that the use of transobturator mesh had a significant lower recurrence rate compared with anterior colporrhaphy alone, however is still 14% vs. 49%.[35] Already in 2001 Weber et al.[32] and Sand et al.[33] pointed out, that use of mesh improves the results. In randomized controlled trials comparing anterior colporrhaphy without and with mesh the success rates were better in the mesh groups, 57% vs. 75% and 37% vs. 42% respectively, but still unacceptably high. Barber et al. found an anterior recurrence rate of 13,7% after SSLF without mesh reinforcement in contrast to 7,2% posteriorly. That means; mesh support without SSLF and SSLF without mesh lead to better results in the anterior compartment than traditional colporrhaphy. Mesh insertion gives a good support to bladder base, however this method is not able to connect the anterior wall with the posterior muscles, a junction needed for backward force to open and close bladder and rectum.

Therefore our idea was to combine both strategies for further improvement. We inserted a transobturator 4-arm-mesh, girdled the posterior arms around the cervix or vault and sutured the arms bilaterally to the sacrospinous ligaments in order to fixthe uterus and/or vaginal vault to the ligaments and to renew the cardinal ligaments. Compared to the recent literature our anatomical results remained at the same level regarding the complete study period, but showed a significant improvement during the last 2 years due to enhanced exercise. Much more important is, that the majority of patients with anterior wall recurrence were asymptomatic (>82%) after ≥1 year and still satisfied with the surgery.

A prolapsed uterus or vaginal cuff can be repaired either abdominally or vaginally.[36] Up to now numerous surgeons still favor the abdominal way to restore the anatomy or to cure symptoms either by laparoscopy[37-42] or by laparotomy.[35,43-45] The success rate, when defined as lack of apical prolapse postoperatively, ranged from 78-100% and when defined as no postoperative prolapse, from 58-100%.[45] Consequently recent Cochrane analyses[35] and review articles[46] come to the conclusion, that "abdominal sacrocolpopexy is the gold standard for vaginal vault prolapse and is superior to vaginal sacrocolpopexy, with fewer recurrent prolapses and less dyspareunia". However, abdominal procedures provide only a small gate for POP reconstruction and a stable and narrow hiatus genitalis is necessary to prevent a recurrence POP after surgery.[2] Laparotomy or laparoscopy as it exists today, enables only the elevation of the descended level 1 structures such as vaginal apex or uterus and can suture a displaced anterior vaginal wall to the arcus tendineus fascia pelvis (ATFP). Furthermore, abdominal sacrocolpopexy does not mimic normal anatomy. Promontorial fixation creates an unphysiological vertical vaginal axis, which may result in high recurrence of prolapse and increased risk of enterocele and pain.[2] Our combination allows a physiological reconstruction of all damaged structures including a normal vaginal axis.[2]

In literature conflicting data still exist regarding the effectiveness of POP surgery with and without uterine preservation.[47-52] Dietz et al. report that uterine preservation is associated with more apical prolapse recurrences than vaginal hysterectomy at the time of POP-repair.[48] These results conflict with data by Maher et al., who found vaginal sacrospinous hysteropexy to be equally effective to vaginal hysterectomy combined with sacrospinous fixation.[51]

In our study no patient underwent concomitant hysterectomy. However, if the hypothesis is valid that uterus preservation deteriorate the outcome, we would expect worse anatomical results in our study group in comparison to the literature. However, this was not the fact. The opposite was true. Therefore, we are convinced that the cervix is the central attachment point and the strongest structure for fixation of artificial ligaments. Hysterectomy weakens the pelvic floor and can generate a significant increase in functional and anatomical recurrences. Furthermore, we do not excise vaginal excessive skin, a routine method in traditional POP surgery, because vaginal mucosa cannot regenerate and excision will only narrow and shorten the vagina.

Our next, up to now not answered question, was whether a combination of P-IVS, SSLF, ATOM and suburethral sling add up the complication rate for every procedure? Complications associated with P-IVS and SSLF are mainly hemorrhage, hematoma, bladder and rectal injuries, mesh exposure or erosions, dyspareunia and pelvic pain. In a recent review article, published by Cosma et al., the overall mean rate for hematoma was 2.6%, 0.8% for rectal injury, 3.3% for pain, 8.5% for mesh erosion, 1.4% for abscess and fistula, and 5.2% for dyspareunia.[14] Complications of SSLF are extensively reviewed by Tseng et al.[53] After SSLF the frequency of bladder and rectal injury was 0-2%, 0.5-8% for bleeding requiring transfusion, 0.3-18% for infection. Postoperative dyspareunia after SSLF occurred in 3% up to 61.1% with a mean of 15.7%.[35]

TABLE 4. – Intraoperative, early postoperative and postoperative complications.

