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63 ISPP Congress 2019, October 6th-8th – Treviso (Italy)
   Pelvic Floor Disorders: Current Status, Technological Advances and Perspectives
A MINIMALLY INVASIVE AND EFFECTIVE BRIDGE BETWEEN CONSERVATIVE THERAPY AND SURGERY FOR BOWEL INCONTINENCE

EFFICIENT
Performed in an outpatient setting

SAFE
Less than 1% complication rate*

EFFECTIVE
Up to 84% of patients experienced significant improvement*

QUICK RECOVERY
Return to normal activities in a few days

SECCA PATIENTS 84% experienced significant improvement

Greater Quality of Life Less than 1% complications

Distributore esclusivo:

MEDERI

INNOVAMEDICA
There have been several recent attempts to resuscitate the pressure transmission theory closure mechanism for the bladder\(^1,2\) and with it, the Integral Theory (IT) itself. How theories can be validated or invalidated has been defined by the lifetime work of Karl Popper, the most eminent philosopher of science of the 20th Century\(^3\). Popper’s view is that no theory is perfect, and that only by being continually challenged, can it be improved, modified or discarded. All these outcomes are good for science.

In 1990, the late Ulf Ulmsten and Peter Petros disproved the main prediction of Enhorning’s theory, elevating the bladder into the “pressure equalization zone”. Stress incontinence\(^1\) cure was demonstrated in 30/30 patients with no evidence of bladder elevation on post-operative x-ray\(^5\). This finding emphasizes one key rule for validation or invalidation of theories, it has to be done by experiment, which has never been done by any critic of the Integral Theory. I report two more studies which experimentally invalidate the pressure equalization theory.

A 1995 study concerned an experiment during a midurethral sling operation performed under LA\(^6\). Two Gaeltec catheters, measured urethral and bladder pressures in equivalent positions inside and outside the bladder and urethra during coughing (Table 1). The pressures inside the bladder were slightly less than outside, but universally greater inside the urethra. Only an active reflex muscle action can explain these findings, which are not possible with a passive “pressure transmission” mechanism.

In a 2009 study by Kamo et al.\(^7\), urethral closure mechanisms during abrupt elevation of intravesical pressure \(P(ves)\) were investigated in a rat experiment. During sneezing, the middle urethral closing response was observed and remained intact even after opening the abdomen. According to the pressure equalization theory, there would be no response to sneezing if the abdomen was open.

### Conflict of interest
NIL

### REFERENCES
1. Bergstrom BS More about the urethral hanging theory (UHT) and a response to Dr. Peter Petros’ comments Article in Neurourology and Urodynamics. March 2019 doi: 10.1002/nau.23960

### Table 1  *Intraoperative Cough Pressure Transmission, Vagina Intact*

<table>
<thead>
<tr>
<th>Patient</th>
<th>Outside bladder ((T_1))</th>
<th>Inside bladder ((T_2))</th>
<th>Inside urethra ((T_1))</th>
<th>Inside urethra ((T_2))</th>
</tr>
</thead>
<tbody>
<tr>
<td>ER</td>
<td>30.00</td>
<td>26.00</td>
<td>18.00</td>
<td>23.00</td>
</tr>
<tr>
<td>KW</td>
<td>22.00</td>
<td>20.00</td>
<td>4.00</td>
<td>10.00</td>
</tr>
<tr>
<td>PB</td>
<td>75.00</td>
<td>73.00</td>
<td>40.00</td>
<td>60.00</td>
</tr>
<tr>
<td>TH</td>
<td>70.00</td>
<td>65.00</td>
<td>80.00</td>
<td>100.00</td>
</tr>
<tr>
<td>MF</td>
<td>22.00</td>
<td>19.00</td>
<td>24.00</td>
<td>45.00</td>
</tr>
<tr>
<td>Mean</td>
<td>44.00</td>
<td>41.00</td>
<td>33.00</td>
<td>47.60</td>
</tr>
</tbody>
</table>

\(*T_1\) is positioned outside the organ and \(T_2\) inside the organ

* It is important to note that this debate on the pressure transmission theory closure mechanism for the bladder concerns only a small part of the 2018 iteration of the IT\(^4\), which states: “Prolapse, bladder, bowel and idiopathic pain symptoms mainly derive, for different reasons, from laxity in the vagina or its suspensory ligaments, a result of altered collagen/elastin.”
Identification of peri-prostatic neurovascular fibers before and after radical prostatectomy by means of diffusion tensor imaging (DTI) with clinical correlations: initial experience

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Abstract: Aim To evaluate if Diffusion Tensor Imaging (DTI) is able to detect morphological changes of peri-prostatic neurovascular fibers (PNF) before and after robot-assisted radical prostatectomy (RARP) and if these changes are related to urinary incontinence (UI) and erectile dysfunction (ED). Materials and methods: From October 2014 and August 2017 26 patients with biopsy-proven prostate cancer underwent prostate multi-parametric magnetic resonance imaging (mp-MRI) including DTI sequencing before and six months after; RARP. Images were analyzed by placing six regions of interest (ROI) respectively at the base, mid-gland and apex, one for each side, to obtain tractography reconstruction of the PNF. Patients were asked to complete an International Consultation Incontinence Questionnaire – Short Form (ICIQ-SF) and International Index of Erectile Function (IIEF-5) questionnaires before RARP and 6 months postoperatively. Fractional anisotropy (FA), number (N) and length (L) of PNF before and after RARP were compared by means of Student’s t-test; Spearman test was used to evaluate the correlation between DTI parameters and questionnaires scores. We observed a significant difference in N values before and after RARP (p<0.001) and a negative correlation between IIEF-5 score and post-operative FA values at both the right (rho=-0.42; p=0.0456) and left (rho=-0.66; p=0.0006) base of the prostate. DTI with tractography of PNF is able to detect quantitative changes in N, L and FA values in PNF after RARP. In particular we observed an inverse correlation between FA of PNF and ED at 6 months after RARP. Further investigations are needed to confirm this trend..

Keywords: MRI; Diffusion Tensor Imaging; RARP; Urinary incontinence; Erectile dysfunction

INTRODUCTION
In clinical practice, robot-assisted radical prostatectomy (RARP) is an effective option for treating prostate cancer (PCA) along with all clinical risk classes 1. However, drawbacks related to the procedure include urinary incontinence (UI) and erectile dysfunction (ED) 1. Nerve-sparing techniques during RARP have shown to reduce the risk of both UI and ED, whose rates vary from 89% to 42% and 32% to 18% for unilateral and bilateral nerve sparing, respectively 2-6. Because the number of preserved periprostatic neurovascular fibers (PNFs) associates with erectile function recovery 7,8, imaging visualization of these fibers is becoming an emerging issue 9.

Multiparametric magnetic resonance imaging (mMRI), which combines T2-weighted (T2W) with dynamic contrast-enhanced (DCE-MRI) and diffusion-weighted imaging (DWI), has an important role for diagnosing and staging PCA 1,10. Furthermore, MRI provides an excellent depiction of pelvic anatomy and also predicts the extent of NVB involvement 11-12. Although MRI is able to assess extracapsular invasion of PCA, the visualization of PNFs remains still difficult 12,13. Diffusion tensor imaging (DTI) is a new MRI modality in the field of Neuroimaging, it is noninvasive and provides a sharp depiction of central and peripheral nervous fibers 14-24. Recently, it has been shown that DTI, which is based on the sensitivity of “anisotropic diffusion” of the water protons measured in a micro-structural environment of biological tissues, is able to map PNFs 9,26-8. Indeed, the anisotropic diffusion represents a condition in which the diffusion of water protons is not casual or “Brownian” but oriented along a determined axis; furthermore, this condition occurs in biological tissues with a strictly orientated texture, such as nervous central and peripheral fibers, including the PNFs 14. DTI is able to quantify this phenomenon throughout the measurement of Fractional Anisotropy (FA) for each single voxel in at least 6 non-coplanar and non-coplanar directions; by the integration of FA of all voxels it becomes possible to represent the direction of nerve fibers in all three dimensions of space, giving both quantitative and qualitative anatomic information. The aim of the study is to evaluate if DTI is able to detect the changes of the PNFs before and after nerve-sparing RARP, and if these changes are related to UI and ED.

MATERIALS AND METHODS

Study population
A prospective study was carried out in collaboration between the Institute of Radiology and the Urology Department of the University of Verona. The study had institutional review board approval. Each patient provided informed consent for all MRI examinations.

In a period ranging from October 2014 to August 2017, the study collected 31 PCA patients underwent RARP with “nerve-sparing” intent. Exclusion criteria were absolute contraindications for the conduct of the MRI, severe post-surgical complications, failure to adhere to 6-month follow-up, disease relapse or death. Patients were classified according to the D’Amico cancer class risk categories 25. Clinical staging was computed according to the 2002 American Joint Committee on Cancer staging system for PCA. RARP, which was associated with the unilateral or bilateral nerve-sparing technique, was delivered by the Si da Vinci Robot System (Intuitive Surgical, Inc, Sunnyvale, CA, USA) and was performed through the transperitoneal approach with antegrade prostatic dissection 30,31. A transurethral 18 Fr Foley catheter was placed in all cases and the balloon was inflated with 7 cubic centimeters (cc) of physiologic solution. Before March 2017, a postoperative drain was placed in the pelvis, which was removed on a postoperative day (POD) one if the output was less than 150 mL/24 h. If the postoperative outcome was unevent-
ful, patients were discharged on POD 4 with the catheter removed on POD 12 without cystography. Extended PLND was performed according to a standard template, which included the obturator fossa, external, internal and common iliac lymph nodes. The operating time was calculated as the interval between incision of the first laparoscopic port and suture of the last laparoscopic port. The surgical procedures were performed by two experienced surgeons. Prophylaxis of deep venous thrombosis with low molecular weight heparin was performed in all cases elected to RARP with extended PLND and with comorbidity risk factors. In all cases, early mobilization was activated starting from the day of surgery (POD 0). Deep venous thrombosis prophylaxis was prolonged till POD 28. In the surgical specimen, tumors were graded and staged according to the modified Gleason score system and TNM classification system. All patients, before and six months after surgery, were assessed by the International Index of Erectile Function (IIEF-5 questionnaire) and International Consultation Incontinence Questionnaire-Short Form, (ICIQ-SF).

MRI technique with DTI study

All MRI investigations were performed with DTI sequences on 1.5T (Ingenia, Philips Medical Systems, Eindhoven, Netherlands). The MRI protocol is shown in Table 1.

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>Plane</th>
<th>Repetition &amp; Echo Time (ms)</th>
<th>Section Thickness (mm)</th>
<th>FOV (mm)</th>
<th>Flip angle</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>T2 TSE</td>
<td>Axial</td>
<td>4100/100</td>
<td>4</td>
<td>380x340</td>
<td>90°</td>
<td>1'30&quot;</td>
</tr>
<tr>
<td>T2 TSE (HR)</td>
<td>Sagittal</td>
<td>2650/90</td>
<td>3.5</td>
<td>200x200</td>
<td>90°</td>
<td>1'40&quot;</td>
</tr>
<tr>
<td>T2 TSE (HR)</td>
<td>Coronal</td>
<td>2500/100</td>
<td>3.5</td>
<td>160x160</td>
<td>90°</td>
<td>3'25&quot;</td>
</tr>
<tr>
<td>T2 TSE (HR)</td>
<td>Axial</td>
<td>3730/90</td>
<td>3.5</td>
<td>160x160</td>
<td>90°</td>
<td>4'10&quot;</td>
</tr>
<tr>
<td>DWI</td>
<td>Axial</td>
<td>4000/90</td>
<td>3.5</td>
<td>300x300</td>
<td>90°</td>
<td>7'47&quot;</td>
</tr>
<tr>
<td>DTI</td>
<td>Axial</td>
<td>1449/88</td>
<td>3</td>
<td>220x220</td>
<td>90°</td>
<td>3'14&quot;</td>
</tr>
<tr>
<td>T1 DIXON Dynamic phase</td>
<td>Axial</td>
<td>4/2</td>
<td>3.5</td>
<td>200x220</td>
<td>90°</td>
<td>3'17&quot;</td>
</tr>
<tr>
<td>b-SSFP</td>
<td>Axial</td>
<td>5000/80</td>
<td>6</td>
<td>400x350</td>
<td>90°</td>
<td>51’</td>
</tr>
</tbody>
</table>

Figure 1A. Prostate apex

Figure 1C. The middle third of the prostate gland

Figure 1E. Prostate base

Fig. 1B. Equivalent plane to prostate apex in a post – RP MRI exam

Fig. 1D. Equivalent plane to the third medium in post-RP MRI exam

Figure 1F. Plane equivalent to the prostate base in post-RP MRI exam
Identification of peri-prostatic neurovascular fibers before and after radical prostatectomy by means of diffusion tensor imaging (DTI)

Table 2. Some clinical and pathological characteristics of 31 patients to undergo an radical prostatectomy nerve-sparing

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N. patients</th>
<th>Age (years): Mean (±SD)</th>
<th>Total prostatic volume: Mean (±SD)</th>
<th>PSA*: Mean (±SD)</th>
<th>Nerve-sparing right: N. (%)</th>
<th>No nerve-sparing right: N. (%)</th>
<th>Nerve-sparing left: N. (%)</th>
<th>No nerve-sparing left: N. (%)</th>
<th>Marginal resection: N. (%)</th>
<th>Pathological TNM: N. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>31</td>
<td>64.03 (±7.05)</td>
<td>45.72 (±22.18)</td>
<td>9.05 (±11.42)</td>
<td>24 (77.4)</td>
<td>7 (22.6)</td>
<td>25 (80.6)</td>
<td>6 (19.4)</td>
<td>20 (64.5)</td>
<td>pT2aNxMx 3 (9.7)</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>pT2bNxMx 1 (3.3)</td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
<td>pT2cNxMx 19 (61.2)</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>pT3aNxMx 4 (12.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>pT3bNxMx 4 (12.9)</td>
</tr>
<tr>
<td>Gleason score:</td>
<td>Median</td>
<td>7 (4-9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sum</td>
</tr>
<tr>
<td></td>
<td>Median (range)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sum 7 (4-9)</td>
</tr>
</tbody>
</table>

Netherlands) using a 32 multi-channel surface coil placed on the lower abdomen. All Patients were fasting with solid foods from 4 to 6 hours before the examination. Peristalsis was suppressed by administering 20 mg intramuscular scopolamine butyl bromide (Buscapan, Boehringer Ingelheim, Yamagata, Japan). Patients were asked to empty the bladder about half of its volume in order to limit involuntary movements. The total duration of the examination was approximately 26 minutes.

