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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
70.0%
13.1%
16.9%
No adjustment
Loosening
Tightening

High success rate
90.3% completely dry
6.4% considerably/substantially improved

Low erosion rate
0.77%
99.23%
Erosion
No erosion

Advantages of Adjustment

Resolves cases of persisting incontinence or urinary retention post-operatively with no surgical re-intervention!

Effective treatment for high-risk groups (e.g. combined SUI and voiding dysfunction), severe SUI, or patients with previous failed treatment.
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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 minising 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 assessment and dejectogram. 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 minising; 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 dysfunction 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.24 POP symptoms are often described in terms of voiding dysfunction eg urinary urge and urge incontinence, frequency, 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.6,7 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 I support by Delancey.3 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).

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 uroterovaginal 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 Dougs 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.11 Since pelvic laxity and prolapse and symptoms of excretory and sexual dysfunction are very rarely life threatening, Ostergard11 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 suggest that there should be zero tolerance for any such operation which may have sig-
significant morbidity. A recent editorial by CW Buttrick 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. 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.

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. 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 Östergard’s criteria. 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.

In 2005 an innovative minimally invasive universal system - Tissue Fixation System (TFS) was developed, whereby ligamentous 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 with uterine preservation (an important advantage) as there is no clear evidence that hysterectomy will improve surgical outcomes. Severe post hysterectomy 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 USG assessment. For these procedures, the Tissue Fixation System applicator (TFS Surgical, Australia) was used to insert an anchor 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 enmeshed 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. 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 cystocele if necessary (2-0 PDS); apply TFS anchor at insertion of CL to ATPF sited approximately 2cms superior and 1cm lateral to the ischial spine. Close tunnel and incision in layers.

Table 1. – Patient demographic.

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

* Diabetes, asthma, hypertension, macro/morbid obesity, COAD, GORD, depression & anxiety.
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 – lcm 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) lcm 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 Perinei 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 posterior medial 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.

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.


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>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior compartment prolapse (POPQ ≥2* No., %)</td>
<td>24 (60)</td>
</tr>
<tr>
<td>Posterior compartment prolapse (POPQ ≥2* No., %)</td>
<td>24 (60)</td>
</tr>
<tr>
<td>Anterior &amp; Posterior compartment prolapse (POPQ ≥2* No., %)</td>
<td>15 (37.5)</td>
</tr>
<tr>
<td>Apical prolapse (POPQ ≥2* No., %)</td>
<td>16 (40)</td>
</tr>
<tr>
<td>Anterior &amp; Posterior &amp; apical prolapse (POPQ ≥2* No., %)</td>
<td>6 (15)</td>
</tr>
<tr>
<td>Previous POP reconstructive surgery (No., %)</td>
<td>14 (35)</td>
</tr>
</tbody>
</table>

According with the ICS POP-Q system.

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

Table 2. – Clinical details.

Table 3. – Operative details.
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 rami which resolved within 21 days. No haemorrhage, 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 haemorrhage, haematoma, small bowel obstruction and mesh erosion.\(^6\) 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?”\(^5\)

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.\(^7\)

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 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.\(^8,9\)

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 cystocele and enterocele formation with figures ranging from 1.1%-9%.\(^10,11\)

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.
ACKNOWLEDGMENTS

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

CONFLICTS

None.

REFERENCES

15. FDA; Public Health Notification - Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence.

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

GHAZALEH ROSTAMINIA, STEPHANIE PICKETT, MICHAEL MACHIORLATTI, S ABBAS SHOBEIRI, MIKIO NIHIRA

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) administrated 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. 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. SUI treatment surgeries traditionally consisted of retropubic urethropexy or pubovaginal sling. 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.

