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Editorial

Living with the FDA 2011 warning regarding adverse effects related to mesh implants for pelvic floor reconstruction

The FDA, acting as public health guardian, released in 2011 a follow up to the previous 2008 warning regarding the adverse effects of mesh implants used for reinforcement of female pelvic floor upon surgical reconstruction. This was based on medical device reports accumulated from manufacturers and a user device experience database, as well as a review of the literature. The FDA concluded that serious adverse events are not rare and not mild and the use of mesh does not conclusively improve the clinical outcome.[1]

It is evident that pelvic organ prolapse (POP) occurs when the supporting pelvic floor becomes weakened or stretched, usually caused by childbirth, leading to descent of the pelvic organs to the vagina and beyond. This contributes to the impairment of pelvic organ function and a deterioration of patient quality of life. POP is estimated to severely affect more than a tenth of the female population.

Advanced POP necessitates a surgical reconstruction that might be achieved via abdominal approach by an open operation, by laparoscopy, by robotic surgery, or via vaginal approach. A non mesh operation entails a rather high incidence of recurrence,[2] *which is understandable as POP is a herniation phenomenon, and mesh reinforcement reduces the rate of recurrence. Synthetic permanent or absorbable meshes or biological grafts, or any synthesis of these may be used for reinforcement of the weakened pelvic floor structures that led to POP. The field of vaginal mesh operations was significantly studied regarding relevant adverse effects, whereas other surgical options have been criticized much less.*[3]

The FDA warning, referring just to the vaginal mesh augmentation operations, quotes about 3.000 urinary anti-incontinence sling and POP mesh adverse events, arising from an estimated total of 300.000 sling and mesh operations performed from January 2008 through December 2010. Most of the adverse events are related to mesh exposure, which is regarded as a minor complication, which can be easily treated with no morbid sequelae. Some cases of chronic pain are reported and 3 fatalities were directly attributed to bowel perforation or hemorrhage, which was likely caused by the surgery itself rather than from the mesh. Yet, the announcement declares that the mesh related complications are not rare and not mild.

As there are no database for the non-mesh or abdominal approach surgical alternatives, the FDA could only analyze vaginal mesh operations. However it is evident that the non-vaginal mesh operation, such as vaginal hysterectomy and open, laparoscopic and robotic abdominal colpo-sacro-pexy which are occasionally performed whenever the uterus is prolapsed, are definitely associated with operation related complications. Vaginal hysterectomy might be related to bladder, ureteral and bowel iatrogenic injuries as well as to operative bleeding and post-operative infection, chronic pain, vaginal shortening and various psychological impacts. This is the case as well with each and every other non-mesh POP reconstructive procedure, such as vaginal colpo-sacrospinous-pexy, abdominal colpo-sacro-pexy and laparoscopic or robotic pelvic floor reconstruction. The nature, occurrence and severity of these operation related complications were never defined properly.

The AUGS (American Urogynecologic Society), SUFU (Society of Female Urology and Urodynamics) and ACOG (American Congress of Obstetricians and Gynecologists) as well as some editorials have all responded to the FDA alarm.[4-6] *The importance of the FDA warning is appreciated, but at the same time the accurate weight is given both to the actual and true modest severity and occurrence rate of the POP vaginal mesh reconstruction complications as well as to the reported severe and rather frequent complications attributed to the non-vaginal mesh POP reconstruction operations.*

These articles emphasize the importance of obtaining specialized thorough and rigorous training prior to implementing mesh augmentation for POP, maintaining good skills by keeping large volume expertise, being vigilant for potential adverse effects, watching for complications carefully, informing patients properly and considering non-mesh POP reconstruction when appropriate.

The need for mesh reinforcement of the weakened fascia for achieving a long lasting cure of herniation processes is unquestionable. Given that the underlying pathology leading to POP is actually just a hernia of the pelvic floor, one must admit that the very same surgical principles used for any hernia repair are applicable for POP.

The distinction between abdominal hernia and POP repair is that the inherited differences between the anterior and inferior abdominal wall need to be addressed properly. This includes the need to take into account two important factors: 1) POP is about horizontal repair and the pelvic floor is not surrounded by "healthy fascia", meaning the apical and peripheral support is needed, and 2) the width of the vaginal wall covering the mesh implant is rather thin, and therefore meticulous surgical measures are required in order to reduce mesh exposure.

The vagina is definitely the best natural orifice for POP surgery, providing both convenient access to the desired surgical field and the easiest recovery and rehabilitation for the patient. There is no doubt that supportive pelvic side wall solid ligaments, such as the Arcus Tendineous Fascia Pelvis and the Sacro-Spinous are accessible via vaginal approach, and that the uterine cervix or the vaginal apex might be anchored to these ligaments.

Most of the adverse effects mentioned with the FDA announcement are likely related to excessive implanted mesh mass, inappropriate mesh placement, applying exaggerated tension forces on the implants and native pelvic tissues and lack of appropriate training and sufficient skills maintenance.

Reading carefully the literature leads one to the notion that non-mesh POP reconstruction drawbacks have unacceptably high recurrence rates (as high as 45%), which necessitate further large-scale operations with limited success rates and inherited specific sever adverse effects.[2]

The FDA must be applauded for taking a stand on behalf of the public and for pointing out the hazards of mesh usage with POP reconstruction. Mesh manufacturers and users must pay careful attention to this and take necessary precautions. However, mesh implants for POP reconstruction provide true and valuable benefits, and therefore should not be abandoned, especially since non-mesh POP reconstruction alternatives do not deliver the long lasting and complication free outcome desired by patients and physicians.

The FDA recommendations for improving the mesh implant usage should be embraced and meticulously implemented. The FDA warning should challenge mesh manufacturers and users to achieve better outcomes. Potential routes for reducing the complication rates and improving clinical outcomes should be looked for, such as improving the minimal invasiveness of the procedure, reducing tissue damage during dissection and placement, standardizing the surgical steps and improving surgical reproducibility, avoiding iatrogenic injuries and morbid consequences. These guidelines can lead to greater usage of mesh repair for the benefit of our patients.

Both, industry and pelvic floor surgeons were discouraged of further using the vaginal mesh augmentation for the cure of POP. Yet, one must always bear in mind the draw-backs of surgical modalities other than vaginal mesh operations when being driven to elect these for his patient. Although vaginal meshes carry potential hazards, so do all operative modalities. Thus, the question is not whether a certain operation is totally safe, because none is. The issue is choosing the best operation for the specific patient, in terms of safety, ease of rehabilitation and long standing therapeutic results. This will lead frequently toward vaginal mesh POP reconstruction.[7-9] Surgical good training and expertise, combined with thorough theoretical knowledge, proper patient selection and transparent patient information providence and counselling are the keys for successful operative treatment.

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Original article

A simplified biomechanical perspective of the Integral Theory System

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Abstract: The Integral Theory offers an entirely anatomical explanation of normal and abnormal pelvic floor function. It states that prolapse, some types of pelvic pain, bladder and anorectal symptoms are mainly caused by laxity in the vagina or its supporting ligaments, a result of altered collagen/elastin. The Integral System is a practical, anatomically-based system for diagnosis and minimally invasive treatment of POP and symptoms based on diagnosing and repairing lax suspensory ligaments/ perineal body. We have taken a different perspective in this paper, starting from the basic science of urine flow through an elastic tube and proceeding to how ligaments become lax, how lax ligaments weaken the muscle forces which open and close the organs, onto the genesis of symptoms and prolapse and finally, how they can be precisely repaired and tensioned.

Key words: Integral Theory; Pelvic Floor; POP.

BASIC SCIENCE

Bladder, uterus and rectum are storage containers for
- Urine
- Foetus
- Faeces

Their contents are evacuated via outlet tubes which communicate with the outside
- Urethra
- Vagina
- Anus

The tubes are elastic so as to allow stretching and kinking for closure and stretching open for evacuation.

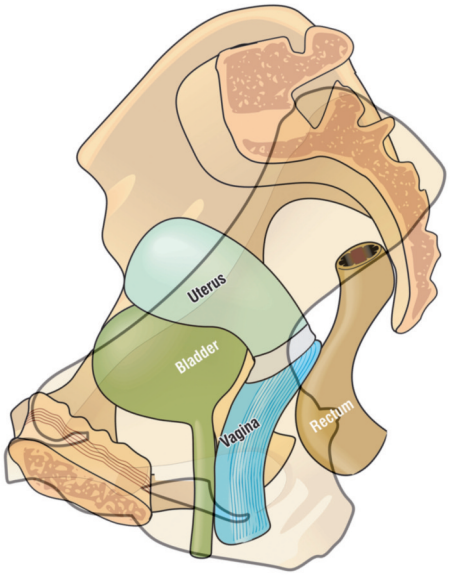

Figure 1. – The organs and their emptying tubes. Perspective: standing position. Simplistically, the vagina and its suspensory ligaments support the bladder anteriorly and the rectum posteriorly

THE BIOMECHANICS OF TUBE CLOSURE

There are 2 ways to close a tube, external pressure and kinking.