The individual sequences and their duration are summarized in Table 1. All MRI investigations were evaluated independently at least by two radiologists who received brief training on PNP. For each RM survey, each operator performed at least two sets of measurements. Prior to the reconstruction of the hinterland, an image recording was performed to correct any artifacts from motion. Track reconstructions were performed directly on the MRI control console, using the Philips Fiber Track application included in the 4.1.3 release of machine management software by designing regions of interest (ROI) of different shapes in the periprostatic adipose tissue using as reference the T2-dependent axial images fused with the DTI recorded images and taking care of not to include muscle fibers of the bladder or shutter muscles to avoid being included in the reconstruction.

RESULTS

The study included 31 patients who were assessed by pre-operative MRI and underwent RARP with nerve-sparing intent. Table 2 shows the clinical and pathologic features of the study population. Mean clinical features were as follows: age 64.03, prostate volume 45.72 cc, total prostate-specific antigen (PSA) 9.05. Neurovascular bundles were preserved on the right and left side in 77.4% and 80.6% of cases, respectively. Involvement of a surgical margin was detected in 11 cases (35.5%). In the surgical specimen, the disease was extraprostatic in 8 cases (28.8%) with extracapsular extension in 4 (12.9%) and seminal vesicle invasion in 4 cases (12.9%). The median Gleason score was 7. Five of the 31 patients were not evaluated by MRI after RARP. Table 3 illustrates the results (mean ± SD) of MRI measurements related to anisotropic fraction, number and length of fibers for each level of the prostate gland (base, mid-gland and apex) at six months from RARP in 26 patients. In par-

Table 3. Mean and Standard Deviation (±SD) of anisotropic fraction, N. of fibers and fibers length for each level of the prostate gland at 6 months from radical prostatectomy nerve-sparing.

<table>
<thead>
<tr>
<th>Level of prostate gland</th>
<th>N. patients</th>
<th>Base right</th>
<th>Base left</th>
<th>Mid right</th>
<th>Mid left</th>
<th>Apex right</th>
<th>Apex left</th>
</tr>
</thead>
<tbody>
<tr>
<td>N. patients</td>
<td>26</td>
<td>0.46 (±0.05)</td>
<td>0.44 (±0.05)</td>
<td>0.46 (±0.07)</td>
<td>0.46 (±0.05)</td>
<td>0.40 (±0.05)</td>
<td>0.41 (±0.06)</td>
</tr>
<tr>
<td>Anisotropic fraction</td>
<td>26</td>
<td>0.46 (±0.07)</td>
<td>0.46 (±0.05)</td>
<td>0.46 (±0.07)</td>
<td>0.46 (±0.05)</td>
<td>0.40 (±0.05)</td>
<td>0.41 (±0.06)</td>
</tr>
<tr>
<td>N. of fibers</td>
<td>26</td>
<td>87.35 (±31.35)</td>
<td>90.92 (±31.66)</td>
<td>66.58 (±25.83)</td>
<td>62.15 (±23.82)</td>
<td>42.62 (±16.19)</td>
<td>41.00 (±15.79)</td>
</tr>
<tr>
<td>Fibers length</td>
<td>26</td>
<td>13.16 (±2.63)</td>
<td>13.18 (±2.36)</td>
<td>14.17 (±2.96)</td>
<td>13.79 (±2.85)</td>
<td>14.38 (±3.27)</td>
<td>13.84 (±2.95)</td>
</tr>
</tbody>
</table>
particular, at six months the number of fibers tracts was significantly decreased at base, mid-gland and apex for both right and left side (p= 0.01 – data not shown). Three of the 26 cases who were evaluated by MRI before and six months after RARP did not have nerve-sparing surgery. Table 4 shows correlations of IIEF-5 score with MRI measurements including anisotropic fraction, number and length of fibers for each level of the prostate gland (base, mid-gland and apex) at six months from radical prostatectomy nerve-sparing intent in 23 patients. There was a significant negative correlation between IIEF-5 score and anisotropic fraction measurements at both right (Pearson’s coefficient = - 0.42068; p=0.0456) and left (Pearson’s coefficient = - 0.66120; p=0.0006) base of the prostate, respectively. It was not detected any significant correlation between IIEF-5 score and anisotropic fraction at the other levels of the gland as well as the number of fibers. Finally, the IIEF-5 score test correlated positively to the length of fibers located at the right apex of the gland (Pearson’s coefficient = 0.42546; p=0.0430), but no significant correlation was detected at the other levels of the prostate. Table 5 shows correlations of ICIQ-SF score test with MRI measurements including anisotropic fraction, number and length of fibers for each level of the prostate.

DISCUSSION

The aim of the present study was to evaluate if DTI is able to detect the changes of the PNFs before and after prostatectomy and if these changes are related to postsurgical complications, such as urinary incontinence and erectile dysfunction. Despite conventional MRI has proven to be a useful modality for the diagnosis of extracapsular invasion of prostate cancer, the visualization of the PNFs remains still difficult. Recently, Diffusion Tensor Imaging (DTI) has been successfully adopted for mapping of the PNFs. Although the recent introduction of “nerve-sparing” techniques has shown to be able to reduce the incidence of these complications in comparison with the “non-nerve-sparing” approaches, their incidence is still not negligible and directly related to the number of the preserved fibers during prostatectomy. In our study, in agreement with Kitajima

<table>
<thead>
<tr>
<th>Level of prostate gland</th>
<th>Base right</th>
<th>Base left</th>
<th>Mid right</th>
<th>Mid left</th>
<th>Apex right</th>
<th>Apex left</th>
</tr>
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<tbody>
<tr>
<td>N. patients</td>
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<td>23</td>
<td>23</td>
<td>23</td>
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<td>23</td>
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<tr>
<td>Anisotropic fraction (r)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Erectile dysfunction</td>
<td>-0.42068</td>
<td>-0.66120</td>
<td>-0.25438</td>
<td>-0.37252</td>
<td>-0.38025</td>
<td>-0.38739</td>
</tr>
<tr>
<td>p=0.0456</td>
<td>p=0.0006</td>
<td>p=0.2415</td>
<td>p=0.0800</td>
<td>p=0.0735</td>
<td>p=0.0678</td>
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<tr>
<td>N. of fibers (r)</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td>0.25587</td>
<td>0.30807</td>
<td>0.13434</td>
<td>-0.12201</td>
<td>0.33809</td>
<td>-0.00850</td>
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<tr>
<td>p=0.2386</td>
<td>p=0.1527</td>
<td>p=5411</td>
<td>p=0.5792</td>
<td>p=0.1146</td>
<td>p=0.9693</td>
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<tr>
<td>Fibers length (r)</td>
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<td></td>
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<tr>
<td>Erectile dysfunction</td>
<td>0.25737</td>
<td>0.19402</td>
<td>0.23542</td>
<td>0.30084</td>
<td>0.42546</td>
<td>0.15761</td>
</tr>
<tr>
<td>p=0.2358</td>
<td>p=0.3750</td>
<td>p=0.2795</td>
<td>p=0.1631</td>
<td>p=0.0430</td>
<td>p=0.4726</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Level of prostate gland</th>
<th>Base right</th>
<th>Base left</th>
<th>Mid right</th>
<th>Mid left</th>
<th>Apex right</th>
<th>Apex left</th>
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<td>N. patients</td>
<td>23</td>
<td>23</td>
<td>23</td>
<td>23</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Anisotropic fraction (r)</td>
<td></td>
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et al., the number of fiber tracts after RARP was significantly decreased at the base, mid-gland, and apex for both right and left side (p<0.01). In this way, an interesting result of our series, which has not been studied before, is exclusively represented by significant negative correlation between IIEF-5 score and anisotropic fraction measurements at both rights (p=0.0456) and left (p=0.0006) base of the prostate. These results allow us to make some considerations. The first of all that the number of fibers is definitely essential for the recovery of erectile function and finally that the preservation of the fractional anisotropy of PNFs at six months is an indicator of probable erectile dysfunction. From a pathophysiologic point of view this aspect could be related to a difficult transmission of the nerve impulse, as normally happens when nerve fibers have a straight course. As known these findings confirm that erection occurs thanks to the preservation of pelvic plexus, as reported in the past by Walsh, and that sphincter urethra is not innervated predominantly by autonomic component. On the other hand in our study, this latter aspect is justified by the absence of a clear correlation between fractional anisotropy and urinary incontinence. In this regard, the role of the autonomic nervous component is somewhat uncertain and morphological studies in this direction show that the somatic nervous system, thanks to the pudendal nerve, is the predominant nervous component that is responsible for external sphincter innervation. In any case, this study shows some limitations. The major one is the potential misscount of nerve fibers because the number of the track on DTI is not the real number of nerve fibers and because linear non-nerve structures such as fibromuscular tissue, arteries, and veins can concur to generate fiber tracts. Finally, the number of patients included in the study is still small and further large-scale prospective studies are needed.

In conclusion, DTI of the periprostatic neurovascular fibers (PNFs) has demonstrated to be a useful and reproducible technique in detecting the changes of the PNFs induced by RARP. In particular, DTI seems to be a fascinating instrumental evaluation that in the future could play the role of predictive investigation for erectile recovery after RARP.

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DISCLOSURE STATEMENTS
There was no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee. The authors of the publication did not receive any financial support by any grant/research sponsor.

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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.

Gynecology...In analogy with the surgical procedure of radical prostatectomy, the radical hysterectomy operation for cancer is responsible of numerous negative effects on sexual functioning1. This is due to the elimination of a large part of pelvic ligaments and pelvic autonomic nerves notoriously involved in clitoral as penile erection (parasympathetic nervous system), and in female orgasm and ejaculation (orthosympathetic nervous system). These autonomic nerves are located in the sacro-coccygeal plexus in the pelvis. Prostate and uterus are organs embriologically correlated, consequently their radical removal causes gender similar sexual, urinary and anorectal dysfunctions. In fact women following radical hysterectomy have a high incidence of sexual dysfunctions (sexual desire, sexual arousal, orgasmic, and sexual pain disorders, data obtained by a self-reported sexual function questionnaire). The preoperative, 1- and 2-year postoperative, sexual dysfunction rates were 50.5%, 86.9%, and 92.3% respectively becoming eventually stable as shown in the recent study of Wang and Chen2 and age, preserved ovary, preserved posterior vaginal wall length, preoperative stage, radiotherapy, and education background were risk factors associated with sexual dysfunction. A metaanalysis of Xue and Zhu3 demonstrated that the nerve sparing radical hysterectomy was associated with less bladder and anorectal dysfunction and a higher score of Femal Sexual Function Index (FSFI) with a similar rate of cancer recurrence. To confirm the result that Siracusano founded in men, it would be very interesting a study on use of Diffusion Tensor Imaging technique on MRI in the prognosis of sexual dysfunction after radical hysterectomy.