	Intraoperative & Early postoperative n (%)	Postoperative 3rd month n (%)	Postoperative 1st year n (%)
Bladder injury	8 (3.0%)		
Rectal injury	3 (1.1%)		
Bleeding requiring transfusion	1 (0.4%)		
Hematoma	0 (0.0%)		
Wound infection	1 (0.4%)		
Mesh erosion		2 (0.7%)	5 (1.9%)
Pelvic pain		26 (9.7%)	12 (4.5%)
Urination problems		11 (3.7%)	4 (1.5%)
Defecation problems		4 (1.3%)	9 (3.4%)
Dyspareunia		5 (1.9%)	27 (10.1%)
Re-operation (POP Surgery)			7 (2.6%)
Re-operation (TOT)			6 (2.2%)

Our data show no increase of complications after complex surgery (Table 4). Mesh erosion is a major concern regarding POP surgery. We had only an erosion rate of 2.6%, which is one of the lowest in the literature. We believe, that this is the result of precise dissection, autologous tissue interposition between mucosa and mesh, estrogen use and above all experience. The most frequent complication was dyspareunia with a rate of 10.1% after ≥12 months. However, compared with the preoperative situation the incidence was reduced by two third.

CONCLUSIONS

Complete vaginal pelvic reconstruction of all damaged compartments with bilateral SSLF and PIVS, anterior transobturator mesh and suburethral sling, if necessary, has, compared with traditional surgery, an extremely high success and low complication rate. Concomitant procedures like ATOM, posterior bridge repair and TOT, performed at the same time when needed, do not increase complications, if the surgeon is experienced and follows the principles of vaginal reconstructive surgery.

CONFLICTS

None.

REFERENCES

1. Petros PP. The Female Pelvic Floor, Function, Dysfunction and Management According to the Integral Theory. Third Edition ed. Springer, Germany 2010.
2. Goeschen K. Review: Role of Uterosacral Ligaments in the Causation and Cure of Chronic Pelvic Pain Syndrome. Pelviperineology 2015; 34: 02-20.
3. Tizzano AP. Historical Milestones in Female Pelvic Surgery, Gynecology and Female Urology. In: Walters MD, Karram MM (eds), Urogynecology and Reconstructive Pelvic Surgery. 3rd Edition ed, 2007; 3-15.
4. DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. Am J Obstet Gynecol. 1992; 166: 1717-24; discussion 24-8.
5. Petros PE, Ulmsten UI. An integral theory of female urinary incontinence. Experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl. 1990; 153: 7-31.
6. Petros PE, Ulmsten UI. An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol Suppl. 1993; 153: 1-93.
7. Petros PE, Ulmsten UI. The role of a lax posterior vaginal fornix in the causation of stress and urgency symptoms: a preliminary report. Acta Obstet Gynecol Scand Suppl. 1990; 153: 71-3.
8. Haylen BT, de Ridder D, Freeman RM et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Neurourol Urodyn. 2010; 29: 4-20.
9. Petros PE, Ulmsten UI, Papadimitriou J. The autogenic ligament procedure: a technique for planned formation of an artificial neo-ligament. Acta Obstet Gynecol Scand Suppl. 1990; 153: 43-51.
10. Farnsworth BN. Posterior intravaginal slingplasty (infracoccygeal sacropexy) for severe posthysterectomy vaginal vault prolapse--a preliminary report on efficacy and safety. Int Urogynecol J Pelvic Floor Dysfunct. 2002; 13: 4-8.
11. Goeschen K, Gent HJ. Das posteriore Fornixsyndrom. Frauenarzt. 2004; 45: 104-12.
12. Bjelic-Radisic V, Hartmann G, Abendstein B, Tamussino K, Riss PA. The posterior intravaginal slingplasty operation: results of the Austrian registry. Eur J Obstet Gynecol Reprod Biol. 2009; 144: 88-91.
13. Capobianco G, Donolo E, Wenger JM et al. Efficacy and 9 years' follow-up of posterior intravaginal slingplasty for genital prolapse. J Obstet Gynaecol Res. 2014; 40: 219-23.
14. Cosma S, Preti M, Mitidieri M, Petruzzelli P, Possavino F, Menato G. Posterior intravaginal slingplasty: efficacy and complications in a continuous series of 118 cases. Int Urogynecol J. 2011; 22: 611-9.
15. Kolusari A, Yildizhan R, Adali E et al. Short-term results of posterior intravaginal slingplasty in grade 4 uterine prolapse. Arch Gynecol Obstet. 2010; 281: 55-8.
16. Lee YS, Han DH, Lee JY, Kim JC, Choo MS, Lee KS. Anatomical and functional outcomes of posterior intravaginal slingplasty for the treatment of vaginal vault or uterine prolapse: a prospective, multicenter study. Korean J Urol. 2010; 51: 187-92.
17. Maher C. Pelvic Organ Prolapse Surgery. In: Abrams P, Cardozo L, Khoury S, Wein A (eds), Incontinence. ICUD-EAU, 2013; 1377-442.
18. Neuman M, Lavy Y. Posterior intra-vaginal slingplasty for the treatment of vaginal apex prolapse: Medium-term results of 140 operations with a novel procedure. Eur J Obstet Gynecol Reprod Biol. 2008; 140: 230-3.
19. Boyles SH, Weber AM, Meyn L. Procedures for pelvic organ prolapse in the United States, 1979-1997. Am J Obstet Gynecol. 2003; 188: 108-15.
20. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol. 1997; 89: 501-6.
21. Whiteside JL, Weber AM, Meyn LA, Walters MD. Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol. 2004; 191: 1533-8.
22. Baden WF, Walker TA. Genesis of the vaginal profile: a correlated classification of vaginal relaxation. Clin Obstet Gynecol. 1972; 15: 1048-54.
23. Barber MD, Brubaker L, Nygaard I et al. Defining success after surgery for pelvic organ prolapse. Obstet Gynecol. 2009; 114: 600-9.
24. Weber AM, Abrams P, Brubaker L et al. The standardization of terminology for researchers in female pelvic floor disorders. Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12: 178-86.
25. Bump RC, Mattiasson A, Bo K et al. The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynecol. 1996; 175: 10-7.
26. Amreich J. [Etiology and surgery of vaginal stump prolapses]. Wien Klin Wochenschr. 1951; 63: 74-7.
27. Cruikshank SH, Muniz M. Outcomes study: A comparison of cure rates in 695 patients undergoing sacrospinous ligament fixation alone and with other site-specific procedures--a 16-year study. Am J Obstet Gynecol. 2003; 188: 1509-12; discussion 12-5.
28. David-Montefiore E, Barranger E, Dubernard G, Nizard V, Antoine JM, Darai E. Functional results and quality-of-life after bilateral sacrospinous ligament fixation for genital prolapse. Eur J Obstet Gynecol Reprod Biol. 2007; 132: 209-13.