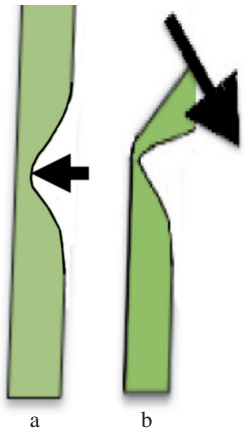

Figure 2a. – Compression closure by an external force, like stepping on a garden hose.
Figure 2b. — Closure by rotation by an external force, like 'kinking' a garden hose.

Opening of an elastic tube.

The easiest way to do this is to anchor the anterior wall and stretch open the posterior wall.

THE CONCEPT OF RESISTANCE WITHIN A TUBE

Simplistically, as a tube narrows, the urine (or fecal) flow encounters frictional forces on the side walls which inhibit its transit in an exponential manner, so that a much higher bladder pressure is required to expel the contents of the bladder or bowel. For urine Hagen-Poisseuille's law applies, the resistance varies inversely to the 4th power for laminar flow and 5th for non-laminar flow.[1] The resistance in the anorectum varies inversely to 3rd power and is more complex, as the biomechanics of anorectum also involve moulding of the stool.[2,3]

HOW EXTERNAL MUSCLE FORCES (ARROWS) ALTER THE INTERNAL RESISTANCE OF A TUBE

Say a tube with diameter 'D' requires a pressure of 160 cm to empty as shown in figure 3.

Closure (continence). If the diameter of the urethral tube can be narrowed to half its diameter (D/2) by external muscle forces (arrows), then the pressure required for urine to

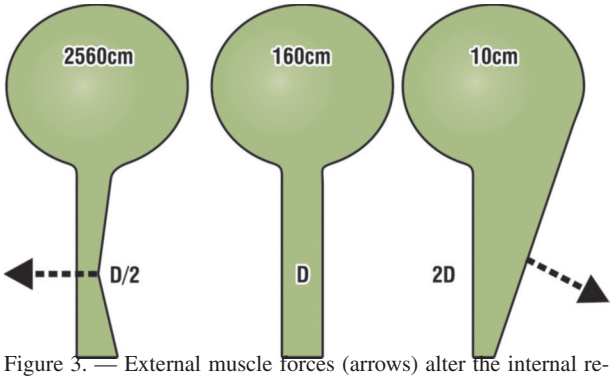

Figure 3. — External muscle forces (arrows) alter the internal resistance of a tube during closure (D/2) and evacuation (2D). 'D' represents resting state of the urethral tube.

leak rises to the 4th power of 2, which is 16 (2x2x2x2), 2560 cm.

Evacuation (micturition). If the posterior wall of the tube can be stretched open to double its diameter (2D) by external muscle forces (arrow), then the pressure required to empty the bladder falls to only 10cm.

External muscle forces are an evolutionary necessity. Fast-twitch striated muscle forces create rapid closure and opening of the evacuation tubes.

WHAT THIS MEANS FROM A CLINICAL PERSPECTIVE

The so-called 'obstructive' micturition or in some cases 'constipation', may be caused not by a mechanical obstruction, but by a functional obstruction, inability to open out the urethra during micturition. It is well known that in such cases, urethral dilatation rarely encounters mechanical obstruction. Dilatation may proceed easily to 12 Hegar with no evidence of blockage.

ROLE OF STRIATED MUSCLES IN CLOSURE (CONTINENCE) AND EVACUATION

A striated muscle contracts efficiently only over a short distance (figure 4).

The importance of Gordon's law If the ligament in which the muscle inserts is lax, the muscle effectively lengthens to E+L (E-optimal length; L-additional length) and rapidly loses its contractile strength.[4]

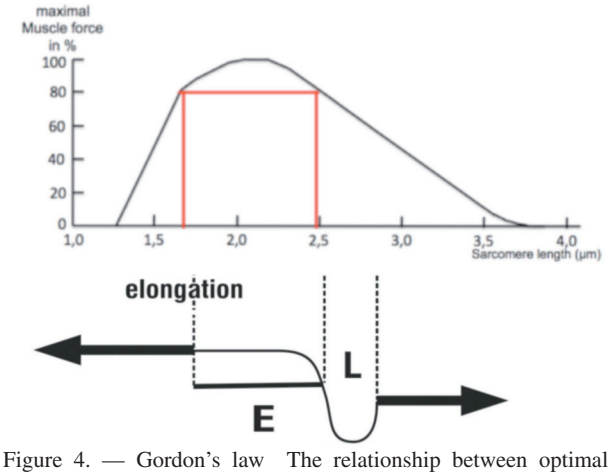

Figure 4. — Gordon's law The relationship between optimal length 'E' and force of muscle contraction. 'L' represents the amount a muscle lengthens when its ligamentous insertion point is lax.

PELVIC LIGAMENTS

Five main ligaments suspend the organs from above, external urethral (EUL), pubourethral (PUL), ATFP, cardinal (CL) and uterosacral (USL). The perineal body (PB) supports the vagina and rectum from below.

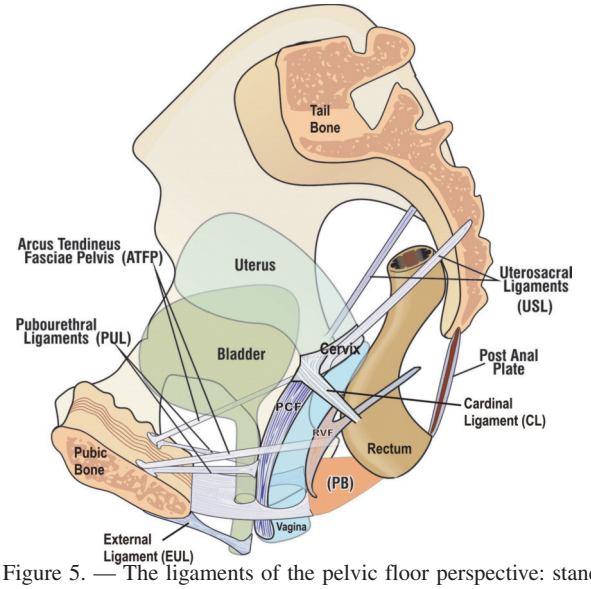

Figure 5. — The ligaments of the pelvic floor perspective: standing position.

PELVIC MUSCLES

In the pelvic floor there are 4 main muscles. These are situated below the suspensory ligaments.

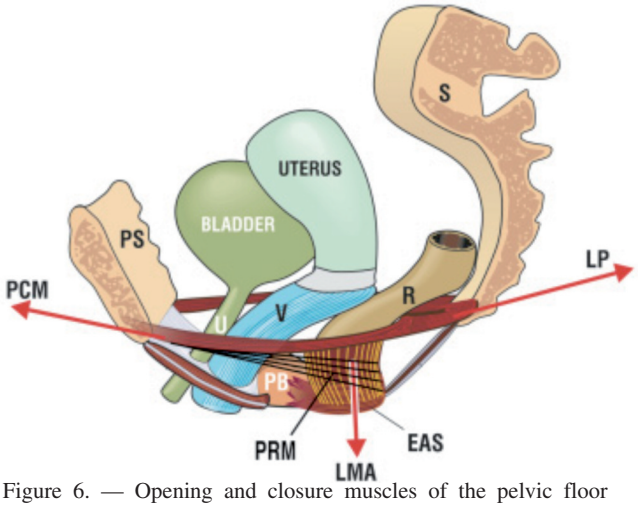

Figure 6. — Opening and closure muscles of the pelvic floor Perspective: sitting position. Four main muscle forces work in a co-ordinated way to close and open the outlet tubes, urethra 'U', vagina 'V' and rectum 'R'. M. pubococcygeus (PCM), M. levator plate (LP), M. conjoint longitudinal muscle of the anus (LMA) contract against pelvic ligaments. Their contractile strength may diminish when their insertion ligaments are lax. M. puborectalis (PRM) contracts directly against the pubic bone and is not affected by lax ligamentous insertion points .

URETHRAL CLOSURE MECHANISMS, (figure 7)

External striated muscles close the urethral tube.