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REFERENCES
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Procto... Surgery for rectal cancer may result in physiologic and psychologic changes that alter a patient’s sexual functioning and quality of life. Most studies examine the male sexual issues of erectile dysfunction and retrograde ejaculation, while female sexual dysfunction is relatively ignored. Women with rectal cancer are reluctant to talk about their sexuality, and if they do, it’s on dyspareunia. Furthermore, validated instruments for measuring sexual functioning have seldom been used in studies of sexual changes after rectal cancer surgery. Data prospectively collected on 295 women who underwent rectal cancer excision, mean age 60.9 years, showed significant impairments in female urinary and sexual outcomes; around half of all cancer survivors experience a decrease in sexual functioning and changes in body image, and with colorectal cancer, the rates can be even higher. In males total mesorectal surgery affects erection and ejaculation in over 82%. Women after rectal cancer surgery are significantly less likely to be sexually active than prior to surgery, their problems being multi-factorial. The type of surgery (abdominoperineal excision vs anterior resection) impact sexual function with less frequent coitus, and being less likely to achieve arousal or orgasm.

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Histopathology findings of the pelvic organ prolapse

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Abstract: Pelvic organ prolapse is a benign condition, which is the result of a weakening of the different components that provide suspension to the pelvic floor. Surgical treatment, traditionally involve a vaginal hysterectomy, although over the last few decades the preservation of the uterus has become more popular. The objective of the paper is to analyze the characteristics of those patients diagnosed with pelvic organ prolapse, whose treatment involved a vaginal hysterectomy and its correlation to the histopathological characteristics. Retrospective, descriptive study. Data recovered from the medical history of patients that underwent surgical treatment for pelvic organ prolapse through vaginal hysterectomy, were analyzed in a 2 years period, in the CHPR, and compared to the pathology results of the uterus. At the level of the cervix, 58.2% presented changes related to the prolapse (acantosis, para and hyperqueratosis) and 43.6% chronic endocervicitis. Findings in the corpus of the uterus were 58.2% atrophy of the endometrium, 21% of endometrial polyps and 30.9% leiomiomas and 1 case of simple hyperplasia without cellular atypias. No malignant lesions were found. The pathology results of the uterus reveal the presence of anatomical changes related to the pelvic organ prolapse and in accordance to the age of the patient, as well as associated pathologies to a lesser extent. As we were able to establish, in most cases the removal of the uterus is not due to a pathology of the uterus itself but to a symptom generated by the failure of the suspension system of the pelvis.

Keywords: Genital prolapse; Pelvic Organ Prolapse; Hysterectomy; Conservative treatment; Histopathology

INTRODUCTION

Pelvic organ prolapse is a very common benign condition, unique to the human species, consequence of bipedalization. It is the result of a weakening of the different components that provide suspension to the pelvic floor, affecting the bi-social wellbeing of the woman. The static of the female genital organs within the pelvis is the consequence between a balance including factors like bipedestation, intrabdominal pressure and structures that provide suspension to the abdominal- pelvic organs. The form and function of these organs is created by a synergy between ligaments, muscles and fascia. This affliction does not present a clinical-anatomical correlation, that is to say, those symptoms generated by different defects may be very diverse among different patients, existing multiple forms of treatment. Knowing with precision each component of the affected anatomical structures allows to find the origin of the organ dysfunction. The variation of symptoms and cascade of events may be secondary to the sum of small imbalances involving structures that maintain form and function. The severity of these symptoms do not correlate with the severity of the organ prolapse. Many women are asymptomatic and do not need treatment. The incidence of symptomatic pelvic organ prolapse is approximately 15%, although it is difficult to estimate due to the lack of methods to evaluate real symptoms and the lack of information regarding patients that in fact make a medical consultation for this matter. It is expected that medical consultations due to symptoms regarding pelvic organ prolapse increase over the next few years due to an increase in life expectancy, especially for women over the age of 65, which means a longer life expectancy post corrective surgery and thus an increase in the possibility of treatment failure and long term complications. This condition presents a recurrence rate in one third of treated patients. Gynecological consults for problems related to genital prolapse are nowadays more frequent as are greater the expectations and demands in regards to treatment. There are a great variety of options when it comes to treatment, non surgical (pelvic floor muscle excercises, pessaries), and surgical. The estimated risk with surgical interventions for prolapse is between 11-19%, with a 29% risk of a second operation. Among those prolapsed compartments, the anterior compartment is the most common, three times more frequent than the posterior compartment and two times more than the apical compartment (uterus or vaginal dome). The pelvic organ prolapse is dynamic and in approximately two thirds of woman more than one compartment is involved. The probability to develop a grade III or IV prolapse in the female population at some time in their lives is around 3 to 6%. The objective of correctional surgery for severe genital prolapse should be the relief of symptoms, maintaining and eventually improving the functionality of the pelvic organs as well as the anatomical reestablishment. Vaginal hysterectomy, including some type of vaginal dome suspension has traditionally been the most common surgical treatment for prolapse of the uterus, despite that the descent of the uterus is a consequence and not a cause of the prolapse, but the preservation of the uterus is a technique that is gaining more ground over time. Over the last few decades, there have been profound changes among women concerning their beliefs and perspectives towards their sexual and reproductive functionality and many women who undergo genital prolapse surgery wish to preserve their uterus. At the time of choosing a procedure, various factors should be taken into account such as age, presence of comorbidities, level of physical activity, the patients preference, as well as the surgical experience and preference of the gynecologist. The objective of this paper is to analyze the clinical and social demographic characteristics of those patients diagnosed with pelvic organ prolapse, who underwent a vaginal hysterectomy and its correlation with the histopathological characteristics of the uterus.

MATERIALS AND METHODS

Descriptive retrospective study. Data taken from medical history charts of patients that underwent a vaginal hysterectomy as a surgical treatment for pelvic organ prolapse and not for pathologies of the uterus itself, between the period

of March 1 2016 through March 1 2017 at the CHPR were analysed and compared to the pathology results of the uterus. The inclusion criteria were those patients who underwent a vaginal hysterectomy as the main treatment for an pelvic organ prolapse.

The variables analyzed among these patients were the age at the moment of consultation, the presence of comorbidities such as hypertension, diabetes, smoking, chronic respiratory disease, body mass index, parity, symptoms that motivated consultation and total grade of organ prolapse, analyzed by component.

RESULTS
55 cases were analyzed. Analysis of the different variables are represented in table 1. The age range with greater incidence was that between 51 and 69 years (36.4%), followed by 61 to 70 years (30.9%). The forms of presentation were: genital tumor (76.4%) and urinary symptoms (50.9%). 58.2% of patients presented a grade III or IV hysterocele.

| TABLE 1. Demographic characteristics and physical findings in patients. |
|-------------------|---|---|
| **Age**          | N (%) | Middle |
| ≥ 50 years       | 1 (1.8) | 47 |
| 51 – 60 years    | 20 (36.4) | 54.9 |
| 61 – 70 years    | 17 (30.9) | 65.2 |
| 71 – 80 years    | 16 (29.1) | 74.5 |
| ≥ 81 years       | 1 (1.8) | 88 |
| **Parity – Vaginal delivery** | | |
| 0                 | 2 (3.6) | - |
| 1                 | 5 (9.1) | 1 |
| 2 – 4             | 31 (56.4) | 2.5 |
| ≥ 5               | 14 (25.4) | 6.6 |
| No data           | 3 (5.5) | - |
| **BMI**           | | |
| 18.5 – 24.9       | 3 (5.5) | 23.2 |
| 25 – 29.9         | 8 (14.5) | 27 |
| ≥ 30              | 6 (10.9) | 36.3 |
| No data           | 38 (69.1) | - |
| **Comorbidities** | | |
| Hypertensión arterial | 30 (54.5) | - |
| Diabetes Mellitus | 8 (14.5) | - |
| Smoker            | 2 (3.6) | - |
| Respiratory pathology | 3 (5.5) | - |
| Dyslipidemia      | 7 (12.7) | - |
| No data           | 4 (7.3) | - |
| **Symptomatology** | | |
| Tumoration         | 42 (76.4) | - |
| IU effort          | 4 (7.3) | - |
| IU urgency         | 8 (14.5) | - |
| IU mixed           | 14 (25.5) | - |
| Incontinence gases| 2 (3.6) | - |
| Incontinence matter| 1 (1.8) | - |
| Other              | 4 (7.3) | - |
| No data            | 5 (9.1) | - |
| **Degree of total genital prolapsed** | | |
| II                | 10 (18.2) | - |
| III               | 23 (41.8) | - |
| IV                | 17 (30.9) | - |
| No data           | 5 (9.1) | - |
| **Degree of uterine prolapse** | | |
| II                | 8 (14.5) | - |
| III               | 16 (29.1) | - |
| IV                | 14 (25.5) | - |
| No data           | 14 (25.5) | - |

In 50 cases only hysterectomy was performed, in 5 cases hysterectomy with annexectomy, in 2 cases of hysterectomy morcellation corresponding to multiple leiomiomas was performed.

The largest uterine dimension measure was in the range of 35 to 110 mm. The weight in a range that went from 35 to 512 grs. Those greater than 100 grs (7 cases) presented endometrial polyps and/or leiomiomas in posterior studies.

At the level of the cervix, 58.2% presented changes related to the prolapse (acantosis, para and hypercheratosis, figure 1) and 43.6% chronic endocervicitis.

Findings in the uterine corpuses were in 58.2% atrophic endometrium (32 cases) figure 2, and 12 cases of endometrial polyps (21%) figure 3, in 17 cases (30.9%) leiomiomas (4 cases associated to polyps) and 1 case of simple hyperplasia without cellular atypias. No malignant lesions were found in this series.

DISCUSSION
The concept that if the uterus is descended it’s removal is necessary dates back to the year 1500, considered the hysterectomy in combination with procedures as the primary

Histopathology findings of the pelvic organ prolapse

- Figure 1. Cervical changes related to the prolapsed
- Figure 2. Atrophic endometrium
- Figure 3. Endometrial polyps
procedure of the prolapsed uterus. Nonetheless, the knowledge of the functional system of support of the pelvic organs, as well as the functional relevance of the uterus beyond its reproductive potential have put and still put to discussion the therapeutic indication of the hysterectomy as a resolution to a hysterocele. From an anatomical functional point of view, the pericervical ring is a section where main structures come together not only for the suspension of the uterus, but also of the bladder, rectum and Douglas. With this in mind, it is not difficult to imagine the anatomical consequences that a total hysterectomy generates. Thus, the premise of current female pelvic organ prolapse surgery is the preservation and maintenance of function, generating less morbidity. The error perhaps arises in an incorrect diagnostic interpretation of the true structures responsible for the hysterocele, being these the therapeutic objective and not the organ in which its flaw is expressed by.

We must highlight that underestimation of the uterus beyond its reproductive function is not exclusive to physicians, women also consider that a hysterectomy will not affect function or change the anatomical structure. Traditionally, the surgical treatment of patients with prolapse consisted in a vaginal hysterectomy with or without colposuspension techniques. Nevertheless, women present with more frequency an increased desire to preserve their uterus for a variety of reasons.

Even in literature on the matter the effectiveness and effects of a hysterectomy for treatment of a prolapse is debated. Recent literature suggest that the preservation of the uterus is an appropriate option for certain women and many of them prefer it. The analysis of the physiopathology of genital prolapse proposes the question concerning what the best procedure for its correction is. Although hysterectomy is still considered a standard practice for the correction of prolapse, even though the descent of the uterus is a consequence and not a cause of it, over the last decades women’s lifestyles, beliefs and perspectives in regard to sexual function and pregnancy have had profound changes and many patients that undergo surgery for the correction of genital prolapse choose to conserve their uterus.

Multiple surgical procedures that conserve the uterus have been described for the correction of an apical prolapse such as: sacrohysteropexia, sacrospinal hysteropexia and procedures based on the use of vaginal surgical meshes, among others. The technique may be vaginal, abdominal or laparoscopic. Another conservative option is the Manchester Fothergill operation. The conservation of the uterus is a safe alternative, feasible and effective for women that wish to preserve the uterus and associated considerations, fisiopatologicas, y de tecnica quirurgica al momento de su correcccion. Rev Chil Obstet Ginecol 2004; 69 (2): 149-156.

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Disclosure Statements

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Bilateral Sacrospineous Colposuspension (BSC) for the treatment of vaginal vault prolapse – description of a novel method

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Abstract: Vaginal vault prolapse is observed with increasing frequency in the era of large ageing populations. Various surgical techniques have been established, varying in performance, difficulty and outcome, specifically complications. A bilateral sacrospinous colposuspension technique (BSC) with a corresponding mesh prosthesis was developed using a direct I-Stitch fixation of the 38 microgram mesh from the vaginal apex or uterine cervix to the sacrospinous ligament or the parasacral tendinous region for the treatment of an anatomical central pelvic floor defect. As a minimally invasive approach with the potential for conservation of the uterus, this technique should be applicable to all age groups including the increasingly frequent elderly patient with significant co-morbidities.