There are seven major types of corrective procedures that have been described for SUI; suburethral fascial plication in anterior colporrhaphy, artificial sphincter, per urethral 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. 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. 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 performed. 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%). 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 1.1% 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 procedure for treatment and in different concomitant surgery cases:

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

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

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

<table>
<thead>
<tr>
<th>Clinical preference</th>
<th>Fall 1998</th>
<th>Fall 2013</th>
<th>P-Value from Rank Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Anterior colporrhaphy</td>
<td>11.7 (8.1, 15.3)</td>
<td>4.9 (2.6, 7.2)</td>
<td></td>
</tr>
<tr>
<td>2 - Artificial sphincter</td>
<td>8.3 (1.2, 15.5)</td>
<td>4.9 (2.6, 7.2)</td>
<td></td>
</tr>
<tr>
<td>3 - Periurethral collagen injection</td>
<td>11.3 (9.7, 12.9)</td>
<td>8.1 (6.6, 9.5)</td>
<td></td>
</tr>
<tr>
<td>4 - Sling procedures</td>
<td>26.1 (21.7, 30.5)</td>
<td>7.4 (2.0, 12.8)</td>
<td></td>
</tr>
<tr>
<td>5 - Transabdominal urethropexy</td>
<td>67.5 (63.1, 71.8)</td>
<td>6.2 (4.4, 8.0)</td>
<td></td>
</tr>
<tr>
<td>6 - Transvaginal (needle) retrourethropexy</td>
<td>16.8 (10.2, 23.4)</td>
<td>5.3 (1.1, 9.6)</td>
<td></td>
</tr>
<tr>
<td>7 - Mid-Urethral Synthetic sling</td>
<td>NA</td>
<td>89.0 (86.5, 91.4)</td>
<td></td>
</tr>
</tbody>
</table>

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. *p = all values were the same so no 95% CI could be calculated.
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 transabdominal 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 relates 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.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 slingsplasty.23 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 slingsplasty 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.2 Schimpf et al. in this review recruited 10 clinical trials that had compared Burch abdominal (open surgery) with MUS.

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

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

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

<table>
<thead>
<tr>
<th>Clinical preference</th>
<th>Fall 1998 n=136</th>
<th>Fall 2013 n=137</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given a patient with a static urethral pressure profile of &lt;20 cm H2O which procedure do you most favor for treatment?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - Anterior colporrhaphy</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2 - Artificial sphincter</td>
<td>0</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>3 - Periurethral collagen injection</td>
<td>8 (6.1)</td>
<td>9 (6.8)</td>
</tr>
<tr>
<td>4 - Sling procedures</td>
<td>110 (84.0)</td>
<td>2 (2.52)</td>
</tr>
<tr>
<td>5 - Transabdominal retropubic urethropexy</td>
<td>13 (9.9)</td>
<td>0</td>
</tr>
<tr>
<td>6 - Transvaginal (needle) retropubic urethropexy</td>
<td>0</td>
<td>1 (0.8)</td>
</tr>
<tr>
<td>7 - Mid-Urethral Synthetic sling</td>
<td>NA</td>
<td>119 (90.2)</td>
</tr>
</tbody>
</table>

| 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. 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. 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. 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 institutions 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 retro pubic 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


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

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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. The TFS (Tissue Fixation System) 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 69.6 years), 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).

Restrict: 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) 95%; 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; Cystoceles; Perineal body; 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. 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 and government cost. Collateral health problems create a concomitant demand for minimally invasive operations to safely correct the prolapses. The TFS (Tissue Fixation System),1,2,4 fig. 1, is a less invasive evolution of the TVT operation;2 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 questionnaires8 and ICIQ SF to assess symptoms, vaginal examination to directly identify the sites of liga- ment 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-
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, figure 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 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.

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 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)

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)

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 complications, 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. Parallely the results of testing the hypothesis Ho: P ≤ p0 vs H1: p > p0 have entered.