Distally-Compression from behind. A distal muscle force (M. pubococcygeus contraction) pulls the vagina forward

against the external urethral and pubourethral ligaments to close the urethra from behind.[5]

Proximally-"kinking". Proximal muscle forces LP (levator plate) and LMA (conjoint longitudinal muscle of the anus) stretch and rotate the proximal urethra around the pubourethral ligament to 'kink' it at the bladder neck.[5]

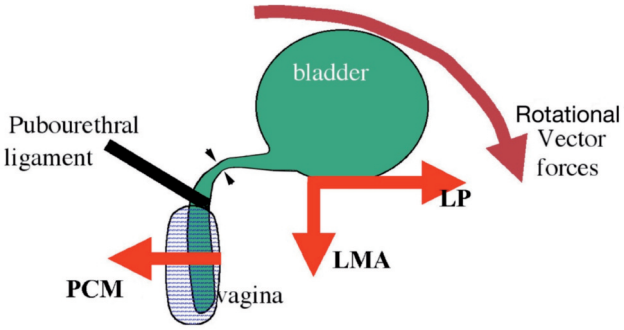

Figure 7. — Normal urethral closure (sitting position). The distal vagina is pulled forward against the pubourethral ligment (PUL) by M. pubococcygeus (PCM) to compress the urethral tube from behind. Proximally, posterior directional forces (LP/LMA) rotate the proximal urethra around PUL to 'kink' the tube proximally (small arrows). LP = levator plate; LMA = conjoint longitudinal muscle of the anus.

HOW A LAX LIGAMENT MAY CAUSE URINARY STRESS INCONTINENCE

The effective insertion point of the directional muscle forces (arrows, figure 6), is the pubourethral ligament (PUL). In figure 8, PUL is elongated (L) and so becomes loose. Because the insertion point PUL is loose, the PCM muscle forces (arrows) are weakened and cannot stabilize the suburethral vaginal hammock 'H' sufficiently for LP/LMA vectors to rotate and 'kink' the proximal urethra . Instead, the posterior urethral wall is pulled from closed 'C' to open 'O', ('funnelling') exactly as happens during micturition.

MICTURITION

During micturition in a normal patient, the geometry is exactly as depicted in figure 8 except that PCM relaxes, PUL lengthens and LP/LMA vectors open out the posterior urethral wall, vastly lowering urethral resistance; detrusor contracts and empties the bladder.

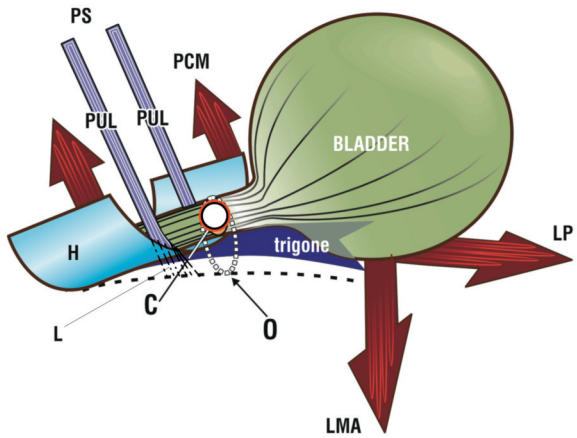

Figure 8. — How a lax ligament may cause urinary stress incontinence. O = open position of urethra; C = closed; L = excessive length of the pubourethral ligament (PUL). The contractile strengths of PCM, LP and LMA are weakened by a lax PUL.

ROLE OF THE UTEROSACRAL LIGAMENT IN MICTURITION

Once the forward PCM vector relaxes, LP vector stretches back the vagina and posterior urethral wall, while the downward LMA vector pulls down on the uterosacral ligament (USL) to open out the posterior urethra (figure 9b). According to Gordon's Law, a lax USL will weaken the muscle contraction (downward vector, figure 9b), so that the detrusor has to contract against a tube not fully opened out. The bladder has to work harder to expel the urine. This is interpreted by the patient as 'obstruction'.

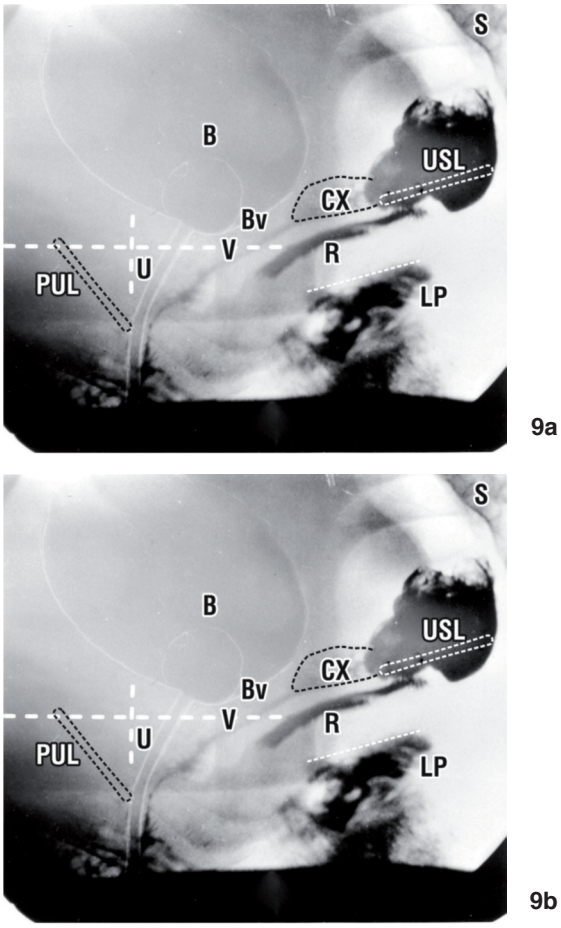

Figure 9a (resting) and 9b (micturition) in a nulliparous female in sitting position. The posterior urethral wall is opened out and pulled back behind the vertical co-ordinate by the posterior vectors (arrows) stretching the vagina'V' backwards/downwards below the horizontal co-ordinate. These vectors (arrows) pull against the uterosacral ligament 'USL'; B=bladder; PUL=pubourethral ligament; R=rectum; V=vagina; LP=levator plate (angulated downwards by the white arrow, the LMA force.

NEUROLOGICAL CONTROL MECHANISMS

These are akin to an electronic system, with peripheral sensors (bladder base stretch receptors, muscle spindles), central processors (cortical, subcortical) and intermediate relay stations (spinal cord). The peripheral sensors work via precise feedback mechanisms which co-ordinate contraction and selective relaxation of smooth and striated muscles, organ filling and emptying.

ROLE OF LIGAMENTS AND VAGINAL ELASTICITY

A central thesis of the Theory is that these peripheral sensors (bladder base stretch receptors, nerve endings) are

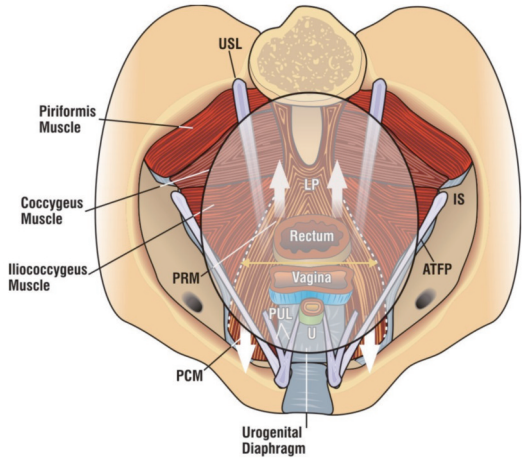

Figure 10. — Stretching of tissues laterally during delivery. The vagina must stretch to almost 10cm. This may dislocate organ attachments to levator hiatus (broken lines) overstretch the suspensory ligaments, and even dislocate pelvic muscle attachments to the pubic bones.[6]

supported by a vaginal membrane stretched by slow-twitch muscle forces contracting against competent suspensory ligaments.

It is evident from figures 9a and 9b that the bladder base is supported by the anterior vaginal wall, and that uterosacral ligament plays a key role in supporting the rectum. There is differential movement of the organs and clearly tissue elasticity and organs spaces are required for this.

OVERSTRETCHING OF LIGAMENTS

The head dilates the cervix to at least 9.5 cm (flexed head) or to 11.2 cm (deflexed head). Even though the collagen is depolymerized prior to delivery, this distension may dislocate the attachments of the organs to the levator hiatus and stretch the suspensory ligaments to cause organ prolapse.