29. Halaska M, Maxova K, Sottner O et al. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. Am J Obstet Gynecol. 2012; 207: 301 e1-7.
30. Yazdany T, Wong K, Bhatia NN. Sacrospinous ligament fixation for pelvic organ prolapse in the era of vaginal mesh kits. Curr Opin Obstet Gynecol. 2011; 23: 391-5.
31. Barber MD, Brubaker L, Burgio KL et al. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. JAMA. 2014; 311: 1023-34.
32. Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001; 185: 1299-304; discussion 304-6.
33. Sand PK, Koduri S, Lobel RW et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol. 2001; 184: 1357-62; discussion 62-4.
34. Winters JC, Togami JM, Chermansky CJ. Vaginal and Abdominal Reconstructive Surgery for Pelvic Organ Prolapse. In: Kavoussi LR, Partin AW, Novick AC, Peters CA (eds), Campbell-Walsh Urology. Tenth Edition ed, 2011; 2080.
35. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev. 2013; 4: CD004014.
36. Sivaslioglu AA, Ilhan TT, Aydogmus S, Uzun M, Dolen I. The comparison of the anatomical and symptomatic outcomes of sacrocolpopexy and posterior intravaginal slingoplasty. Int Urogynecol J. 2011; 22: 1363-8.
37. Agarwala N, Hasiak N, Shade M. Laparoscopic sacral colpopexy with Gynemesh as graft material-experience and results. J Minim Invasive Gynecol. 2007; 14: 577-83.
38. Bojahr B, Tchartchian G, Waldschmidt M, Ohlinger R, De Wilde RL. Laparoscopic sacropexy: a retrospective analysis of the subjective outcome in 310 cases. Obstet Gynecol Int. 2012; 2012: 538426.
39. Ganatra AM, Rozet F, Sanchez-Salas R et al. The current status of laparoscopic sacrocolpopexy: a review. Eur Urol. 2009; 55: 1089-103.
40. Higgs PJ, Chua HL, Smith AR. Long term review of laparoscopic sacrocolpopexy. BJOG. 2005; 112: 1134-8.
41. Ross JW, Preston M. Laparoscopic sacrocolpopexy for severe vaginal vault prolapse: five-year outcome. J Minim Invasive Gynecol. 2005; 12: 221-6.
42. Sundaram CP, Venkatesh R, Landman J, Klutke CG. Laparoscopic sacrocolpopexy for the correction of vaginal vault prolapse. J Endourol. 2004; 18: 620-3; discussion 3-4.
43. Baessler K, Schuessler B. Abdominal sacrocolpopexy and anatomy and function of the posterior compartment. Obstet Gynecol. 2001; 97: 678-84.
44. Maher CF, Qatawneh AM, Dwyer PL, Carey MP, Cornish A, Schluter PJ. Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study. Am J Obstet Gynecol. 2004; 190: 20-6.
45. Nygaard I, Brubaker L, Zyczynski HM et al. Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. JAMA. 2013; 309: 2016-24.
46. Nygaard IE, McCreery R, Brubaker L et al. Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol. 2004; 104: 805-23.
47. Carramao S, Auge AP, Pacetta AM et al. [A randomized comparison of two vaginal procedures for the treatment of uterine prolapse using polypropylene mesh: hysteropexy versus hysterectomy]. Rev Col Bras Cir. 2009; 36: 65-72.
48. Dietz V, van der Vaart CH, van der Graaf Y, Heintz P, Schraffordt Koops SE. One-year follow-up after sacrospinous hysteropexy and vaginal hysterectomy for uterine descent: a randomized study. Int Urogynecol J. 2010; 21: 209-16.
49. Diwan A, Rardin CR, Kohli N. Uterine preservation during surgery for uterovaginal prolapse: a review. Int Urogynecol J Pelvic Floor Dysfunct. 2004; 15: 286-92.
50. Hefni M, El-Toukhy T, Bhaumik J, Katsimanis E. Sacrospinous cervicocolpopexy with uterine conservation for uterovaginal prolapse in elderly women: an evolving concept. Am J Obstet Gynecol. 2003; 188: 645-50.
51. Maher CF, Cary MP, Slack MC, Murray CJ, Milligan M, Schluter P. Uterine preservation or hysterectomy at sacrospinous colpopexy for uterovaginal prolapse? Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12: 381-4; discussion 4-5.
52. Roovers JP, van der Vaart CH, van der Bom JG, van Leeuwen JH, Scholten PC, Heintz AP. A randomised controlled trial comparing abdominal and vaginal prolapse surgery: effects on urogenital function. BJOG. 2004; 111: 50-6.
53. Tseng LH, Chen I, Chang SD, Lee CL. Modern role of sacrospinous ligament fixation for pelvic organ prolapse surgery--a systemic review. Taiwan J Obstet Gynecol. 2013; 52: 311-7.