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>No of cured</th>
<th>observed cure rate (%)</th>
<th>95% - lower CI</th>
<th>96% - upper CI</th>
<th>Test results: Ho: P ≤ p0 vs H1: p &gt; p0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolapse</td>
<td>278</td>
<td>257</td>
<td>92.10</td>
<td>89.0 - 95.2</td>
<td>95.4 - 94.8</td>
<td>*</td>
</tr>
<tr>
<td>Urgency</td>
<td>133</td>
<td>124</td>
<td>90.20</td>
<td>88.1 - 92.3</td>
<td>92.4 - 90.9</td>
<td>*</td>
</tr>
<tr>
<td>Nocturia</td>
<td>86</td>
<td>62</td>
<td>72.10</td>
<td>68.1 - 76.1</td>
<td>76.2 - 68.1</td>
<td>9</td>
</tr>
<tr>
<td>Day time frequency</td>
<td>132</td>
<td>120</td>
<td>90.10</td>
<td>88.1 - 92.1</td>
<td>92.2 - 88.0</td>
<td>/</td>
</tr>
<tr>
<td>Dragging pain</td>
<td>56</td>
<td>52</td>
<td>92.90</td>
<td>90.8 - 95.0</td>
<td>95.1 - 90.8</td>
<td>9</td>
</tr>
<tr>
<td>Fecal incontinence</td>
<td>52</td>
<td>46</td>
<td>88.50</td>
<td>85.5 - 91.5</td>
<td>91.6 - 85.5</td>
<td>/</td>
</tr>
</tbody>
</table>

*‘*’, ‘#’ 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.

<table>
<thead>
<tr>
<th>Time after TFS</th>
<th>Cure of prolapse</th>
<th>Cure of urgency</th>
<th>Cure of nocturia</th>
<th>Cure of day time frequency</th>
<th>Cure of dragging pain</th>
<th>Cure of fecal incontinence</th>
</tr>
</thead>
<tbody>
<tr>
<td>12th month</td>
<td>62/63</td>
<td>91.2%</td>
<td>96.5%</td>
<td>94.4%</td>
<td>93.6%</td>
<td>92.5%</td>
</tr>
<tr>
<td>95 % (lower CI; upper CI)</td>
<td>0.87 &amp; 0.86</td>
<td>0.63 &amp; 0.99</td>
<td>0.90 &amp; 0.99</td>
<td>0.95 &amp; 0.99</td>
<td>0.93 &amp; 0.99</td>
<td>0.92 &amp; 0.99</td>
</tr>
<tr>
<td>Test results of: 0.80 vs. H1: p = 0.80</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>24th month</td>
<td>57/69</td>
<td>87.7%</td>
<td>83.2%</td>
<td>86.7%</td>
<td>93.8%</td>
<td>92.4%</td>
</tr>
<tr>
<td>95 % (lower CI; upper CI)</td>
<td>0.83 &amp; 0.85</td>
<td>0.81 &amp; 0.91</td>
<td>0.76 &amp; 0.91</td>
<td>0.80 &amp; 0.93</td>
<td>0.84 &amp; 0.95</td>
<td>0.86 &amp; 0.97</td>
</tr>
<tr>
<td>Test results of: 0.80 vs. H1: p = 0.80</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>48th month</td>
<td>43/59</td>
<td>84.2%</td>
<td>82.8%</td>
<td>81.6%</td>
<td>80.8%</td>
<td>89.8%</td>
</tr>
<tr>
<td>95 % (lower CI; upper CI)</td>
<td>0.77 &amp; 0.76</td>
<td>0.69 &amp; 0.89</td>
<td>0.70 &amp; 0.90</td>
<td>0.74 &amp; 0.81</td>
<td>0.80 &amp; 0.90</td>
<td>0.86 &amp; 0.97</td>
</tr>
<tr>
<td>Test results of: 0.80 vs. H1: p = 0.80</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

*‘*’, ‘#’ 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 AFTP U-Sling, disappearance of low rectocele and perineocoele 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 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 enterocoele, 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.,10 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 macroprop 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 1 billion p.a.17 Chronic pelvic pain is another disabling condition which occurs in 10-20% of women 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 defecation13 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

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 Reconstrucive Surgery of Pelvic Floor
University Milano Bicocca, San Gerardo Hospital
Monza, June 4-6, 2015

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Last 4-5-6 June, the 3rd International Course on Functional Reconstrucrive 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 Spezzini (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.