ANATOMICAL CONSEQUENCES OF LIGAMENT/ VAGINAL LAXITY

"Overactive bladder"

Given that the directional muscle forces contract against the suspensory ligaments, it is not possible for the muscle forces (figures 9a and 9b) to adequately stretch the vaginal membrane if the suspensory ligaments are lax. The bladder base stretch receptors will not be adequately supported, so that the stretch receptors may fire off at a lower bladder volume, prematurely activating the

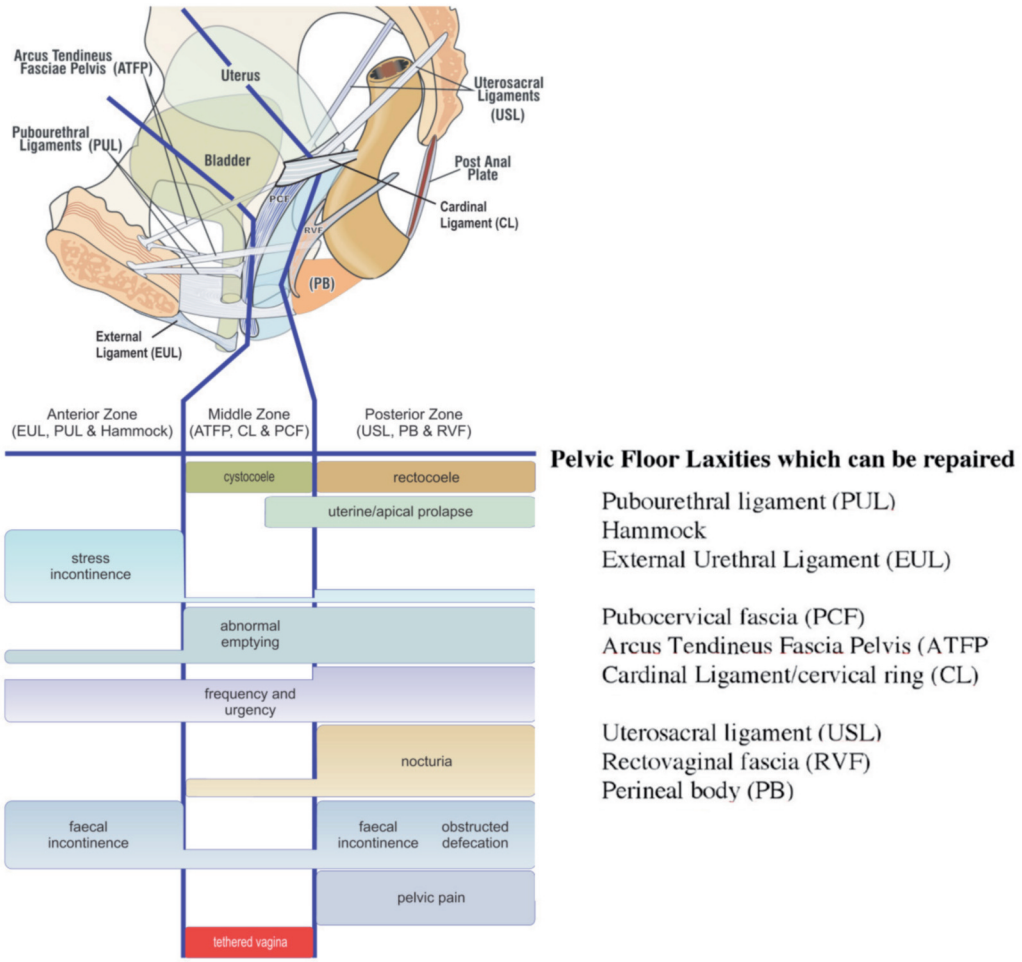

Figure 11. — The Pictorial Diagnostic Algorithm (standing position) summarizes the Integral System. Specific symptoms are associated with specific ligamentous defects and organ prolapse. The size of the bar gives an approximate indication of the prevalence (probability) of the symptom. All symptoms are caused by laxity except the "tethered vagina", an iatrogenic condition caused by excessive tightness (usually due to scar tissue), in the bladder neck area of vagina.

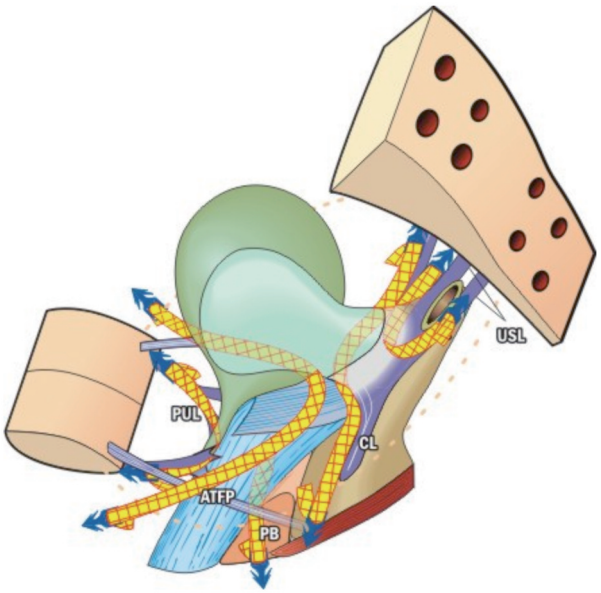

Figure 12. — Surgical TFS repair. Repair of stretched ligaments and repositioning of laterally displaced tissues with the TFS tensioned sling, from left to right, pubourethral ligament, ATFP, cardinal ligament, uterosacral ligaments and perineal body.[13-15] This repair corrects prolapse and improves/cures pelvic floor symptoms as for figure.[10]

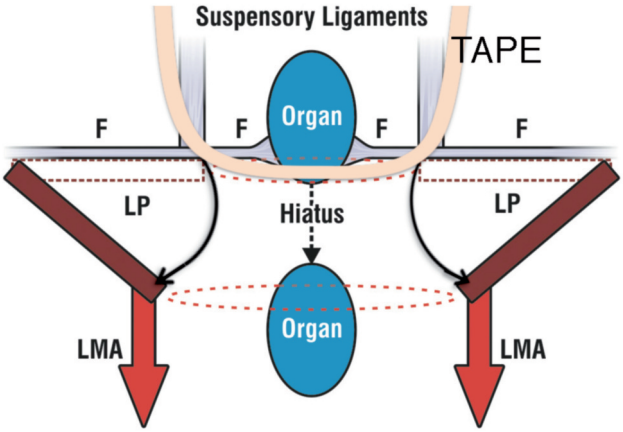

Figure 13. — Minisling repair of cystocele reinforces existing supporting structures. The tape reinforces the damaged ligaments, reattaches fascial connections 'F' to the organ and hiatal muscles ("LP"), restricting opening out of the hiatal space during straining (arrows).[15]

micturition reflex.[7] This sends afferent impulses to the brain and these are interpreted as urgency symptoms. The bladder empties more frequently, 'frequency' which at night is called 'nocturia'. "Bladder abnormality" is therefore not required to explain these symptoms as they are all consistent with premature activation of the micturition reflex. If this is so, then repair of suspensory ligaments should also cure urgency in some patients.

Rezapour[8] reported a high percentage cure of urge as well as stress with a midurethral sling, and Neumann[9] reported 90% cure of urgency in patients who had urge incontinence with no USI after a posterior sling which reconstituted the posterior supports of the apex.

"Detrusor overactivity" ('DO') is explained as a detrusor contracting against a striated muscle (forward vector 'PCM', figure 8) intermittently trying to close the urethral tube. A striated muscle contracts only over a short period of time. It is a fact that if the detrusor contracts against a tube which is sufficiently opened out to vastly decrease frictional resistance, there will be no micturition pressure recorded, as all the detrusor energy will be converted to flow.[10]

Bowel function

With reference to figure 9b, laxity in the USL may allow prolapse inwards of the anterior rectal wall. This would narrow the anorectal cavity and increase the intracavity resistance causing 'constipation' This explains the common co-incidence of 'constipation' in patients with apical/uterine prolapse and cure of both conditions with a posterior sling operation.[11]

THE RELATIONSHIP OF LAX LIGAMENTS TO SYMPTOMS

The biomechanical explanations were key to creation of the Diagnostic Algorithm (figure 11). The natural site of the suspensory ligaments has given rise to a slightly different classification as 3 "zones", not compartments.

Anterior zone: external meatus to bladder neck. It contains EUL, PUL and the underlying vagina termed 'hammock'.

Middle Zone: bladder neck to cervix. It contains ATFP and cardinal ligaments attaching to the cervical ring, with underlying vagina termed 'PCF', pubocervical fascia.

Posterior Zone: cervix to perineal body. It contains Uterosacral ligaments (USL), perineal body (PB) and the posterior vaginal termed 'RVF', rectovaginal fascia.

The uterus forms part of the middle zone via its anterior cervical ring and the posterior zone via its posterior cervical ring.