Keywords: Bilateral sacrospinous colposuspension; Operative therapy; Single incision; Vaginal mesh placement; Vaginal vault prolapse; Macroporous; Lightweight

INTRODUCTION
Vaginal vault prolapse is a known clinical entity observed increasingly frequently in the era of large ageing populations. Historically, treatment options included abdominal surgical interventions such as sacrolcopexy or fascial slings, and operations via the vaginal approach such as the unilateral Amreich-Richter operation with the vaginal apex sutured to the sacral bone after hysterectomy. More recently, extensive reconstructions using prosthetic mesh for the induction of neo-ligaments and neo-fasciae have been advocated, sometimes also in the context of primary surgical interventions in the untreated patient. Intravaginal slings (IVS) placed transischiorectally have been proposed by Petros and Farnsworth and shown to be promising in a small series of cases. However, rectal injury and erosions were identified as major problems of this technique which led to the abandonment of IVS. A multi-center series in Austria yielded better results but still described severe complications.

It appears that total lack of a formalized anatomically based procedure was a major contributing factor to these unfavorable outcomes, as well as a deficit of education in potential surgeons, potentially even amplified by encouragements and assurances of “simplicity” by the manufacturers. Several parts of the technical description itself already harbored the potential for major complications, for example the para-anal entry point at the six o’clock position where the rectal arteries is found. In the development of our refined transperineal bilateral sacrospinous colposuspension (TPBCF) technique, we have successfully optimized the surgical procedure of transperineal vaginal sling placement regarding the anatomical and clinical outcome and the potential for complications. Details were published recently. With the advent of the i-Stitch instrument, finger-guided placement of sutures in the pelvis without extensive dissection became a reality. Equally, lightweight polypropylene mesh as described for the InGynious Mesh became available. These two factors lead to the development of the BSC-Mesh abolishing the transperineal phase of the TPBCF in favour of a direct i-Stitch-sutured fixation to the sacrospinous ligament or to the more cranially located parasacral tendinous insertion of the pelvic floor muscles. The weight of the material was significantly reduced in comparison to the transperineal tape, as no pull-through forces need to be applied in the direct approach. Anatomical studies lead to the determination of the width of the apical part of the BSC Mesh as well as the angle of the “arms” leading to the points of fixation in the pelvis. These arms were given extra length for adaptability of the positioning of the vaginal apex to the individual pelvic anatomy.

SURGICAL TECHNIQUE

Step 1: Pre-operative treatment
Each patient is treated with vaginal or systemic estriol application for four weeks before surgery. Single dose anti-biotic prophylaxis with a combination of a cephalosporin and metronidazole is administered i.v. half an hour before starting the procedure. The vagina is thoroughly disinfected with copious amounts of antiseptic solution during the initial phase of the operation. The anus is thereafter covered with an adhesive sterile impermeable membrane and thereby sealed off from the operative field.

Step 2: Incision in the posterior vaginal wall
A longitudinal incision is made in the midline of the posterior vaginal wall 3 cm distal to (not at) the vaginal apex. The injection of vasocostringent medication under the vagina before incision may be considered, is, however, by no means necessary as significant bleeding is the exception when choosing this approach.

Step 3: Access to the sacrospinous ligament
A canal designated to admit the index finger of the surgeon is formed by advancing Metzenbaum scissors immediately under the vaginal wall horizontally in the direction of the pelvic side wall. By inserting the finger, a direct access to the sacrospinous ligament can thereafter be developed by blunt dissection. No extensive mobilization of tissue planes or retractor placement, nor visualization of the target structure is required at this point.

Step 4: Dissection of a horizontal space under the cranial vaginal tissue
From the upper end of the longitudinal vaginal incision, the tissues of the rectovaginal septum are dissected off the posterior aspect of the vaginal wall. This will facilitate the subsequent attachment of the prosthetic tape under the intact vagina, thereby removing it from the incision and thus from potential contamination during wound healing and physiological inflammatory reactions, which both would
Step 5: Choosing the future fixation points for the BSC Mesh
It is a matter of personal preference, on which side the I-Stitch suture is placed first. Being right-handed, we have mostly placed it first on the right side of the patient and then on the left. This means that the I-Stitch instrument is guided to the surgeon’s index finger that is placed on the desired fixation point. We found it advantageous to advance it with the tip up, then turn it to the tissue immediately after anchoring. This minimized tissue resistance during placement. The internal index finger thereafter pushes the tip of the I-Stitch firmly into the tissue, (not the external hand holding the i_stitch instrument), the suture is advanced into the receiving groove, the hollow guiding needle is retracted, the instrument is removed and the suture tested for stability to traction. The sutures are not knotted but guided laterally to the thighs of the patient where they are held i.e. by short Kocher clamps.

Step 7: Fixation of the tape to the underside of the vaginal apex or the posterior aspect of the cervix
It is probably a more philosophical question, whether one should use resorbable or permanent suture for fixing the tape to the underside of the vagina. In an effort to assure suture stability during fibroblast invasion of the graft, while at the same time avoiding permanent multi-knotted strings under the vaginal skin, we have adopted the use of non-resorbable polypropylene threads (USP 3-0) for this purpose.

Two sutures are placed, the first and second in the midline, the second and third 2-3 cm lateral on either side of the mid-line (“turning point sutures”). The suture technique involves prepositioning of the sutures holding them i.e. with short Kocher clamps centrally and i.e. Overholt forceps laterally for distinction of the sutures during later threading. As results six sutures will have been placed for the fixation of the BSC-Mesh: Two I-Stitches (one on each side) , two median ones, and two lateral “turning point” ones (one on each side). An identical approach is used when fixing the mesh to the posterior cervix.

Step 8: Threading the sutures through the mesh
The prepositioned sutures are threaded through the mesh from posterior to anterior: The two median sutures first with one thread of each suture on one side of the central marking on the tape, the other on the other side. Again, after threading the sutures are held with the respective clamps and not yet tied. This is followed by guiding the two lateral files through the mesh in the same posterior to anterior direction at the turning point of the U-shaped BSC Mesh from the nearly horizontal part to the straight part of the “arms”. Finally, the I-Stitch sutures are threaded through the mesh at an individually chosen distance from the turning point sutures adapting the later tension of the suspension to the individual anatomical circumstances.

Step 9: Tyning of the sutures
The median sutures are tied and cut short first, bringing the mesh in contact with the patient’s tissue for the first time. We have found it practical to tie the most cranial of the two median sutures first followed by the second. Thereafter the two turning point sutures are knotted and cut short. The two “arms” of the mesh can now be guided into the designated spaces towards the fixation points. Before tying the I-Stitches we place and tie a braided resorbable suture USP 2-0 across the cranial angle of the colpotomy facilitating later closure after the prolapse is resolved.

In a final step, the two I-Stitch sutures are tied in the process re-elevating the vaginal apex (Figure 2) or the cervix (Figure 3) to their original physiological position. The vaginal incision is closed with the pre-positioned running suture.

Step 10: Preparation for postoperative care
At the end of the procedure, a vaginal gauze pack liberally coated with estriol ointment is inserted into the vagina over night together with a Foley catheter for bladder drainage. If outpatient treatment is desired, which is definitely an option due to the excellent tolerability of the intervention, this step can probably be safely omitted. In any case, weekly vaginal estriol applications are prescribed, as known from other clinical management guidelines after vaginal mesh placement.

DISCUSSION
Fascia lata slings and suspension procedures using the round ligaments have been abandoned as have resorbable meshes due to the fact, that the body does not maintain neo-ligaments without continuing stimulation of fibroblasts on site. Sacrocolpopexy with or without prosthetic mesh interposition should be combined with a Burch procedure for optimal results as shown by the studies of the NIH Pelvic Floor Disease Network.\(^{13–15}\). In sum, this amounts to a significant surgical intervention with laparoscopic techniques adding...
their own spectrum of possible complications due to their transabdominal nature.

Amreich-Richter results are known for their surgery-induced dyspareunia, deep pelvic pain and secondary urinary continence problems making them unattractive especially for, but not limited to, the younger patient. While having been in clinical use for a long time, systematic studies of this entity are few. Modifications using unilateral or bilateral non-resorbable sutures that serve as fixing strings suspending the vaginal apex at a distance from the sacrum have never been formally evaluated and remain experimental with anecdotal results.

Large prosthetic implants as a primary treatment approach for female genital prolapse are meeting with increased scepticism due to their potential for complications. The FDA has recently issued a statement to the effect, that large meshes are contraindicated as primary treatment in such situations. The TPBCF approach outlined before offered the potential for the generation of an anatomy-analogous support of the vaginal vault or the uterus mimicking the sacrospinous ligament or the uterosacral ligament. As a minimally invasive approach with the direct digital control of the suturing results in optimal safety. The surgeon is not satisfied with the position of the anchor point after the first placement or the stability to traction is deemed unsatisfactory. Palpatory selection of the anchor point and the BSC Mesh is 38 micrograms making it weigh the equivalent of a 0-0 suture used during the Amreich Richter procedure and less than the average postal stamp.

Using suturing instead of an anchor system for fixation inside the pelvis allows for repositioning of the suture if the surgeon is not satisfied with the position of the anchor point after the first placement or the stability to traction is deemed unsatisfactory. Palpatory selection of the anchor point and direct digital control of the suturing results in optimal safety. The indication for BSC is vaginal vault or ureteral prolapse, it is not designed to correct anterior, posterior or lateral pelvic floor defects. As a minimally invasive approach with the potential for conservation of the uterus BSC would potentially be applicable to all age groups and from the increasingly frequent elderly patient with significant co-morbitides to the younger woman desiring restoration of a physiological anatomy with minimal use of foreign material. BSC-Mesh placement can be combined with an anterior an/ or posterior colporrhaphy. If indicated, this step should be performed first, as the performance of vaginal reconstruction becomes markedly more cumbersome after correction of the prolapse.

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Introducing a new service of a midwife-led telephone follow-up clinic for 3a & 3b Obstetric Anal Sphincter Injury: retrospective service evaluation and patients’ satisfaction survey

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Diakonissenkrankenhaus Flensburg, Flensburg, Germany

Abstract: Background Most patients with 3a and 3b perineal tears will be asymptomatic. The need for all patients to attend a hospital appointment can be questioned. We set up a midwife-led telephone review clinic for such injuries. We aim to evaluate this service by auditing it and also by analysing patients’ satisfaction through a patient satisfaction survey. Methods We performed retrospective analysis of the patients’ notes over 18 months. We evaluated this service by auditing its adherence to specified standards within the local guidelines and by performing a patients’ satisfaction survey of the new service via anonymised postal Friends and Family test. Results We looked at 66 sets of notes, of which 48 had datasets with complete clinical/symptomatic data. 14/21 3a and 17/27 3b OASI were asymptomatic and discharged. Only 3 patients with 3a tear and 6 with 3b tear were referred to the consultant-led clinic. From 89 patients who had a midwife-led telephone clinic, 21 responded to the postal survey (23.6%). Two had not received their telephone appointment. 17/19 (89.4%) responded very good or good to the question ‘how well do you think your questions and concerns were addressed’. 16/19 (84.2%) responded extremely likely or likely to the question ‘how likely are you to recommend this service to friends and family’. Conclusions A midwife-led telephone follow-up clinic for patients who sustained 3a and 3b tears seems to be an acceptable service for these patients with high satisfaction rate. We believe that this service has the potential to save time and resources for both patients and healthcare providers.

Keywords: Midwife-led; Perineal clinic; OASI; OASIS; Telephone clinic

INTRODUCTION
The reported incidence of Obstetric Anal Sphincter Injury (OASI) appears to have tripled between 2000 and 2012 from 1.8% to 5.9%, and much of this is likely to be due to better recognition1. The overall incidence is 6.1% in primiparas and 1.7% in multiparas2. The Royal College of Obstetricians and Gynaecologists (RCOG) guideline has recommended a system for grading the perineal tears3. Approximately 80% of injuries are 3a and 3b tears, and the rest are 3c and 4th degree tears4,5. The data on the presence of symptoms varies enormously. The presence of symptoms in those with a 3a and 3b injuries can be as high as 31.7% at 3 months postnatal6 and as little as 7% at 6 months postnatal7 and by far the most common symptom being faecal urgency.

The RCOG guideline recommended that all patients with OASI should have follow-up appointment by clinicians with a special interest in OASIS. However, it did not comment on different methods of follow-up or care for different grades of OASI. The need for routine hospital review of all women with 3a injuries has been called into question, and given that only 8.6% of 3b injuries are symptomatic at 6 months4, hospital follow-up may not be required in this subgroup either.

We introduce a new service of a midwife-led telephone follow-up clinic for all patients who sustained 3a and 3b tears. We aim to evaluate this service by auditing its adherence to specified standards within the local guidelines and also by analysing patients’ satisfaction with this service through an anonymous patient satisfaction survey.

MATERIALS AND METHODS
The Clinic Process
We introduced the midwife-led telephone follow-up clinic for patients suffering from 3a and 3b OASI in September 2013. This clinic is led by three midwives (band 6/7), who are already trained to discuss Obstetric trauma and morbidity for the ‘Talking about Birth’ (TAB) clinic. They use a set proforma to assess and counsel patients over the telephone.