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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 Martius1 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 Theory2 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.3–5 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.3–5

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 polypropylene slings to repair damaged suspensory ligaments according to the Theory.3–5

The reaction to my initial results with these surgical methods3–5 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 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, 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. 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. Grade 1 was defined as prolapse to the mid-vagina, grade 2 prolapse extending to the introitus, grade 3 extending 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).

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), **Cure:** less than 2 times.
- **Bladder emptying difficulty:** Presence of at least one of these symptoms:
  - 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% wet 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 cystotomy 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 using the Halfway Classification System according to Baden-Walker.

In all 198 patients a posterior intravaginal sling-plasty (pIVS) according to Peter Petros was performed with repair of all 3 DeLancey levels following the surgical principles described by Petros. Additionally the tape was fixed to the sacrospinous ligament on both sides with a prolene su- ture 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 we incorporated patients with (n=66 group “HX”) and without previous hys-

<table>
<thead>
<tr>
<th>Table 1. – Distribution of symptoms in the two groups: Patients after „hysterectomy =HX“ and with „no hysterectomy = NoHX“.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No HX n=132 (100%)</strong></td>
</tr>
<tr>
<td><strong>Frequency, urge</strong></td>
</tr>
<tr>
<td><strong>Nocturia</strong></td>
</tr>
<tr>
<td><strong>Pelvic pain</strong></td>
</tr>
<tr>
<td><strong>Bladder emptying problem</strong></td>
</tr>
<tr>
<td><strong>Urge incontinence</strong></td>
</tr>
<tr>
<td><strong>Stress incontinence</strong></td>
</tr>
<tr>
<td><strong>Stool outlet problems</strong></td>
</tr>
<tr>
<td><strong>Fecal incontinence</strong></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Table 2. – Distribution of prolapse grades in all patients n = 198 (100%).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Grade 1</strong></td>
</tr>
<tr>
<td>Pre-op n=198</td>
</tr>
<tr>
<td>(7.5%)</td>
</tr>
</tbody>
</table>
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 extra peritoneal haematomas in the cranial rectovaginal space evacuated spontaneously. 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>
<thead>
<tr>
<th>post op</th>
<th>normal</th>
<th>improved</th>
<th>unchanged</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=40 one year after OP</td>
<td>32 (80%)</td>
<td>5 (12.5%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>HX one year after OP</td>
<td>22 (79%)</td>
<td>3 (11%)</td>
<td>3 (10%)</td>
</tr>
</tbody>
</table>

**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).

**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).

**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).

**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>
<thead>
<tr>
<th>post op</th>
<th>normal</th>
<th>improved</th>
<th>unchanged</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=23 one year after OP</td>
<td>15 (65%)</td>
<td>6 (26%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>HX one year after OP</td>
<td>13 (60%)</td>
<td>6 (30%)</td>
<td>2 (10%)</td>
</tr>
</tbody>
</table>

**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>
<thead>
<tr>
<th>post op</th>
<th>normal</th>
<th>improved</th>
<th>unchanged</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=40 one year after OP</td>
<td>30 (75%)</td>
<td>5 (12.5%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>HX n=30 one year after OP</td>
<td>24 (92%)</td>
<td>3 (10%)</td>
<td>3 (10%)</td>
</tr>
</tbody>
</table>