Correspondence to:
Alpaslan Caliskan - Semikler Mah. Osmangazi Cad. Golkent sitesi 20085 Denizli - Turkey
E-mail: alpilein53@yahoo.de

Multidisciplinary UroGyneProcto Editorial Comment

To improve the integration among the three segments of the pelvic floor, some of the articles published in *Pelviperineology* are commented on by **Urologists, Gynecologists, Proctologists/Colo Rectal Surgeons** or **other Specialists**, with their critical opinion and a teaching purpose. Differences, similarities and possible relationships between the data presented and what is known in the three fields of competence are stressed, or the absence of any analogy is indicated. The discussion is not a peer review, it concerns concepts, ideas, theories, not the methodology of the presentation.

THE COLORECTAL SURGEON'S OPINION

In the series of patients considered in this work, the percentage of proctological symptoms seems to be low: 1.1% fecal incontinence; 22.1% obstructed defecation. This may depend on the small number of hysterectomized patients (25 of 267; 9.4%), and on a methodological limit in the search of symptoms and of anatomical/functional defects as well. When analyzing the efficiency of the mechanisms of continence and defecation, studies on the posterior compartment use scores that allow the quantification of the type of leakage and of the difficulty on expelling stools (Wexner, CCS, Agachan, Rome criteria, AMS, etc). Not using these items makes it more difficult to identify which patients require further diagnostic workup. The morphological and functional evaluation provides a series of diagnostic tests: proctoscopy and colonoscopy to rule out organic diseases including occult prolapses or stenoses, anorectal manometry/solid sphere test to measure tone, contraction/relaxation of the sphincters and rectal sensitivity, defecography/RMI to assess the extent of any prolapse and intussusception, ultrasound to check the integrity of the sphincters, anorectal EMG, transit time study. These investigations rule out colorectal diseases that, if proven, may require a specific specialist proctologic approach. In the interests of scientific validation, the good anatomical and functional results and symptoms reported by Caliskan after total pelvic reconstruction need to be verified in the long term with some of the above described methods, preferably with the participation of an interested colorectal reconstructive surgeon. For now, functional surgery in the posterior compartment at present seems to need a very careful and cautious approach with limited indications.