Prior to discharge, all patients who sustained a third or fourth degree tear were provided with a patient information sheet on OASI and pelvic floor muscle exercises. After discharge, all the notes were reviewed by a consultant urogynaecologist with an interest in pelvic floor trauma. Patients with 3a and 3b tears were scheduled to have a midwife-led telephone appointment at 12 weeks postpartum unless they didn’t speak English, or if there were any specific reasons warranting their review by a consultant.

An appointment time and date were sent out with the appropriate explanation to be near the telephone and allow minimum of 10 minutes either side of the appointment time. If the midwife could not speak to the patient on the telephone despite trying twice over a 10 minutes period, the patient was sent a further appointment. If on this occasion there was no reply, the patient was classified as having defaulted the appointment (DNA) and therefore discharged back to primary care (Fig. 1).

The telephone discussion included faecal symptoms, pain, intercourse, debrief of the trauma and options for future deliveries. Patients were informed that if they had no symptoms, the chance of developing new symptoms after a further vaginal delivery was low and further discussion regarding mode of delivery could take place in the future pregnancy when other factors could be considered, before the final decision was made. All patients were given the option of attending the consultant clinic if they wished.

All patients who had ongoing faecal symptoms at first review were referred to the consultant clinic. Those with anal discomfort but no faecal symptoms received further telephone reviews from the midwife until resolution and discharge or referral to the consultant. The degree of bothersomeness on a 0-10 analogue scale was recorded for faecal incontinence, faecal urgency, flatal incontinence and perineal pain for each patient.
The Database:
An OASI database had been kept by the trust just prior to the set-up of the midwife-led telephone clinic, to enable contemporaneous audit. This database continued to be used during the period of the study. As part of this service evaluation, we evaluated the outcome data from the database for the index period: 1st January 2014 – 30th June 2015.

Figure 1. Process of follow-up for patients with OASI

Notes of patients with OASI are reviewed by an experienced Consultant Urogynaecologist

Patients with 3a and 3b tears

Patients with 3c, fourth degree tear or any concerns warranting review by the Consultant

Telephone follow-up through the midwife-led clinic within 12 weeks

Follow-up in a Consultant-led clinic within 12 weeks

Discharged to GP care

Postal satisfaction survey:
All the patients who had scheduled follow-up by the midwife-led clinic received a trust produced anonymised postal patient satisfaction questionnaire six months following delivery, which included the ‘friends and family’ test (www.england.nhs.uk/ourwork/pe/fft/) with a stamped addressed envelope for its return.

Audit department permission was granted for the notes review and the postal questionnaire. Ethics approval was not required as all data was anonymised for the audit.

RESULTS
1. Outcome data from the database for index period
During the 18 month period under review, there were 6708 deliveries out of which 5339 were vaginal. 147 women sustained OASI which constituted 2.7% of vaginal deliveries. 54 injuries were 3a (36.7%), 59 were 3b (40.1%), 19 were 3c (12.9%), 15 were 4th degree OASI (10.2%).

During that period, 89 of 113 3a and 3b OASI patients were scheduled as new patients for the telephone clinic and the remaining 24 were scheduled for the consultant clinic for various reasons as above. Of the 89 listed for the telephone clinic, 23 (26.1%) ‘did not attend’ (DNA) and an additional 15 patients were scheduled as follow up within the index period, of whom 1 did not attend (6% DNA rate).

Table 1 and Table 2 describe the patients’ demographics and symptoms at the first review respectively.

2. Audit of midwifery clinic adherence to guidelines
We looked at 66 sets of notes, of which 48 had datasets with complete clinical/symptomatic data. In the remaining 18 sets of notes, clinical data were missing for a variety of reasons (see below).

3a Injuries: There were 21 patients who had sustained a 3a OASI, of whom 14 (66.6%) were completely asymptomatic at telephone follow-up and discharged. Seven patients were symptomatic at telephone follow-up, 3 of whom were felt that 100% adherence would not be proper for this latter standard as there might be circumstances when it would be inappropriate to discuss this at first consultation.

We performed retrospective data collection for 66 patients (random sample of notes) who sustained OASI in the period from 1st January 2014 to 30th June 2015, who had an appointment with the midwife-led telephone clinic, to establish whether these standards had been met. The patients were identified by using our clinic management IT system Camis.

Table 1. Graded Obstetric Anal Sphincter Injury for the period 01.01.14 – 30.06.15. Total Unit data collected from local OASI database

<table>
<thead>
<tr>
<th></th>
<th>3a (n=54)</th>
<th>3b (n=59)</th>
<th>3c (n=19)</th>
<th>4 (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of vaginal deliveries - 5339</td>
<td>1.01%</td>
<td>1.11%</td>
<td>0.36%</td>
<td>0.28%</td>
</tr>
<tr>
<td>Proportion of all OASI</td>
<td>36.7%</td>
<td>40.1%</td>
<td>12.9%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Age (years) – mean (range)</td>
<td>27.6 (19 – 37)</td>
<td>28.5 (20 – 42)</td>
<td>29 (17 – 35)</td>
<td>28.7 (20 – 33)</td>
</tr>
<tr>
<td>Parity</td>
<td>0 = 39</td>
<td>0 = 49</td>
<td>0 = 16</td>
<td>0 = 9</td>
</tr>
<tr>
<td></td>
<td>1 = 14</td>
<td>1 = 9</td>
<td>1 = 3</td>
<td>1 = 4</td>
</tr>
<tr>
<td></td>
<td>2 = 1</td>
<td>2 = 1</td>
<td>2 = 0</td>
<td>2 = 2</td>
</tr>
<tr>
<td>Previous 3rd degree Tear</td>
<td>4</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Mode Of Delivery</td>
<td>Normal = 40</td>
<td>Normal = 23</td>
<td>Normal = 14</td>
<td>Normal = 10</td>
</tr>
<tr>
<td></td>
<td>Forceps = 14</td>
<td>Forceps = 30</td>
<td>Forceps = 4</td>
<td>Forceps = 4</td>
</tr>
<tr>
<td></td>
<td>Ventouse = 0</td>
<td>Ventouse = 6</td>
<td>Ventouse = 1</td>
<td>Ventouse+forceps = 1</td>
</tr>
<tr>
<td>Birth Weight (g) – mean (range)</td>
<td>3654 (2260 – 4600)</td>
<td>3634 (2350 – 4595)</td>
<td>3516 (2910 – 4255)</td>
<td>3690 (2685 – 4375)</td>
</tr>
<tr>
<td>Episiotomy rate</td>
<td>16 (29.6%)</td>
<td>18 (30.5%)</td>
<td>6 (31.6%)</td>
<td>6 (40%)</td>
</tr>
</tbody>
</table>
Introduction of a new service of a midwife-led telephone follow-up clinic for 3a & 3b Obstetric Anal Sphincter Injury

Table 2: Symptoms at First Review for all patients (Total unit data collected from local OASI database) during index period. Symptoms bothersomeness graded 0 – 10, 0 = no bother, 10 = maximum bother.

<table>
<thead>
<tr>
<th>Grade of OASI</th>
<th>3a</th>
<th>3b</th>
<th>3c</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. patients in group</td>
<td>54</td>
<td>59</td>
<td>19</td>
<td>15</td>
</tr>
<tr>
<td>No. patients with symptom data</td>
<td>35</td>
<td>41</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>No. patients with faecal incontinence</td>
<td>2 (5.7%)</td>
<td>3 (7.3%)</td>
<td>1 (8.3%)</td>
<td>1 (7.7%)</td>
</tr>
<tr>
<td>Faecal incontinence bother – Mode Median</td>
<td>2</td>
<td>4</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>2.2</td>
<td>4.3</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>No. patients with faecal urge</td>
<td>4 (11.4%)</td>
<td>13 (31.7%)</td>
<td>4 (33%)</td>
<td>3 (23%)</td>
</tr>
<tr>
<td>Faecal urge bother – Mode Median</td>
<td>2</td>
<td>3.9</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>2.6</td>
<td>4.6</td>
<td>4.5</td>
<td></td>
</tr>
<tr>
<td>No. patients with flatal incontinence</td>
<td>1 (2.9%)</td>
<td>11 (28.6%)</td>
<td>3 (25%)</td>
<td>3 (23.1%)</td>
</tr>
<tr>
<td>Flatal incontinence bother – Mode Median</td>
<td>2</td>
<td>7</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Interquartile range</td>
<td>2</td>
<td>7</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>No. patients with pain</td>
<td>5 (14.3%)</td>
<td>10 (24.4%)</td>
<td>3 (25%)</td>
<td>1 (7.7%)</td>
</tr>
</tbody>
</table>

Table 3: Postal Satisfaction questionnaire results (answers are from a 7 point scale except for question 5, which is from a 5 point scale)

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Midwife telephone clinic N=19</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How well do you think your questions and concerns were addressed?</td>
<td>Very good / Good</td>
<td>17 (89.4%)</td>
</tr>
<tr>
<td></td>
<td>Satisfactory</td>
<td>2 (10.5%)</td>
</tr>
<tr>
<td></td>
<td>Neither good nor bad Poor, Bad or Very bad</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>2. How good was the explanation detailing the injury you had?</td>
<td>Very good / Good</td>
<td>16 (84.2%)</td>
</tr>
<tr>
<td></td>
<td>Satisfactory</td>
<td>3 (15.8%)</td>
</tr>
<tr>
<td></td>
<td>Neither good nor bad Poor, Bad or Very bad</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>3. How well do you feel your options in a future pregnancy were discussed</td>
<td>Very good / Good</td>
<td>12 (63.2%)</td>
</tr>
<tr>
<td></td>
<td>Satisfactory</td>
<td>3 (15.8%)</td>
</tr>
<tr>
<td></td>
<td>Neither good nor bad Poor, Bad or Very bad</td>
<td>4 (21.0%)</td>
</tr>
<tr>
<td>4. Overall rate the service</td>
<td>Very good / Good</td>
<td>12 (63.2%)</td>
</tr>
<tr>
<td></td>
<td>Satisfactory</td>
<td>5 (26.3%)</td>
</tr>
<tr>
<td></td>
<td>Neither good nor bad Poor, Bad or Very bad</td>
<td>2 (10.6%)</td>
</tr>
<tr>
<td>5. How likely are you to recommend this service to Friends and Family? (5 point scale)</td>
<td>Extremely likely / Likely</td>
<td>16 (84.2%)</td>
</tr>
<tr>
<td></td>
<td>Neither likely nor unlikely / Unlikely / Extremely unlikely (I don’t know)</td>
<td>3 (15.8%)</td>
</tr>
</tbody>
</table>

referred on to the consultant clinic. Of the 4 patients ultimately discharged by the midwife clinic, 3 had discomfort around the anal area, which on subsequent telephone review had resolved, the fourth in addition to discomfort also described flatal incontinence but declined further review. Of the 3 patients referred to the consultant clinic, 2 had faecal urgency and the other had pain in the perineum. The documentation suggests that 19 of the 21 patients had a discussion about the next delivery.

3b Injuries: there were 27 patients who sustained a 3b OASI, of whom 17 (62.9%) were completely asymptomatic at telephone review and discharged. Of the 10 patients who had symptoms, 6 were referred on to the consultant clinic. Of the 4 patients discharged by the midwife, 1 had faecal urgency but declined further follow-up, 1 had pain and rectal bleeding and was referred on to the GP, 1 had rectal bleeding and declined further follow-up and the last one had faecal urgency and rectal bleeding and her outcome was uncertain (inadequate documentation).

Of those 6 patients referred to the consultant clinic, 2 had faecal urgency (1 of whom did not attend the consultant appointment), 1 had flatal incontinence (she did not attend the consultant appointment), 2 patients had faecal incontinence, faecal urgency and flatal incontinence, and a one patient had a ‘bulge in her perineum’. The documentation suggests that 24 of the 27 patients had a discussion about the next delivery. Therefore, in 1 of the 17 symptomatic patients with a 3a or 3b OASI, there is uncertainty from notes review, as to whether they were offered a consultant review, giving a 94.2% adherence to the first standard. In addition, there was evidence of a discussion regarding mode of delivery in 89.6% notes.

Of the 18 sets of notes where there was incomplete data, 11 patients missed their telephone appointments on 2 occasions and were discharged. In 2 notes, the OASI pathway was missing, 2 patients declined follow-up. And in the remaining 3 patients, there was inadequate documentation by the midwife. Overall, when the OASI pathway document was present, there were 4 (6.3%) notes out of the 64 where the documentation was inadequate to determine whether the patient should have been, or was offered a consultant review.

3. Postal satisfaction survey of the midwife-led telephone OASI service

Of the 89 patients scheduled for the midwife-led telephone follow-up, 21 responded to the postal survey (23.6%). Two had not received their telephone appointment. The results of the remaining 19 appear in table 3.

As the response rate was low, the answers have been grouped into 3 groups: 1. very good/good, 2. satisfactory or 3. neither good nor bad/poor/bad/very bad.