**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>
<thead>
<tr>
<th>post op</th>
<th>normal</th>
<th>improved</th>
<th>unchanged</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=25 one year after OP</td>
<td>20 (80%)</td>
<td>3 (12%)</td>
<td>2 (8%)</td>
</tr>
<tr>
<td>HX n=30 one year after OP</td>
<td>24 (92%)</td>
<td>3 (10%)</td>
<td>3 (10%)</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>frequency</th>
<th>9 to 12</th>
<th>&gt;12</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=81 pre OP</td>
<td>30 (37%)</td>
<td>51 (63%)</td>
</tr>
<tr>
<td>NOHX one year after OP</td>
<td>60 (81%)</td>
<td>11 (14%)</td>
</tr>
<tr>
<td>HX n=46 pre OP</td>
<td>18 (39%)</td>
<td>28 (61%)</td>
</tr>
<tr>
<td>HX one year after OP</td>
<td>36 (79%)</td>
<td>7 (14%)</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>frequency</th>
<th>&lt;2</th>
<th>2 to 4</th>
<th>&gt;4</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=42 pre OP</td>
<td>24 (56%)</td>
<td>18 (44%)</td>
<td></td>
</tr>
<tr>
<td>NOHX one year after OP</td>
<td>33 (79%)</td>
<td>6 (14%)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>HX n=46 pre OP</td>
<td>18 (86%)</td>
<td>3 (14%)</td>
<td></td>
</tr>
<tr>
<td>HX one year after OP</td>
<td>17 (81%)</td>
<td>3 (14%)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>

**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.

**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.

**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.

**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.

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

<table>
<thead>
<tr>
<th>post op</th>
<th>normal</th>
<th>improved</th>
<th>unchanged</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=51 one year after OP</td>
<td>25 (81%)</td>
<td>4 (13%)</td>
<td>2 (6%) *</td>
</tr>
<tr>
<td>HX n=25 one year after OP</td>
<td>20 (79%)</td>
<td>4 (16%)</td>
<td>1 (5%) *</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>post op</th>
<th>cured</th>
<th>improved</th>
<th>unchanged</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=132 one year after OP</td>
<td>107 (81%)</td>
<td>16 (12%)</td>
<td>9 (7%)</td>
</tr>
<tr>
<td>HX n=66 one year after OP</td>
<td>52 (79%)</td>
<td>10 (15%)</td>
<td>4 (6%)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>post op</th>
<th>Tremendous</th>
<th>Little or no effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOHX n=132 one year after OP</td>
<td>113 (86%)</td>
<td>19 (14%)</td>
</tr>
<tr>
<td>HX n=66 one year after OP</td>
<td>56 (85%)</td>
<td>10 (15%)</td>
</tr>
</tbody>
</table>

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 anaesthesia.

DISCUSSION

In 1946 Martius 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%. Previous and lifetime risk of undergoing POP between 11 and 19% 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 surgery lead to complete restitution in a range of 60% to 95%. The difference between the HX- and NOHX-groups is significant. Compared with our data from 2004 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 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 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.

Complications and recurrences are more likely in patients with higher POP grades. A complete protrusion of all prolapse can not be fixed surgically, hence a recurrence is frequent. 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 case. We had no recurrence in both groups. Only 2 of the uterus- and none of the no-uterus-group developed a de novo cystocele.

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 case. 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 and Nygaard et al. 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% up to 63%. 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. 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.

<table>
<thead>
<tr>
<th>Cure rate</th>
<th>frequency</th>
<th>nocturia</th>
<th>emptying</th>
<th>pelvic pain</th>
<th>quality of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>78%</td>
<td>78%</td>
<td>81%</td>
<td>71%</td>
<td>86%</td>
</tr>
<tr>
<td>2015</td>
<td>81%</td>
<td>81%</td>
<td>79%</td>
<td>79%</td>
<td>85%</td>
</tr>
</tbody>
</table>

Klaus Goeschen

In 1946 Martius 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%. Previous and lifetime risk of undergoing POP between 11 and 19% 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.
Our strategy is to reconstruct, on the base of Petros Integral Theory and DeLancey’s three level repair, all damaged compartments simultaneously using artificial mesh for damaged ligaments or fascia. This can only be done vaginally.

Bojahr 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 insufficient as well.