SURGICAL CURE ACCORDING TO THE INTEGRAL SYSTEM

Using minimally invasive methods, discrete lengths of tape are inserted in the precise position of the loose ligaments diagnosed as causing the symptoms or prolapse.

The first such application was the midurethral sling operation first performed in 1990[5] known as the intravaginal slingplasty or "TVT".[12]

Subsequently a less invasive tensioned sling operation was developed in 2005[12-14] (figure 12), which could reinforce and tension all 4 suspensory ligaments and perineal body and at the same time, "reglue" the attachments of the organs to the levator hiatus (figure 13).[13-15]

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Original article

Evacuation proctography and magnetic resonance defaecography: a retrospective study

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Abstract: *Objective:* to compare supine magnetic resonance defaecography (MRD) and evacuation proctography (EP) for evaluation of the posterior pelvic compartment. *Materials and Methods*: Data were collected retrospectively for patients with OD who underwent both MRD and EP between 2008 and 2011. Comparison was made using McNemar test for correlated proportions. Sixteen patients underwent both diagnostic studies. The average patient age was 39 years, and 81% were female. *Results*: Recto-rectal intussusception was apparent in 50% of patients on EP vs. 43% on MRD (p = 0.999), and 62% of patients had a rectocele on EP vs. 56% on MRD. During EP, 75% of the patients were able to evacuate more than half of the pre-instilled rectal contrast, compared to only 37% during MRD ($p = 0.016$). The rate of incomplete evacuation was significantly greater during MRD than during EP. *Conclusion*: no significant difference was evidenced in detection of posterior pelvic compartment pathology between EP and MRD.

Key words: Dynamic MR; Defecography; Proctography; Rectocele; Intussusception.

INTRODUCTION

Evacuation proctography (EP) has been used to evaluate patients with pelvic floor dysfunction for more than 50 years. EP is simple to perform and widely available, and it detects structural and functional abnormalities in defaecatory disorders.[1] Magnetic resonance defaecography (MRD), with its intrinsic advantages, has become an attractive option. It does not require the use of ionising radiations, and it provides high-quality multiplanar imaging and simultaneous visualisation of all 3 pelvic compartments.[2] The aim of this study is to compare supine magnetic resonance defaecography and evacuation proctography for the evaluation of the posterior pelvic compartment.

MATERIALS AND METHODS

Data were collected retrospectively by reviewing clinical letters, anorectal physiology reports, and radiology reports for patients with OD who underwent both MRD and EP between 2008 and 2011. Comparisons were made using McNemar test for correlated proportions. Data were analysed using SPSS version 15.0.

MRD examinations were performed on a 1.5 Tesla closed magnet Siemens Symphony scanner. The patient lies supine on a waterproof mat in the MRI scanner, with knees slightly flexed; legs apart and a pillow underneath. A flexible transmit/receive radiofrequency Siemens 6 channel multiphase coil is wrapped around the pelvis. Patient evacuates pre-instilled rectal contrast (ultrasound gel) on the MR table.

During EP the patients were seated on a commode, feet placed on the footrest of an upright positioned examination table in front of a fluoroscopic unit. Patient evacuates pre-instilled rectal contrast in a sitting position.

RESULTS

There were 118 MRDs and 102 EPs performed at our institution during the study period. Sixteen patients underwent both diagnostic studies. The average patient age was 39 years, and 81% were female. The median interval between studies was 4.5 months (inter quartile range, 2.25 to 11.25).

Common presenting symptoms were sensation of incomplete evacuation (93%), digitation (43%), faecal incontinence (31%), urgency (18%), and prolapse (18%).

During EP, 75% of the patients were able to evacuate more than half of the pre-instilled rectal contrast, compared to only 37% during MRD (p = 0.016).

Recto-rectal intussusception (Figure 1b) was apparent in 50% (8/16) on EP, vs. 43% (7/16) on MRD (p = 0.999); 56% (9/16) had a rectocele (Figure 1a) on EP, vs. 62% (10/16) on MRD. About 20% (2/9) of rectoceles showed contrast trapping on EP, compared to 10% (1/10) on MRD.

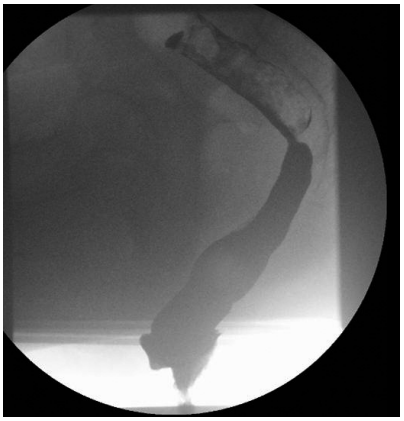

Figure 1A. – Evacuation proctography revealed a small rectocele and mucosal folds.

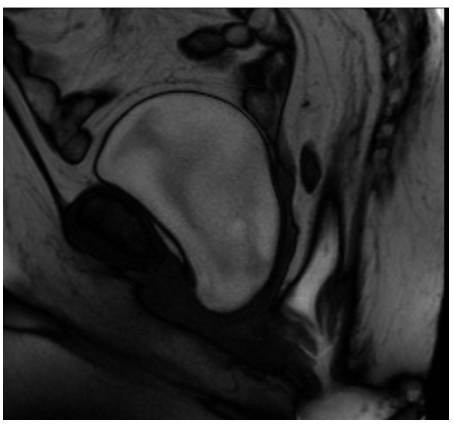

Figure 1B. – Magnetic resonance defaecography for the same patient clearly demonstrates intussusception.

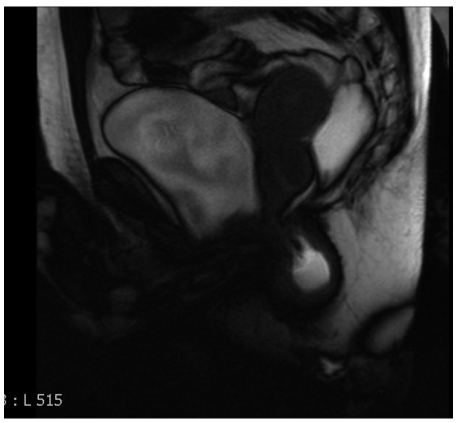

Figure 2A. – Magnetic resonance defaecography shows no evacuation, suggesting an anismus.

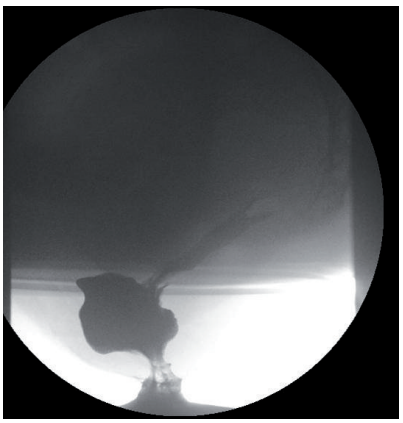

Figure 2B. – Evacuation proctography performed a few months later revealed an intussusception and a rectocele.

Anismus (Figure 2a) was reported in 2 patients on MRD and in none on EP. Both these patients were found to have increased resting pressures and impaired rectal sensitivity. Table 1 compares findings exclusive to MRD and EP.

Furthermore, in 19% of patients, MRD detected pathology in other pelvic compartments that was not apparent on EP and clinical examination.

TABLE 1. – Comparison of pathology detected by magnetic resonance defaecography and evacuation proctography exclusively.

	Magnetic Resonance Defaecography	Evacuation Proctography
Intussusception	2	3
Rectocele (Trapping)	3 (1)	4 (2)
Anismus	2	0

DISCUSSION

Obstructive defaecation (OD) is a cause of constipation. The pathology underlying OD may be multifactorial and often involves more than 1 pelvic compartment.[3] Assessment of patients presenting with OD includes history, clinical examination, colonic transit studies, anorectal physiology testing, and defaecography.

Traditionally, EP has been used to evaluate morphologic (e.g., rectocele and recto-rectal intussusception) and functional (e.g. anismus) causes of OD. However, in the last 20 years, MRD has been increasingly studied for evaluation of obstructive defaecation. MRD has many advantages: it does not require use of ionising radiation, and it provides high-quality multiplanar imaging enabling simultaneous visualisation of all 3 pelvic compartments.