Overall, patients’ acceptance of the midwife-led telephone clinic seemed to be high with high satisfaction rates. 89.5% of the patients rated the service as very good, good or satisfactory. 84.2% of the patients answered that they are likely or extremely likely to recommend this service to friends and family.

DISCUSSION

The aim of this service evaluation was to determine whether the adherence to our standards was met, and to determine the acceptability of the service to our patients through the patients’ satisfaction survey. The audit of adherence to agreed standards revealed few points of practice that could be improved. There was 1 symptomatic patient in whom the documentation appeared to be inadequate to explain why this patient was not referred on to the consultant clinic. 3 further patients appeared to have no documentation. The reason for this is uncertain but could include failure to document or documentation in the incorrect place. The second standard reviewed; evidence of a discussion regarding mode of delivery fell just short of the standard
set. The need for documentation has been re-emphasised, including reason for non-compliance with guidelines, and these will be re-audited at a later date.

Our data from the postal survey reveals that the patients were generally happy with the midwife-led telephone consultation with 84%, likely or extremely likely to recommend this service to friends and family. The results suggest that appropriately trained midwives can provide the first follow-up consultation over the telephone following an OASI, referring on those patients with continuing symptoms for further assessment. The published data regarding the management of OASI is mainly retrospective and is often conflicting. Therefore, counselling patients can be challenging. Understandably, much of the published literature infers a worse outcome and a greater frequency of symptoms following a 3c or 4th degree OASI compared to less severe injuries.

Review at 3 months, in one large study, suggested that the frequency of symptoms in the 3a and 3b OASI were similar to 3c and 4th⁶. However, there appears to be an increasing frequency of faecal symptoms with worsening grade of injury at six months review⁷. This may suggest that some of those with asymptomatic 3a and 3b OASI become asymptomatic between 3 and 6 months. Several studies have suggested that by twelve months postnatal 60-80% of patients will be asymptomatic⁸. The emphasis in the updated version of the RCOG guideline is slightly more pragmatic suggesting, ‘Women who have undergone anal sphincter repair should be reviewed at a convenient time (usually 6-12 weeks postpartum). Where possible, the review should be by a clinician with a special interest in OASIS’. Experienced midwives are performing an increasing number of roles, previously performed by doctors. Although review by an experienced consultant with the appropriate expertise may be optimal, this is of little benefit to some if they struggle to get to the hospital and are therefore more inclined not to attend. Telephone consultations are used in many specialties such as dermatology, ENT, colorectal surgery⁹-⁸ and indeed in urogynaecology⁷. Following urogynaecological surgical procedures, the need for routine follow-up has been called into question, suggesting patients will re-present if they have complications¹⁰. However, follow-up after OASI, is for information giving, as much as it is about information gathering and some time is required to allow the new mother to adjust to the changes in her life, so a discussion downstream from delivery is appropriate, as well as immediately post-delivery.

To the best of our knowledge, this is the first paper to introduce and evaluate a midwife-led telephone clinic for the follow-up of patients who sustained 3a and 3b OASI. As the midwife telephone consultation at 12 weeks postnatal is in part a triage service, with symptomatic patients offered a hospital appointment, the authors feel this is a promising service. The response to the question from the telephone clinic: ‘How well do you feel your options for a future pregnancy were discussed’, was suboptimal with 63.2% answering very good/good, 15.8% answering satisfactory, but 21.0% answering from neither good nor bad to very bad. Although the clinic is run by experienced midwives, this may be an area, they are less comfortable with, or capable of discussing and this will be explored further at a later date (out with this paper).

We serve a large geographical area where travelling times can be up to 2 hours to reach our unit. We, therefore feel we can considerably reduce the burden for some patients with new babies, in terms of travel time, parking, and waiting time, by providing a telephone consultation.

One limitation to our study is the poor response rate to our postal survey with only 23.6% responding. A response rate of 56% can be achieved in postal surveys of postnatal women³. We did not send out reminders, which could have improved the response rate³ as our survey was anonymised. Other limitations include the retrospective design resulting in missing data, and the use of non-validated questions. In addition, the three midwives may counsel patients differently, but this reflects ‘real life’.

The study, however, suggests that a midwife telephone clinic can be used as a triage service for symptomatic patients and as consultation for non-symptomatic patients. More robust data is required. Fundamental to this clinic set up is the option given to all patients to have a face-to-face consultant consultation.

CONCLUSION

A midwife-led telephone follow-up clinic for patients who sustained 3a and 3b perineal tears at the time of vaginal delivery, seems to be an acceptable service for these patients with high satisfaction rate. We believe that a midwife-led telephone clinic has the potential to save time and resources for both patients and healthcare providers.

REFERENCES


DISCLOSURE STATEMENTS

There was no conflict of interest, informed patient consent was obtained, and the study was approved by the local ethical committee. The authors of the publication did not receive any financial support by any grant/research sponsor

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INTRODUCTION
The prevalence of constipation in the general population is approximately 20% although it can range anywhere from 2% to 27%, depending on the definition used and population studied. A population-based study reported that the cumulative incidence of chronic constipation is higher in the elderly (~20%) compared to a younger population. Severe constipation is more common in elderly women with rates of constipation two to three times higher than that of their male counterparts. The new criteria for ROME IV represent another attempt by brain noise to streamline scientific research in order to understand the pathophysiology of chronic constipation in patients of different age and sex, which should improve the diagnosis and treatment of this common disease. The new Rome IV criteria now supersede Rome III. In general, these minor amendments are unlikely to lead to substantial improvement in accuracy and use in routine clinical care.

Clinical criteria for functional constipation (FC) in elderly consist of < 3 bowel movements per week, straining, the presence of lumpy or hard stools, the sensation of anorectal obstruction, the sensation of incomplete defecation, and manual maneuvers. Almost all symptoms are subjective. This is so-called self-defined constipation. These criteria are significantly different from the criteria for obstructive constipation in children (1-18 years old), where the stool has a large diameter and emptying occurs with large volumes of feces. It is obvious that the clinical criteria of FC in the elderly do not allow to put a pathophysiological diagnosis. If the organic causes of constipation are excluded (cancer, anorectal fissure, etc.) and the standard treatment has no effect, these symptoms serve for the initial selection of patients for following examination (digital rectal examination, anorectal manometry, balloon expulsion test, defecography and colonic transit study). It is known that the amount of obstructive constipation in the elderly does not increase, in comparison with the young, but the total number of patients with FC is almost 2 times greater. There is no unambiguous answer about the pathogenesis of this type of FC. Roque and Bouras subdivide FC on pelvic floor dysfunction and slow colonic transit. Abnormalities in pelvic floor dysfunction include failed relaxation of the pelvic floor, paradoxical contraction of the pelvic floor muscles, or the inability to produce the necessary propulsive forces needed in the rectum to expel the stool completely. De Giorgio et al. describe other causes of FC: slow colonic transit, outlet obstruction: constipation by difficult or unsatisfactory expulsion of feces from rectum and constipation in IBS. Andromanakos et al consider that primary FC can be classified into normal transit constipation, slow transit constipation, and pelvic outlet obstruction. The purpose of this study is to examine the X-ray symptoms of functional constipation in the elderly and to determine their origin.

MATERIAL AND METHODS
The barium enema, as described below, was performed to 37 patients aged 65 to 93 years with complaints of chronic constipation. Twenty-two patients were female, 10 males. This group does not include patients with tumors and rectal fissure. The control group consisted of 15 adolescents (11-17 years) without disturbance of the intestinal function. They had a barium enema to diagnose the cause of anemia, chronic abdominal pain and localization of the space occupation lesion. The results of this study were accepted as a norm. In addition to the standard barium enema, we applied a barium paste to the perineum near the anus or a radio contrast marker attached to the tip, which was located near the anus. On the lateral radiographs of the anorectal zone, the distance between the barium in the rectum and the contrast marker near the anus along the posterior contour of the tip was measured. This non-contrast zone forms an anal canal closed around the tip. Thus, the length of this distance is equal to the length of the functioning anal canal. The width of the rectum was measured in the widest part above the anal canal (Fig 1.A). In patients of the control group, a barium was introduced into the colon up to the reflex into the terminal ileum. In elderly patients, a contrast agent was administered in a volume of up to 300 ml, i.e. up to the splenic flexure of the colon. First, because some patients could not retain more of the barium volume, secondly, as our studies have shown, the
filling of the colon proximal to the splenic flexure does not change the parameters of the rectum and anal canal. The radiographs were done after the administration of 100, 200, 300 ml of barium. After that, the frontal abdominal radiograph was made. The true dimensions were calculated by multiplying the parameters measured on the roentgenogram by the projection increase factor, which under standard conditions is 0.72. Statistical analysis was performed by the method of the Student’s t-test. The level of significance was set as \( P<0.05 \).

**RESULTS**

In the control group, the length of the anal canal along the posterior contour of the tip was within \( 3.1-3.7 \) cm (\( 3.43 \pm 0.07 \) cm) and was unchanged throughout the study. Periodically, the barium penetrated into the upper part of the anal canal in front of the enema tip, while the posterior wall of the anal canal at this level densely pressed against this tip (Fig. 1, B). After a few (7-12) seconds the barium was squeezed into the rectum and disappeared from the anal canal. Only in 3 (8%) patients the length of the anal canal was normal and did not change during the whole study. In the remaining observations, the anal canal was significantly shorter than in the control group (Table 1).

We noticed that in some cases the anal canal decreases during filling of the bowel with barium. The more barium is introduced, the shorter the anal canal becomes (Fig. 2). In other cases, the anal canal was twice shorter the minimum limit norm immediately after the onset of barium administration. They always had an expanded rectum. Therefore, in cases where 300 ml of barium were administered to the colon, we grouped them according to the width of the rectum (Table 2).

In patients with a rectum width of more than 5 cm, which

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**Table 1. Dependence of the rectal width and the anal canal length on the administration of the barium volumes.**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Control group</th>
<th>Elderly patients (65-94 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st X-ray</td>
<td>2nd X-ray</td>
</tr>
<tr>
<td>The rectal width (cm)</td>
<td>15</td>
<td>3.6-4.6</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>3.1-3.9</td>
</tr>
</tbody>
</table>
| The anal canal length (cm) | \( p^1 \)    | \( p^2 \)  | \( p^3 \)  | \( p^4 \)  |}

<table>
<thead>
<tr>
<th>Parameters</th>
<th>The rectal width &lt; 5 cm</th>
<th>The rectal width &gt; 5 cm</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>The rectal width (cm)</td>
<td>17</td>
<td>3.5-5.0</td>
<td>4.1( \pm )0.11</td>
</tr>
</tbody>
</table>
| The anal canal length (cm) | \( p^1 \)    | \( p^2 \)  | \( p^3 \)  | \( p^4 \)  |}

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**Table 2. Dependence of the anal canal length on the width of the rectum.**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>The rectal width &lt; 5 cm</th>
<th>The rectal width &gt; 5 cm</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>The rectal width (cm)</td>
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</tr>
</tbody>
</table>
| The anal canal length (cm) | \( p^1 \)    | \( p^2 \)  | \( p^3 \)  | \( p^4 \)  |}

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Michael D. Levin
corresponds to the concept of obstructive constipation (Fig. 3), the length of the functioning anal canal was significantly less than in those where the width of the rectum was less than 5 cm, i.e. within the limits of the norm.

Meanwhile, in patients with normal rectal width (up to 5 cm), the length of the anal canal also was significantly less than in the control group (p <0.001). The shortening of the anal canal immediately after the introduction of the first portion of the barium is corresponds to the notion of a fixed descending perineum syndrome.

In 6 patients without rectal expansion on the frontal abdominal radiographs, signs of high colonic tone were found, which was the probable cause of slow transit constipation. Among them were 3 women with severe irritable bowel syndrome (Figure 4, A), two patients with several functional sphincters in the colon (Figure 4, B) and one man with diverticula of the sigmoid colon (Fig. 4, C).

DISCUSSION

The gap between the barium into the rectum and the marker near the anus is due to the contraction of the anal canal. In patients of the control group, its length is equal to the length of the anal canal measured by the manometric, ultrasound and MRI methods.

In healthy individuals during the barium enema, the length of the anal canal, along the posterior contour of the enema tip remains unchanged. Periodically penetration of barium from the rectum into the upper part of the anal canal in front of the enema tip observed, which is accompanied by a decrease in anal pressure. This picture is due to the relaxation of the internal anal sphincter (IAS). At this time, the posterior wall of the anal canal is pressed against the tip of the enema by the contracted puborectalis muscle (PRM), which together with the external anal sphincter (EAS) prevents the leakage of barium. After 7-13 seconds, barium is squeezed back into the rectum, which is accompanied by the restoration of pressure to the basal level. This reaction of the anal canal to an increase in the rectal pressure is the radiographic equivalent of the inhibitory anorectal reflex.

In healthy people, the rectum on the lateral roentgenogram unfolds forward and is actually subdivided into vertical and horizontal branches.