Benito Ferraro
S. Antonio Hospital, Padova, Italy - Colorectal Surgeon
benito.ferraro@sanita.padova.it0

APPLICAZIONI UNITARIE di SISTEMA

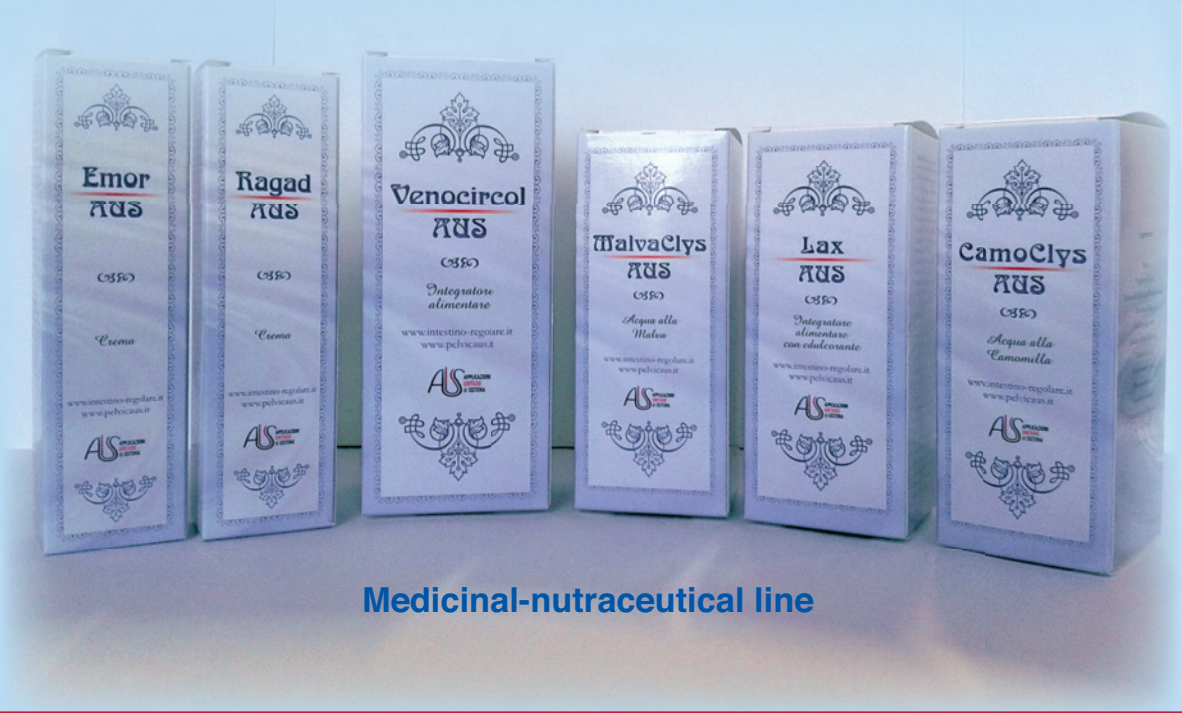
Unitary System Apps s.r.l.

Why AUS?

AUS treats all aspects of the pelvic floor area considered a unitary anatomical and functional structure composed of three main compartments: front / *urinary*, middle / *genital* and rear / *intestinal.*

Our comprehensive product lines including *medical*, *hygienic* and *medicinal-nutraceutical* are based on a long experience in the field of clinical physiology treating the most diverse diseases of the pelvic floor.

AUS's priority is to provide concrete benefits to patients in the simplest way possible through the use of innovative technologies and age old wisdom while keeping in mind the sensitivity required in the treatment of this area.



Medicinal-nutraceutical line

A.U.S. srl - Via Croce Rossa, 42 - 35129 Padova - email: info@pelvicaus.it

www.intestino-regolare.it • www.pelvicaus.it

DILAGENT®

Curative “exercises” for anal fissures, haemorrhoids, hypertonic muscles and postsurgical stenosis

DILAGENT is a **soft silicone** anal dilator.
It is indicated for the treatment of anorectal diseases caused by a hypertonic sphincter, namely anal fissures, haemorrhoids and painful spasms after surgical treatment of the anorectal segment. It is also effectively used in cases of postsurgical stenosis of the anal canal.

sapimed S.p.A.
www.sapimed.com