Earlier comparative studies (1990–1997) reported that EP was clearly superior in detecting pathology contributing to OD[4,5] and showed poor agreement with magnetic resonance imaging (MRI) techniques,[6] suggesting that the erect position used in EP is physiological, and therefore preferable to the supine position used in MRI. These studies did not use rectal contrast in MR imaging; therefore, patients were not imaged during evacuation. Furthermore, a study comparing sitting-up and supine MRD detected similar proportions of cystoceles and rectoceles.[7] Studies comparing magnetic resonance and evacuation colpocystoproctography found that the 2 methods have similar rates of detection of pelvic organ prolapse.[8-10] However, colpocystoproctography is invasive and involves instillation of contrast in the bladder, vagina, and rectum. In our routine clinical practice, we use rectal contrast with or without oral contrast in EP and only a rectal contrast in MRD.

A common criticism of supine MRD is that patients frequently fail to adequately evacuate in the supine position, making it difficult to diagnose intussusception and to differentiate between trapping and non-trapping rectoceles. In the present study, although significantly lower proportions of patients evacuated >50% of rectal contrast during MRD compared to EP (37% vs. 75%, p = 0.016), the prevalence of intussusception and trapping rectoceles were similar between MRD and EP (43% vs. 50%, p = 0.999 and 10% vs. 20%, p = 0.999, respectively). Furthermore, in 19% of patients, MRD detected abnormalities of other pelvic compartments that were missed on clinical examination and EP. In one study, MRD detected pelvic floor abnormalities that had not been detected by clinical examination alone in up to 34% of patients.[11] However, it remains a challenge to determine the clinical relevance of such additional findings.

Although the rate of evacuation of rectal contrast observed in this study was significantly less in MRD, we did not find any significant difference in the posterior compartment pathology detected by EP and supine MRD. This finding may be due to our small sample size and the retrospective nature of the study. Further prospective studies with adequate power are warranted to compare these 2 diagnostic modalities and to evaluate their effect on patient management.

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Original article

An anatomical basis for vaginal remodelling without excision of vaginal tissue

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Abstract: The vagina is an elastic tube which is stretched around the penis by 3 directional muscle forces in the manner of an elastic glove. These are reflex contractions and no learning is required. In contrast, narrowing the vagina by "squeezing upwards" is a learnt activity activated by voluntary contraction of the puborectalis muscle (PRM) which functions normally even with a loose vagina. The 3 striated muscle forces require adequate insertion points into the pubourethral (PUL) / uterosacral (USL) ligaments and perineal body (PB) in order to function properly. Loose suspensory ligaments/perineal body may result in the sexual partner feeling a "looseness" on entering the vagina. Based on this anatomy, the keys to vaginal remodelling are repair of the suspensory ligaments (to restore muscle force) and conservation of vagina (to preserve elasticity). Restoration of PUL/USL and PB restores the 3 directional muscle forces which contract to reflexly narrow the vagina.

Key words: Vaginal remodelling; Pubourethral ligament; Puborectalis; Uterosacral ligament; Sexual function.

INTRODUCTION

The core element of my thesis is based on the Integral Theory:[1] the vagina is an elastic tube which is stretched around the penis by directional muscle forces in the manner of an elastic glove. These striated muscle forces require adequate insertion points into the suspensory ligaments and perineal body in order to function properly. Loose suspensory ligaments/perineal body may result in the sexual partner feeling a "looseness" as he enters the vagina.

The keys to vaginal remodelling, as I see it, are

1. Repair of the suspensory ligaments (to restore muscle force)
2. Conservation of vagina (to preserve elasticity)

The penis enters the vagina and sets off an involuntary reflex which causes contraction of 3 striated muscles. The forward vector is. m. pubococcygeus (PCM). The posterior vectors are m. conjoint longitudinal muscle of the anus (LMA) and m. levator plate (LP). In the context of intercourse, LP stretches the posterior vaginal wall against perineal body (PB) , and the anterior vaginal wall against PUL (Figure 1). LMA pulls against the utero-sacral ligaments "USL". These stretch the vagina backwards/downwards to grasp the penis like a glove. These striated muscles cannot function adequately if their suspensory ligaments, PUL and USL are weak or over-extended.

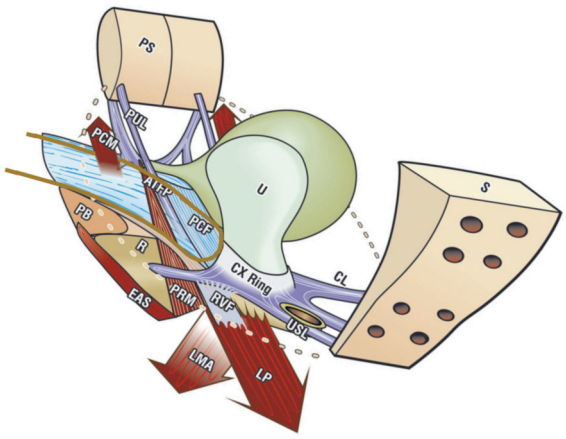

Figure 1. – What happens during intercourse in the normal woman.

RADIOLOGICAL PROOF OF THE THREE MUSCLE VECTORS

The pelvic muscles contract against the suspensory ligaments PUL and USL to stretch the vagina backwards and downwards to narrows the vagina and constrict the penis. The downward movement creates a rhythmic "pulling" sensation on the penis.

Urine loss during intercourse is a related manifestation. My experience over many years indicates that the principal anatomical defect is laxity in the pubourethral ligament (Figure 1). Cure is simple: insert a midurethral (preferably retropubic) sling.[2, 3]

ROLE OF PUBORECTALIS

Voluntary contraction during intercourse* is activated by voluntary contraction of m. puborectalis (Figure 5).[2,3] This is quite different from the reflex contraction occurring during exercise, straining, intercourse and other activities which activate the 3 directional muscle forces (Figures 2 and 3). *This action does not depend on intact suspensory ligaments and is an excellent technique for women who have a lax vagina.*

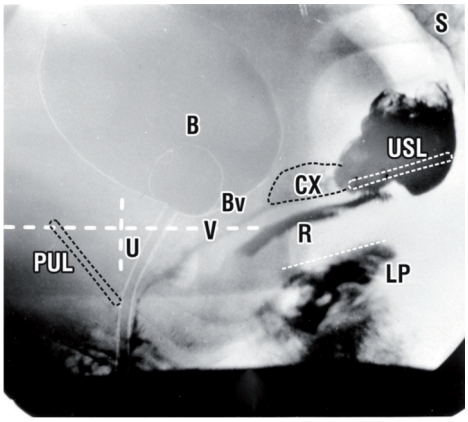

Figure 2. – Resting x-ray. The vagina'V', rectum 'R', urethra 'U' are stretched backwards by slow-twitch muscle fibres . The gentle downward displacement of the upper border of levator plate (LP) (broken lines) is by the by slow-twitch muscle fibres of the conjoint longitudinal muscle of the anus (LMA).

* "The Shanghai Clip" of Wallis Simpson, Duchess of Windsor. This was an infamous false assertion propagated by certain members of the British Aristocracy. The rumour was that while in Shanghai during her 1st marriage to an American servicemen, she visited a Shanghai brothel and learnt how to voluntarily contract her pelvic floor muscles to narrow her vagina.

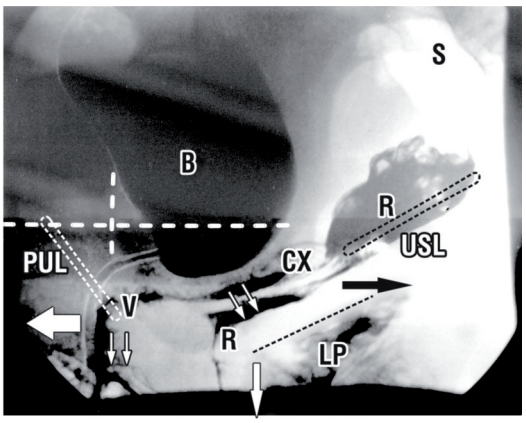

Figure 3. – Straining x-ray. Any stimulus (straining, coughing, intercourse) which stimulates fast-twitch muscle contractions stretch the vagina and rectum backwards and downwards by 3 directional muscle forces acting against PUL and USL. This action narrows the vagina and grasps the penis tightly.