Based on the analysis of clinical and radiological data, we found among 37 patients with FC the three homogeneous groups of patients. The first group consisted of 6 (16%) patients with a rectal width more than 5 cm. The second group comprised 25 (68%) patients with normal rectum width, but with a short anal canal. The third group included 6 (16%) patients with increased colonic tone. The width of the rectum and the length of the anal canal were within normal limits in 3 of them but in 3 cases the anal canal was shorter than normal.

In patients with megarectum (1st group), the anal canal was almost 2 times shorter than the minimum limit of norm and was always shorter than in patients in the 2nd group. The shortening was detected immediately after the introduction of a small volume of barium. As shown by us earlier, the shortening of the functional part of the anal canal is due to the weakness of the pelvic floor muscles. Weak PRM cannot close up the upper part of the anal canal, and during a bowel movement a weak LAM cannot wide open the anal canal. Thus, the upper part of the anal canal is expanded and looks as a part of the rectum.

This picture corresponds to concept of a fixed form of the descending perineal syndrome. In the first group there was always no horizontal branch of the rectum. Based on these six observations, we came to the conclusions that the reason of constipation in them is an outlet obstruction that arose either in childhood or in the late period as a result of anal stenosis or fissures. Stool retention in the rectum led to the development of a megarectum. Wide feces under the influence of a strong peristaltic wave stretched the upper part of the anal canal, in which the stool masses begin to accumulate.

In 25 patients of the second group the width of the rectum was within normal limits. They did not suffer from abdominal pain and in the frontal radiograph the large intestine had normal size and shape. They had two branches of the rectum.

Figure 3. Lateral radiographs of the anorectal zone of two elderly patients with constipation, who have an expansion of the rectum. In both cases, there is no horizontal branch of the rectum. The anal canal is 2 times shorter than the minimum limit of normal. A. Sigmoid colon is narrow, irritated, which can be the result of prolonged use of bisacodyl. B. The width of the sigmoid colon is greatly expanded - megacolon. Sigmoid colon width - red line.

Figure 4. Radiographs of patients with increased tone of different segments of the colon. A. In a patient with irritable bowel syndrome, the left half of the colon is sharply narrowed, without haustration. B. The arrows show functional sphincters in the form of colon contraction, between adjacent chambers containing gas and feces. The rectum is empty. C. High tone of the sigmoid colon with diverticula. The size of the rectum and anal canal is within normal limits.
tum: vertical and horizontal. The anal canal was shortened during the introduction of the contrast medium, which corresponds to the dynamic form of the descending perineum syndrome 1. Consequently, in these patients, the pelvic floor muscle weakness was less pronounced than in patients of first group with outlet obstruction. It is caused by age-related changes in the muscles of the pelvic floor. The normal width of the rectum indicates that the anal canal did not interfere with the promoting of the stool. We assumed that in these cases there is a so-called self-determined form of constipation, which is characterized by patients’ complaints about the difficulty of defecation and a feeling of incomplete emptying. The mechanism of occurrence of these sensations can be explained by the penetration of small fecal boluses into the upper part of the anal canal due to the weakness of the PRM. Irritation of sensory elements in this part of the anal canal by fecal bolus causes a need for defecation, but a small amount of bolus is unable to create a threshold volume of defecation. Because of this, patients are forced to use a finger maneuver, i.e. removal of feces with a finger through the vagina or anus. The rest of small fecal lumps in this part of the anal canal provokes a feeling of incompletely emptying (Fig.5).

In 6 patients of the third group, FC was combined with abdominal pain. The width of the rectum and the length of the anal canal were within normal limits in 3 of the patients, and in the remaining 3 patients with irritable bowel syndrome the rectum was narrow. On the frontal radiographs the signs of an increased tone of the colon of different nature were found, which inevitably caused the slow transit through the colon.

One of the reasons for the high tone of the colon is irritable bowel syndrome (IBS). Some researchers exclude IBS from the analysis of FC 1. We consider necessary to include it in a differential series for two reasons. First, because there are no clear clinical criteria for diagnosis of IBS. Secondly, as we showed earlier, obstructive constipation, as a form of chronic obstruction, can cause the development of nonspecific inflammation of the colon and an increase its tone. In such cases, chronic constipation may be accompanied by pain in the abdomen (see Fig. 3.A) and differential diagnosis of FC and IBS is not possible. The main pathognomonic symptoms of IBS are the increased sensitivity of the colon to intestinal irritation (pressure) 9. It is necessary to distinguish delayed transit through the colon, as a result, of an increase in the tone of its different segments, which is the cause of FC, from delayed transit, which in obstructive constipation is observed as a symptom. Prolonged accumulation of large feces in the rectum and left colon invariably causes a slowing of the movement of feces.

In the process of ontogenesis, functional sphincters appear in the colon. A total of 11 functional sphincters are described. The most extensively studied are colosigmoid sphincter (“CSS) and rectosigmoid sphincter (RSS). Between the descending and sigmoid colon there is a physiological CSS by a length of 2.1±0.9 cm. In this zone, the pressure was significantly higher than in the adjacent segments. After a quick inflation of the balloon of large diameter in the descending colon, the decrease of pressure in the CSS was noted. After inflating the same balloon in the sigmoid colon, the pressure in the CSS increases. On the other hand, inflation with a small balloon did not affect the tone of this sphincter. It is clear that the CSS is involved in a passage of large intestinal contents. CSS retains the feces until it reaches a certain volume 10. Between the rectum and sigmoid is located the intestinal segment of 2.8±0.9 cm length with the layer of circular muscle thickened in comparison to the segments above and below it 11. While the pressure in the sigmoid colon increases, this functional RSS relaxes. In response to increased pressure in the rectum, its tonus rises 12. Different reactions of RSS to different volume of the balloon were found. After a quick inflation of the balloon in the sigmoid with 52.1±3.6 ml of liquid, the tone of the RSS increased but the rectal pressure did not change. After the rapid inflation into the balloon of 86±4.1 ml, the RSS relaxed and the balloon was dispelled to the rectum. It was accompanied by an increase of the rectal pressure, and the balloon was expelled 13-14. On the roentgenogram of the spine (Fig.4.B), at least 4 oval chambers containing gas and feces are seen that are separated from each other by contracted functional sphincters. They are opened and passed feces only when a large volume of feces gathers in the chambers above the sphincters. This dramatically slows the passage of feces across the colon, which corresponds to the concept of slow transit constipation.

High pressure in the sigmoid colon can be so strong that diverticula are formed. It is always accompanied by chronic constipation and abdominal pain. However, as can be seen in Fig. 4.C, the rectum and anal canal are of normal size and shape and do not cause chronic constipation. This is also one of the forms of slow transit constipation in the elderly.

CONCLUSION

We found 3 types of FC in the elderly. In the structure of FC are dominated by cases of self-defined constipation (68%), where there is no mechanical obstruction for defecation. The reason for the sense of constipation and incomplete emptying is due to the age-related weakness of the pelvic floor muscles. In 16% of patients, obstructive constipation with a megarectum and a fixed descending perineum syndrome was detected. This pathology originated in childhood or after anal fissures, and childbirth. In 16% of patients, the cause of constipation was a high tone of the colon, what can be the result of an irritable bowel syndrome, the formation of functional sphincters in the colon and diverticula of the sigmoid colon. An increase in the tone of the colon causes a slow transit constipation.
REFERENCES


NOTES

For the first time functional constipation in the elderly is assessed from the point of view of the anorectal zone function using mathematical analysis.

DISCLOSURES

There was no conflict of interest, informed patient consent was obtained, the study was approved by the local ethical committee and the author of the publication did not receive any financial support by any grant/research sponsor.

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.

Uro... It is well known that human defecation is a complex physiologic mechanism that involves integrated and coordinated sensorimotor functions orchestrated by central, spinal and peripheral neural activities. In this way when the rectum is filled with feces the pressure within it is increased allowing the passage of the fecal material through the anal canal which has further increased by muscles of pelvic floor helping to pull the anal canal walls apart and causing a further filling of the anal canal by feces that can be expelled due to relaxation of internal and external spinchers.

This coordinated neuromuscular activity is analogous also for what concerns filling and bladder emptying phase, since the innervation of the bladder and of sphincteric mechanism is similar to the rectum and of the anal canal one.

A close functional relationship between urinary retention and constipation in the elderly is therefore evident. In fact in this age group it is very probable the presence of a detrusor underactivity like an equally disabling condition to produce the necessary propulsive forces needed in the rectum to expel the stool completely. Most likely the cause, from an uro...
On collagen, ageing and surgical treatment options following commercial kit withdrawals- a critical analysis

BURGHARD ABENDSTEIN, DMITRY SHKARUPA, PETER PETROS

Abstract: The banning of all mesh for prolapse by the FDA has failed to recognize that there is a major difference between mesh sheets applied behind the vagina for POP and repair of POP by shortening and reinforcing damaged suspensory ligaments, much as is used in the midurethral sling (MUS) which retains endorsement by the FDA. Mesh sheets interfere with the vaginal elasticity essential for function and may cause pain and massive urine loss post-operatively, in some cases; tapes far less so, as they have little contact with vagina and work by shortening and reinforcing damaged ligaments in the same way as the MUS operation. The main pathogenesis of POP is leaching out of collagen after the menopause. Weakened ligaments cannot support the organs so they prolapse. Only artificial collagenous neoligaments created by implanted tapes (as per the MUS) can create the new collagen required to repair these ligaments.

The major advances developed over the past 30 years for treatment of POP using these ligament repair techniques has in one stroke been abolished. The treatment of POP has been set back 100 years. In their twilight years, many women will suffer the consequences of loose posterior ligaments, major prolapse, urge, nocturia, chronic pelvic pain, obstructed micturition defecation and fecal incontinence. The FDA needs to reconsider its ban, at least for tapes, which are supported by individual, multicentre and long-term studies.

Keywords FDA; Mesh sheets; Mesh tapes; Neoligaments; Collagen; Menopause

COMMENTARY

The stimulus for this commentary was two news items, withdrawal of Bard’s mini sling followed later by the announcement by the FDA of recall of all mesh kits, for pelvic organ prolapse (POP).

Both are grim reminders of Dr Nager’s insightful 2016 predictions1. The end point of his well-reasoned analysis was that despite overwhelming scientific evidence and recommendations from learned societies, even the midurethral sling (MUS), the most validated operation in history, was in danger of disappearing.

Our aim in this brief commentary is to elaborate on three main points from Nager’s article and add a 4th, the rationale behind the MUS; collagen loss in the PUL suspensory ligament in an ageing female population.

1. Midurethral slings ‘MUS’, tape surgery, is very different from mesh sheets used for repair of pelvic organ prolapse.

2. MUS is minimal surgery. Complications are far less than those of major surgery; no surgery for MUS is disastrous as regards QOL.

3. Disappearance of midurethral slings from the market is a dire situation for women.

Collagen 1 (breaking strain 18,000 lbs/sq inch) is the key structural component of the body. At menopause, there is a twofold increase in excretion of urinary collagen I breakdown products, which persists for the entire postmenopausal period2. Collagen loss causes joint, osteoporosis and organ prolapse problems, the latter generally attributed to loss of level 1 supports, fig 1. Collagen I is the major structural component of ligaments, (breaking strain 300mg/mm2); collagen III, weaker, more elastic, allows vagina (breaking strain 60mg/mm2) to stretch extensively (VIDEO Xray https://youtu.be/eif4G1mk6EA ). We can deduce from collagen breakdown data2, that if collagen deficiency in a structural ligament is the cause of a pelvic floor problem, whether it be prolapse or symptoms, no “native tissue repair” will fix it. New collagen needs to be created.

The original hypothesis which led to the MUS was that SUI (stress urinary incontinence) was mainly caused by collagen-deficient pubourethral ligaments. A new surgical principle, using an implanted tape to create artificial collagenous pubourethral ligaments, became the basis of the MUS, now implanted in 5,000,000 women3.

Fig 1. Uterine prolapse caused by weakened level 1 supports. If collagen leaches out of the cardinal (CL) and uterosacral (USL) ligaments, they will elongate. Shortening and reinforcing of ligaments is required. Critical for any long-lasting repair is the quality of ligament collagen.

Fig 2. Normal urethral closure in the female during coughing or straining
PCM = m.pubococcygeus, LP = levator plate; LMA = conjoint longitudinal muscle of the anus; PUL = pubourethral ligament. ZCE (zone of critical elasticity), allows separate action of forward and backward vectors.
On collagen, ageing and surgical treatment options following commercial kit withdrawals: a critical analysis

Added to Nager’s statement that midurethral slings (MUS) are very different from mesh sheets as they implant much less mesh is the effect of mesh on vaginal elasticity. The VIDEO XRAY https://youtu.be/eiF4G1mk6EA shows that vagina requires very significant elasticity to implement its functional roles during straining, micturition, squeezing upwards; in contrast, the vaginal anchoring points, pubourethral ligament and uterosacral ligaments remain immobile. Placing a mesh sheet behind vagina, or removing a segment of vagina (“native tissue repair”) will only fibrose vagina. One complication from fibrosis is sudden massive incontinence immediately after mesh sheet implant. Its cause, “Tethered Vagina Syndrome” (TVS), explains ongoing massive urine loss following Obstetric Fistula closure in 50% of patients.