Therefore, it is not surprising that Sivaslioglu 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. 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, demonstrates that surgical success rates after sacrospinous ligament fixation (SSLF) or uterosacral ligament vaginal vault suspension (ULS) ranged between 60.5% and 59.2% respectively. In our opinion, these not convincing data are mainly due to the fact, that damaged tissue was approximated to damaged tissue and not reinforced by artificial 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 enterocoele 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. Therefore, according to the recent literature, the possibility for enterocele formation.

Furthermore, unilateral SSLF pulls the vagina to one side. Therefore, 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 enterocoele formation.

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

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

<table>
<thead>
<tr>
<th></th>
<th>grade I (%)</th>
<th>grade II (%)</th>
<th>grade III (%)</th>
<th>grade IV (%)</th>
<th>Normal &gt;1 year after OP (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swift</td>
<td>51</td>
<td>46,5</td>
<td>2,5</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Nygaard</td>
<td>34</td>
<td>64</td>
<td>2</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Bojahr</td>
<td>23,5</td>
<td>51</td>
<td>24,5</td>
<td>1</td>
<td>77,6</td>
</tr>
<tr>
<td>Barber</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ULS</td>
<td>37,3</td>
<td>59</td>
<td>3,7</td>
<td>59,2</td>
<td></td>
</tr>
<tr>
<td>SSLF</td>
<td>39,3</td>
<td>54,8</td>
<td>5,9</td>
<td>60,5</td>
<td></td>
</tr>
<tr>
<td>Goeschen</td>
<td>2004</td>
<td>38</td>
<td>52</td>
<td>10</td>
<td>90</td>
</tr>
<tr>
<td>Goeschen</td>
<td>2015</td>
<td>7,5</td>
<td>19,5</td>
<td>54</td>
<td>19</td>
</tr>
</tbody>
</table>

pared with anterior colpoporrhaphy alone, however is still in a level of 14% vs. 49%.

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

Of our patients 96 (49%) presented a concomitant anterior or 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 additionally 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. 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 Schieritz and Meschia 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 cystometry and so called simulated operations. 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 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., lead to a statistically significant improvement of the anatomy and decrease of recurrence rate.

### REFERENCES

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6 Petros PE & Ulmsten U. Urethral pressure increase on effort originates from within the urethra, and continence from muscle-vaginal closure. Neurourology and Urodynamics, 1995; 14: 139-150.
25 Goeschen K. Review: Role of Uterosacral Ligaments in the Causation and Cure of Chronic Pelvic Pain Syndrome J Pelviperineology. 2015; 34-02.
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 (25%), 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 utmost importance to support fibro-muscular vaginal structures in the posterior compartment, and therefore in the long-term to prevent vaginal prolapse, urinary and fecal 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 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 pubococygeal 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 urotero-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 USL. 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 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” 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 physiobonatomy 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.

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 proctological field, where, at the moment the role of conservative treatment (rehabilitation, SNS) is highly regarded both in constipation and in fecal incontinence.

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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, University Rockhampton, Australia

Abstract: Data is presented indicating that nocturia and other “posterior fornix” symptoms such as urgency, abnormal emptying and chronic pelvic pain can be cured/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; 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. A recent supplement in Neurourology and Urodynamics more extensively investigated this problem, summarizing current thoughts on etiology, renal physiology, economic impact, effect on patient quality of life, role of pharmacotherapy and future research. The conclusions were that nocturia has a major effect on quality of life, costs the community up to 62 billion dollars p.a. 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. 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. 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.

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, but was abandoned by 1994 in favour of the posterior sling (Infracoccygeal Sacropexy or Posterior IVS) because of diminishing longer term cure rates. However, in the context of nocturia being an “incurable disease”, 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 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. 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%. In 2005, Sivaslioglu reported cure rates for pelvic pain 82%, urgency 75%, nocturia 86%, ‘obstructed’ micturition 93%. In 2007, Abendstein reported cure rates for urge incontinence 76%, pelvic pain 79%, nocturia 86%.

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. 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.