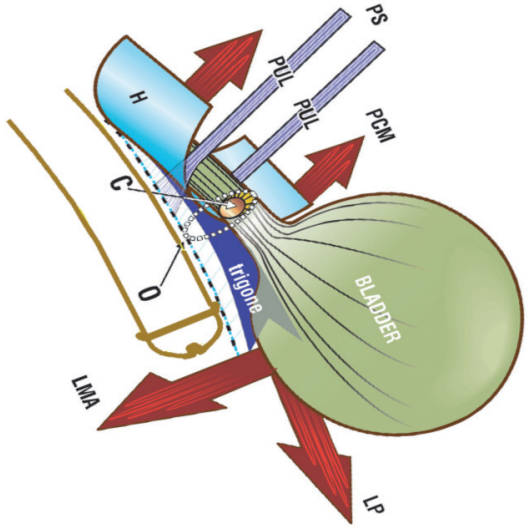

Figure 4. – Mechanism for urine loss during intercourse. The penis stretches the vagina downwards and opens out the posterior urethral wall. If the pubourethral ligament (PUL) is weak or overextended, the forward vector, m. pubococcygeus (PCM) cannot function. The posterior vectors m. conjoint longitudinal muscle of the anus (LMA) and m. levator plate (LP) stretch the vagina backwards/downwards to open out the posterior wall of the urethra.

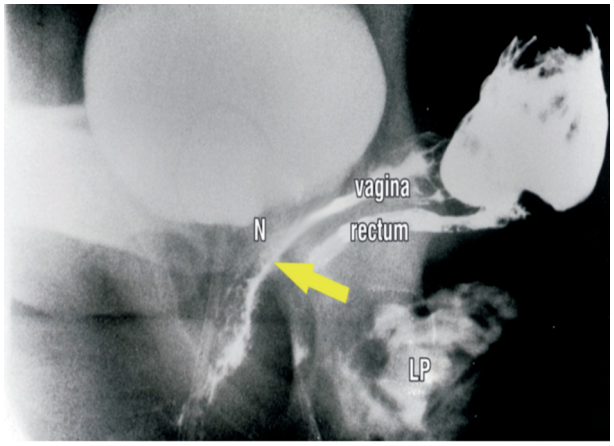

Figure 5. – Voluntary contraction of m. puborectalis during intercourse. The same patient as Figures 2&3. This elevates and narrows the rectum and vagina (forward arrow).

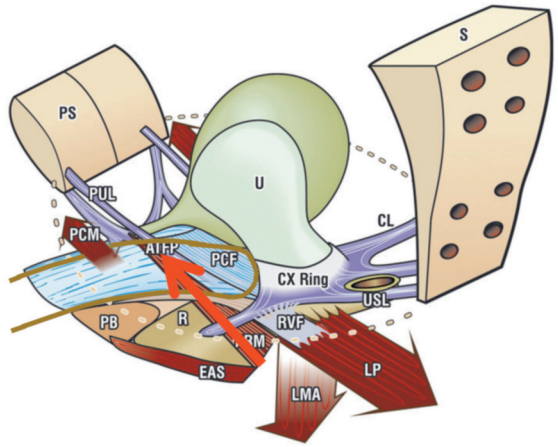

Figure 6. – Forward contraction of m. puborectalis 'PRM" against the pubic symphysis (PS).

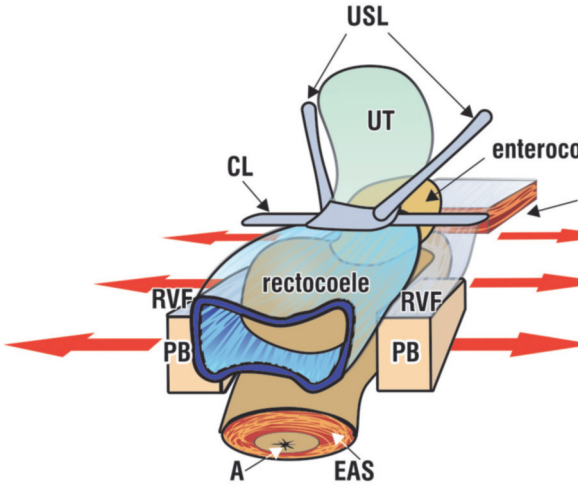

Figure 7. – Role of perineal body. If the two perineal bodies (PB) are separated, the rectovaginal fascia (RVF) is ruptured or overextended, so that LP cannot stretch the vaginal wall backwards to 'grip" the penis.

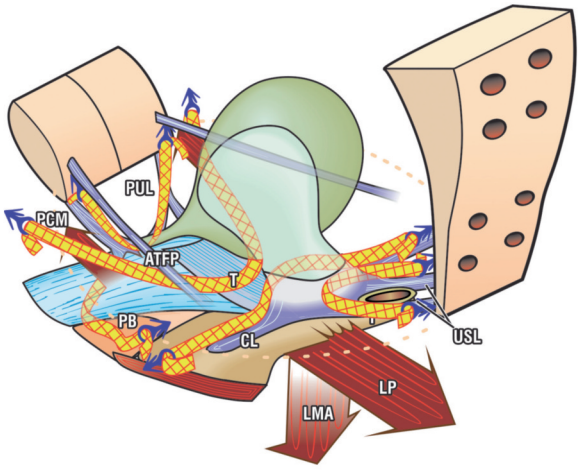

Figure 8. – Surgical treatment. Site specific reinforcement of damaged ligaments/perineal body 3D view of the pelvic cavity from above and behind. The 11x4 mm blue anchors are placed in the precise position of 4 suspensory ligaments, pubourethral (PUL), ATFP, cardinal (CL) uterosacral (USL) and perineal body (PB). At the base of the anchor is a one-way tensioning system which simultaneously shortens and reinforces the damaged ligaments. At the same time, the musculo elastic layer of the vagina- also known as 'pubocervical" and rectovaginal" fascia- which has been split and laterally displaced is brought back into the midline.

ROLE OF THE PERINEAL BODY

The perinael body,"PB" (Figure 7) supports 50% of the posterior vaginal wall.[4] Birth-related trauma pushes the two perineal bodies laterally, allowing the anterior rectal wall to protrude as a rectocele. If the trauma occurs along the whole length of the posterior vaginal wall, the uterosacral ligaments are laterally displaced at the upper end, the musculo-elastic layer of the vagina (rectovaginal fascia "RVF") is split and is displaced laterally, Figure 7. The inferior attachment point of RVF (Figure 6) is ruptured and this prevents LP from stretching the vagina around the penis during intercourse.

SURGICAL TREATMENT

The aim is to restore the muscle forces which stretch the vagina backwards to "grip" the penis.

1. Reinforce the damaged ligaments, PUL and USL with precisely inserted tapes. This provides a firm insertion point for the directional muscle forces.
2. Bring together the laterally displaced musculo-elastic layers of the vaginal wall.

The TFS tensioned minisling (Figure 8), is the only instrument which can accurately accomplish this task.[5,6,7]

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Update

Surgical mesh reconstruction for post hysterectomy vaginal vault prolapse. Part I: Introduction, pathophysiology, diagnosis

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Abstract: Pelvic organ prolapse (POP) entailing many subgroups as vaginal wall relaxation, uterine prolapse, post hysterectomy vault prolapse (PHVVP) and others, occurs with up to 50% of parous women. It was reported to cause a variety of urinary, bowel and sexual symptoms and to necessitate surgical correction in 11% of the female population. Up to 30% of all females suffer from pelvic floor relaxation which has progressed to a level which has a negative impact upon their quality of life. Hysterectomy probably results in damage to the integrity and blood supply of the endo-pelvic fascia as well as to the innervation of the pelvic floor musculature. This might potentially contribute to a subsequent POP manifestation. As well as a lack of data, there is considerable debate as to the role of vaginal hysterectomy in POP repair, with opinion divided whether hysterectomy is essential or contra-indicated for a long lasting repair. The natural history of post hysterectomy pelvic floor status has never been looked at properly to determine whether the prolapsed uterus should be removed or preserved in terms of POP cure. The perioperative complications and general QoL outcomes including the impact on female body image and sexuality following hysterectomy in comparison with preservation of the prolapsed uterus or uterine cervix is also controversial. Nevertheless, post hysterectomy vaginal vault prolapse commonly challenges the healthcare practitioner, requiring a thorough understanding of the surgical pathology and adequate skills to treat it. Various aspects of PHVVP are discussed in depth, including pathophysiology, management, complications, and associated pathologies.

Key words: Post hysterectomy vaginal vault prolapse; POP; Prolapse surgery; Prolapse mesh reconstruction; Recommendations.

1. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: BACKGROUNDS

The accurate occurrence of post hysterectomy vaginal vault prolapse (PHVVP) is obscure. It is presumed that the reported rate only reflects the tip of the iceberg. Pelvic organ prolapse (POP), entailing many subgroups such as vaginal wall relaxation, uterine prolapse, PHVVP and others, occurs in up to 50% of parous women. It was reported to cause a variety of urinary, bowel and sexual symptoms and to necessitate surgical correction in 11% of the female population. Up to 30% of all females suffer from pelvic floor relaxation which has progressed to a level which has a negative impact upon their quality of life. The affected women frequently require manual assistance to urinate and report frequency, urgency and urge incontinence as well as sex and bowel function-related symptoms. The lifetime risk of undergoing prolapse surgery is one in eleven; whereas up to 30% of those who underwent surgery eventually will have repeat prolapse surgery, part of them after hysterectomy. Being age-related, it is assumed that the prevalence of POP will further increase with the ageing of the population.