Pathogenesis
Excess scarring, whether from fistula or mesh fibrosis may “tether” (connect) the more powerful posterior muscle closure forces to the weaker anterior forces, so the urethra is forcibly pulled open on the signal to close, resulting in massive uncontrolled urine loss3, figs2&3. A skin graft to the anterior vagina restores elasticity and function4, fig4. Tapes rarely cause this problem as they attach directly to the skeleton with minimal contact with vagina.

Is there a difference between tapes and mesh sheets?
Mesh sheets work by blocking organ descent; post-op. 2D ultrasound reveals continued presence of the prolapse. The MUS tape principle, fig1, works by shortening and reinforced the elongated USLs, with a posterior sling, literally a “reverse TVT.” A sling in front of cervix reduces post-surgical cystocele. A tensioned mini sling repairs all 5 suspensory ligaments, with 79% anatomical cure rate for major prolapse at 5 years, using 3rd generation lightweight tapes with no vaginal excision and low erosion/surfacing rates3.

“Native tissue” repair
There is no greater condemnation of “native” vaginal repair than the 2016 Lancet PROSPECT study. Failure rate at 6 months was >85%. CL/USL plication may be a better “native tissue” option. Evidence for this is from an RCT, CL/USL plication against Trospium which was stopped by the St Petersburg University EC because of rapidly deteriorating cure rates in the post-menopausal arm, 17% cure (n=48) at 18 months post-op, as against 80% cure for pre-menopausal women (n-40), (Shkapura, as yet unpublished data). The high failure rate was attributed to collagen leaching out postmenopausally from the ligaments, consistent raised collagen1 breakdown products2.

CONCLUSIONS
It is unfortunate that whatever the expert opinion guiding the FDA’s actions, it was ignorant of the fact that posterior slings for POP work in exactly the same way as the midurethral sling which it has endorsed. Posterior slings do not have the same severe pain or tethered vagina syndrome complications as mesh sheet kits. This FDA decision will have severe unintended consequences. After the menopause, women lose the collagen which supports their ligaments2. Weak ligaments cannot be repaired by any type of “native tissue repair”. They can only be repaired by the artificial neoligament technique developed on experimental animals in the years 1987-8 at Royal Perth Hospital4, the very method endorsed by the FDA for cure of SUI. The major advances developed over the past 30 years for treatment of POP using these ligament repair techniques has in one stroke been abolished. The treatment of POP has been set back 100 years. In their twilight years, many women will suffer the consequences of loose posterior ligaments, major prolapse, urge nocturia,chronic pelvic pain, obstructed micturition defecation and fecal incontinence. The FDA needs to reconsider its ban, at least for tapes, which are supported by individual, multicentre and long-term studies5-19.

Fig 3. Xray Normal patient, sitting position, straining. Oppositely acting vector forces during straining (arrows) indicates the imperative of an elastic zone at ZCE so as to allow the vector closure forces to operate independently. Labelling as in 1A. CX=cervix; R=rectum; B=bladder; USL=uterosacral ligaments; S=sacrum.

Fig 4. Augmentation of ZCE with a skin-on Martius Graft restores independent movement of the vector forces. LM=labilum majus ; G=graft sutured to bladder neck area of vagina to cover the tissue deficit.
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NOTES

VIDEO https://youtu.be/eiF4G1mk6EA Note the enormous elasticity of the vagina which is required to squeeze (lift up) the organs and also during micturition.
Dear Editors,

I write to comment on the Levin hypothesis

1. Levin M The role of detrusor rigidity in the lower urinary tract dysfunction. Hypothesis Pelviperineology 2018; 37: 70-73

As a pelvic floor surgeon with a major interest in bladder and anorectal function, I found Dr Levin’s hypothesis1 most interesting. His hypothesis starts from the known, symptoms of bladder emptying and urgency increase with age. He provides evidence of fibrosis within the detrusor smooth muscles then proceeds seamlessly to elaborate his hypothesis. The hypothesis is an admirable example of deductive logic. However, it fails on one major point, it cannot explain reported surgical cures of overactive ‘OAB’2 and underactive bladder ‘UAB’3-4. Furthermore it fails to mention the external mechanisms which open and close the urethra, figs1&2. The reason why UAB has a slow flow (at least in females) can be attributed to the effect of this external mechanism on the urethral tube which, by narrowing or expanding the urethra, exponentially affects urine flow4 figs 3&4, in an inverse relationship with the 4th power of the radius, Poiseuille’s Law5.

The bladder is a receptacle with only one role, to empty. Electrical transmission is smooth muscle to smooth muscle6 and the bladder empties by spasm. This is evident on viewing any video of micturition.

Control of evacuation is by muscle forces acting at the urethral outlet tube, in turn controlled by closure or micturition reflexes7. The diameter of the urethra is varied by external muscle forces: it is narrowed for closure, or expanded just prior to evacuation, figs 1,2, 4. These muscles forces are external to the urethra. They rapidly alter the urethral diameter and therefore, the resistance to flow, exponentially5. Almost all bladder dysfunctions can be explained by the effect of the closure or micturition reflexes.
Fig 3 Exponential nature of urine flow is related to urethral diameter. For a flow rate of 50ml/sec (thick blue line), opening the urethral diameter from 3.5mm to 4 mm reduces the head of pressure required by detrusor to expel the urine from 172 cm H2O to 100 cm H2O. Expanding to 6mm (yellow lines), reduces the head of pressure to 20cm H2O. The blue line is the total urethral resistance to flow. The broken lines are dynamic and frictional flow components.

Fig 4 How external muscle forces alter urethral tube diameter to facilitate closure or evacuation. The arrows indicate how muscle forces can externally alter urethral diameter. The 160cm pressure needed to empty through resting urethral radius \( r \) is a nominal figure. Pressure needed to empty following active closure to \( (r/2) \) or opening to \( (2r) \) is calculated by applying Poiseuille’s Law, whereby internal resistance to flow varies inversely by the 4th power of the radius. For example, if the urethral tube can be stretched open to twice the radius \( (2r) \) during micturition, the pressure needed to evacuate the bladder falls by a factor of 16 \( (2x2x2x2) \), from 160cm to 10cm H2O. Broken lines indicate change in diameter by muscle forces (arrows).

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2. Bernhard LiedF, Hiromi Inoue, Yuki Sekiguchi, Darren Gold6, Florian Wagenlehner6, Max Haverfield6, Peter Petros6 Update of the Integral Theory and System for Management of Pelvic Floor Dysfunction in Females European J of Urology EURSUP-738 http://dx.doi.org/10.1016/j.eursup.2017.01.001
Dear Colleagues,

The 12th annual Congress of the International Society of Pelvic-Perineology will be held in Treviso/Venice, Italy, from October 6th to the 8th. It is a honour to organize this meeting, involving ISPP members, experts in the field of the pelvic floor from other International Societies, and with an important participation of the Italian scientific societies of the various specialties having common pelvic interests. The approach to the pelvic floor belongs to urologists, gynecologists, colorectal surgeons, gastroenterologists, physiatrists, obstetricians, nurses, physiotherapists, psychologists, radiologists, sexologists, andrologists: a patient-centered vision is needed!

The themes chosen “Current status, technological advances and perspectives” have the ambitious aim to provide not only a consensus on the management of pelvic floor disorders, according to the evidence-based medicine and the international guidelines, but to look forward considering which are the perspectives of the new technologies. We hope that the numerous topics of the Congress (pelvic anatomy, mesh in prolapse surgery, chronic pelvic pain, therapy of urinary and fecal incontinence, pelvic floor imaging, innovation in pelvic floor surgery, pelvic floor rehabilitation) could stimulate participants to submit abstracts and videos showing their personal experience and current or future researches.

In addition, pre and post-congress courses and workshops will let young doctors to receive training and education on specific topics. The aims of the ISPP, that will be confirmed and developed in the congress, are a quick realization of Masterclasses, Fellowships and of the School for the formation of the Pelvic Surgeon, as well as of Technology Partnership with all the interested Companies in our field.

Treviso, located in close proximity to Venice, is an amazing tourist destination and has a great deal to offer for those who are willing to explore. It has a Celtic origin, however in 89 BC the settlement was turned into a roman commune and developed into an important city. Throughout the middle age Treviso was part of the Lombard League and was involved in various sieges and conflicts, hence the need for stunning city walls and defensive towers. It is the site of the production of Prosecco wine and the birthplace of the dessert Tiramisù.

We wish to meet you in Treviso for a successful ISPP 2019!

Giulio A. Santoro & Giuseppe Dodi
Saturday October 5th, 2019

SOCIAL EVENTS
Tour of Treviso
Tour of Venice
Tour of Prosecco production

Sunday October 6th 2019. DAY 1

<table>
<thead>
<tr>
<th>TIME</th>
<th>TITLE</th>
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<tbody>
<tr>
<td>08:00 - 13:00</td>
<td>WORKSHOP 1 - PF Anatomy, Function and Dysfunction. Diagnostics and Therapy According to the Integral System</td>
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<tr>
<td>08:00 - 13:00</td>
<td>WORKSHOP 2 - PF Rehabilitation</td>
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<tr>
<td>08:00 - 13:00</td>
<td>WORKSHOP 3 - Aesthetic Gynecology and Plastic Surgery in Pelvic Floor</td>
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<tr>
<td>08:00 - 13:00</td>
<td>WORKSHOP 4 - New Technologies in Pelvic Floor Surgery</td>
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<tr>
<td>14:00 - 17:00</td>
<td>SESSION 1: Mesh in PF Surgery: Current Status, Technological Advances and Perspectives</td>
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OPENING CEREMONY
17:30 - 17:50 Welcome Address:
ISPP President, Congress Presidents, CEO of Treviso Hospital, Mayor of Treviso, Rector Magnificus of the University of Padua
17:50 - 18:20 Honorary Lecture
18:20 - 19:00 Concert
19:00 - 21:00 Welcome Buffet at the Exhibition Area
### Monday October 7th, 2019. DAY 2

<table>
<thead>
<tr>
<th>TIME</th>
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<tbody>
<tr>
<td>08:00 - 10:30</td>
<td>SESSION 2: Posterior Compartment Disorders: Current Status, Technological Advances and Perspectives</td>
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<tr>
<td>11:00 - 13:00</td>
<td>SESSION 3: Pelvic Pain: Current Status, Technological Advances and Perspectives</td>
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<tr>
<td>13:00 - 14:00</td>
<td>LUNCHEON SYMPOSIUM I: New Horizons in the Treatment of Hemorrhoids</td>
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<tr>
<td>13:00 - 14:00</td>
<td>LUNCHEON SYMPOSIUM II: New Horizons in the Treatment of Anal Fistulas</td>
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<tr>
<td>14:00 - 16:00</td>
<td>SESSION 4: Video-Session and Podium Presentations</td>
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<tr>
<td>16:00 - 18:00</td>
<td>SESSION 5: Genetics and Hormones: Current Status, Technological Advances and Perspectives</td>
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**ISPP ASSEMBLY**

<table>
<thead>
<tr>
<th>TIME</th>
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<tbody>
<tr>
<td>18:30 - 19:00</td>
<td>ISPP ASSEMBLY</td>
</tr>
<tr>
<td>19:00 - 19:15</td>
<td>Announcement of ISPP Congress 2020</td>
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**SOCIAL DINNER**

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<th>TIME</th>
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<tr>
<td>20:30 - 22:30</td>
<td>Social Dinner at Castello di Roncade*</td>
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### Tuesday October 8th 2019. DAY 3

<table>
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<th>TIME</th>
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<tr>
<td>08:00 - 10:30</td>
<td>SESSION 6: Anatomy, Physiology and Imaging of the PF: Current Status, Technological Advances and Perspectives</td>
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<tr>
<td>11:15 - 13:15</td>
<td>SESSION 7: Incontinence: Current Status, Technological Advances and Perspectives</td>
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**ISPP 2019 CLOSURE**

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<th>TIME</th>
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<tr>
<td>13:00 - 13:15</td>
<td>Final Lecture</td>
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<tr>
<td>13:15 - 13:30</td>
<td>Best Video and Best Podium Presentations Awards</td>
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<tr>
<td>13:30</td>
<td>Closure of the Congress</td>
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<tr>
<td>14:00 - 18:00</td>
<td>WORKSHOP 5 - Sacral Nerve Stimulation in Pelvic Floor Disorders</td>
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<td></td>
<td>WORKSHOP 6 - PF and Anorectal Ultrasound</td>
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<td></td>
<td>WORKSHOP 7 - HPV-Related Lesions in Urogynecological and Proctological Practice</td>
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<tr>
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<td>WORKSHOP 8 - Laparoscopic Training in Pelvic Floor</td>
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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.