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 stimulated, activating the micturition reflex. If the uterosacral ligaments (USL) are loose, 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. Cure rates reported after posterior TFS (Tissue Fixation System) sling 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, 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. All patients 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.

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

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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<0.001) 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 Lancey4 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,56 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 urodynamic 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 Ulmsten7 such as abnormal emptying of the bladder,
frequency, urgency, nocturia, fecal incontinence, obstructed defecation or pelvic pain.

Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) form and International Urogynecological Association (IU-GA) and International Continence Society (ICS) definitions were also included in the questionnaire. 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 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 saccrospinous 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.

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**Table 1. – Patient demographics (n = 267).**

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

**Figure 1. – Surgical algorithm.**

**Figure 2. – Surgical instruments.**

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

The pubocervical fascia was narrowed with U-sutures to the remaining sacrospinous sutures, one right and one left. 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 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. One prolene suture from each side was stiched through the middle arcus tendineus fasciae pelvis (ATFP). Extensive diathermy was used to destroy the superficial vaginal epithelium covering the mesh. The skin incision was closed. The remaining 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.

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

<table>
<thead>
<tr>
<th>Repair of the anterior vaginal wall:</th>
</tr>
</thead>
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| 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 sacrospinous sutures on both sides were fixed to the free lower two ends of the meshes and tied at the end of the procedure.

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. – Preoperative and postoperative prolapse grades.

<table>
<thead>
<tr>
<th>Repair of the posterior vaginal wall:</th>
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| 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.
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 82.4% 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 Petsos et al.⁷ created a new vaginal procedure for pelvic floor surgery based on the Integral Theory and DeLancey’s 3-level-classification.⁷ Using Petsos new treatment high cure rates for widely varied symptoms such as UI, urgency, nocturia, chronic pelvic pain were reported by Farnsworth in 2002 and confirmed by Goeschen in 2004. In more recent publications anatomical success rates ranged from 37% to 100%.²⁻¹²⁻¹⁸

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 liga-ment, 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 deficit 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 anatomical 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 Petsos strategy based on DeLancey’s recommendations. Meanwhile this idea got support by Karram and Maher.²⁶ 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 and later on for replacement of the uterus and the fornix. The success rates of SSLF range between 64% and 97%. 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.

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. Our complex vaginal reconstruction is performed 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 and still at least two times higher than posteriorly. Weber et al 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.

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%. Already in 2001 Weber et al and Sand et al 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 fix the 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 2 year and still satisfied with the surgery.

A prolapsed uterus or vaginal cuff can be repaired either abdominally or vaginally. Up to now numerous surgeons still favor the abdominal way to restore the anatomy or to cure symptoms either by laparoscopy or by laparotomy. 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%. Consequently recent Cochrane analyses and review articles 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. 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 enterocoele and pain. Our combination allows a physiological reconstruction of all damaged structures including a normal vaginal axis. In literature conflicting data still exist regarding the effectiveness of POP surgery with and without uterine preservation. Dietz et al. report that uterine preservation is associated with more apical prolapse recurrences than vaginal hysterectomy at the time of POP-repair. These results conflict with data by Maher et al., who found vaginal sacrospinous hysterepopexy to be equally effective to vaginal hysterectomy combined with sacrospinous fixation.

In our study no patient underwent concomitant hysterectomy. However, if the hypothesis is valid that uterine 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, 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. Complications of SSLF are extensively reviewed by Tseng et al. 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%.
Long term results of modified posterior intravaginal slingplasty (P-IVS) in patients with pelvic organ prolapse

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

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

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 transtuburator 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

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Pienology and anorectal manometry/solid sphere test to measure tone, contraction to rule out organic diseases including occult prolapses or stenoses, provides a series of diagnostic tests: proctoscopy and colonoscopy makes it more difficult to identify which patients require further CCS, Agachan, Rome criteria, AMS, etc). Not using these items type of leakage and of the difficulty on expelling stools (Wexner, 2009; 185: 1299-304; discussion 304-6).


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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 coloscopy 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.

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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.
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.