2. VAGINAL APEX SUPPORT NATURAL ARCHITECTURE

Based on cadaver dissections, three pelvic levels of support are described: the first relates to the upper vagina, found to be suspended with paravaginal tissue fibers, connected to the cardinal ligaments. The second one supports the mid vagina by fibers connecting it to the arcus tendineus facia pelvis and the levator muscles. The lower vaginal part is supported with the perineal membrane and the perineal body. These vaginal supporting fibers and ligaments are actually condensations of the endo-pelvic fascia, forming anterior support: the cervico-pubic ligaments, lateral support: the cardinal ligaments and posterior support: the sacro-uterine ligaments. The endo-pelvic fascia attaches the supportive pelvic floor musculature, mainly the levator muscles to the vagina, assembling the supportive effect. The pelvic floor plate consists of the endo-pelvic fascia and musculature (mainly the levator muscles) and forms a supportive trampoline. This pelvic floor anatomical specific unit is ligamentarily stretched both on the antero-posterior and lateral dimensions. Thus, carrying the pelvic organs, it enables their proper function.[4-5]

3. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: DEFINITION.

Prolapse is defined as protrusion of an organ or structure beyond the normal anatomical position. Mild prolapse is very common and is generally not associated with quality of life impairment, thus it is regarded as a non-pathologic situation. PHVVP, according with Baden classification is defined as: 1st degree: the vaginal vault is slightly descended from the natural level, 2nd degree: the vaginal vault is visible at the introitus, 3rd degree (procidentia): the vaginal vault is protruded out of the introitus, at any extension. Prolapse of the apical segment of the vagina was redefined by the International Continence Society Standardization Committee, on 2002, to be: "any descent of the vaginal cuff scar (after hysterectomy), below a point which is 2 cm. or more, less than the total vaginal length above the plane of the hymen", and the prolapse degree is defined according with the ICS Pelvic Organ Prolapse Quantification System (POPQ). According with the POPQ is the normal position of the vaginal apex (C point) level measured 8 cm above the genital opening, hence defined as (-)8. Total vaginal vault prolapse is measured as 8 cm below the genital opening, defined as (+)8. The vaginal vault prolapse might be isolated or combined with prolapse of the anterior vaginal wall and anterior pelvic floor compartment, including bladder prolapse (cystocele) and/or urethral prolapse (urethrocele) at various degrees. Similarly the posterior vaginal wall and the posterior compartment of the pelvic floor may be affected by the supportive defect, and enterocele, rectocele and/or perineal body damage can be associated with the apical prolapse.[6]

4. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: INCIDENCE

Pelvic organ prolapse is very common, and to some degree normal, especially among older women. Over all

pelvic organ prolapse (POP) may occur in up to 50% of parous women. It is reported to significantly impair quality of life and necessitate surgical correction in 11% of the female population. Up to 30% of those who underwent surgery will have repeat prolapse surgery for failure within 3 years. The accurate incidence of over all vaginal apex supportive defect and particular PHVVP has never been properly evaluated. It is probably correct to assume that hysterectomy, vaginal rather than abdominal, aggravates the risk for further vaginal prolapse. This might be due to surgical damage as well as to unaddressed preexisting weakness of the pelvic floor. It is widely accepted that the reported rate of post hysterectomy vaginal vault prolapse reflects only the iceberg tip of the problem and that the accurate incidence of it is yet poorly defined.[7-9]

5. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: RISK FACTORS

Pelvic floor relaxation and pelvic organ prolapse is related to some well established risk factors. Among those are parity, obstetrical pelvic floor trauma, obesity, tobacco smoking, aging, chronic bronchial asthma and constipation. All these are regarded as related to increasing intra-abdominal pressure. Then, extra strain is applied to the supportive structure and pelvic nerves, yielding further damage and eventually prolapse of various degrees. Another risk factor is lately identified - the tissue factor. The tissue inherited strength is gaining recognition as a crucially important one, manly the tissue collagen content and structure. Patient having a bio-molecular alteration with the collagen amount, architecture, bio-degradability or production, might be predisposed to POP. This condition may arise from a genetically inherited predisposition. Post hysterectomy vaginal vault prolapse could be related to surgical factors, as failure to suspend the vaginal apex to the sacro-uterine ligaments or further suture break down. This might be due as well to unaddressed preexisting weakness of the pelvic floor, rather common with circumstances attached to vaginal hysterectomy performance.[10-12]

6. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: SYMPTOMS.

Symptoms may be vague, and are not necessarily indicative of the degree of prolapse. In extreme prolapse the lump emerging from the introitus may interfere with simple daily activities as walking and sitting. A significant degree of cystocele, enterocele, rectocele and enlarged vaginal hiatus is often associated with specific symptoms such as urinary urge and stress incontinence, urgency and frequency, urinary obstruction. Pelvic floor relaxation may mask stress incontinence which becomes evident after surgical correction of the prolapse. Posterior pelvic floor compartment relaxation might be associated with fecal urgency and frequency, urge and stress incontinence. In general, POP might lead to sexual intercourse mechanical impairment; negatively affecting the body image and self esteem of the patient and cause severe QoL impairment. The POP women frequently require manual assistance with prolapse reduction for facilitation of urination and defecation. The association between the site of anatomical defect, the nature and degree of prolapse and the symptoms is comprehended with the aetiology of the pelvic floor relaxation on the function and malfunction of the pelvic organs. Understanding the causative factors enables targeted corrections of specific defects to preserve and restore physiological pelvic organs functions.[13-16]

7. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE DIAGNOSIS: ANATOMIC AND FUNCTIONAL CLINICAL ASSESSMENT

Accurate POP diagnosis is crucial for proper design of comprehensive therapeutic plan. Therefore, obtaining patient history is the key to understanding the patient's needs and expectations. Pre-interview completion of pelvic floor impact questionaires may help to clarify the impact of prolapse on quality of life. Then a pelvic examination under Valsalva maneuver is mandatory, as post hysterectomy vaginal vault prolapse frequently coexists with anterior and posterior vaginal walls prolapse. Differential diagnosis and accurate mapping of the patient’s whole pelvic floor is essential. It is easy to differentiate as the bladder neck is clearly seen when it is not emptied, as the anterior vaginal wall is normally rich with rugae, the cervix or the dimpled points marking the sacro-uterine ligaments insertion are visible to define the vaginal apex. The posterior vaginal wall with entero-rectocele is defined-able as well. Prolapse level of each and every site of the pelvic floor is to be properly determined by any acceptable measurement method, both for therapy planning and for cure assessment. Other issues of importance are the vaginal mucosa status (local estrogen therapy might be considered to reinforce this tissue when atrophy is present prior to surgery), evidence of urinary and fecal incontinence, hiatus dimensions and perineal body integrity. Functional impairments, related to the pelvic floor herniation process, such as urine and fecal storage and emptying problems and sexual intercourse difficulties are to be addressed when clinical pelvic floor assessment is carried out. All these above mentioned anatomical defects and functional deprivations might coexist with various combinations and different prolapse degrees. The preoperative clinical data collection should be accompanied by some laboratory studies. Further to the standard preoperative ECG, chest x-ray, blood and urine analysis, ultrasound scan might be of benefit to rule out coexisting pelvic organ pathology including urinary obstruction. In the presence of fecal storage or passage abnormality is an ano-rectal work-up indicated. The accurate place of urodynamic studies in terms of pointing the best therapeutic approach and prediction of cure or complication rates is in dispute. Many argue the benefit to be of no clinical value while others claim that the information provided enriches the understanding of the individual pathological backgrounds and hence improves the treatment.[17-19]

8. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: DIAGNOSIS, QUALITY OF LIFE (QOL) ASSESSMENT

Given that the main therapeutic goal is restoration of the pelvic function rather than anatomical reconstruction, one must acknowledge the importance of QoL assessment tools. These tools, namely validated questionnaires, are crucial for both, preoperative as well as postoperative evaluations. Comparison of the two will determine the true treatment value from the patient’s point of view. The surgeon's judgment was found to differ largely from the self reported patient's perspective, as the physician tends to strongly underestimate the patient's complaints, this is partially explained with complains being relatively mild, thus not mentioned at the interview. Another bias leading to the surgeon's – patient's judgment discrepancies emerges out of slight differences with the questions presented to the patient at interview and on the questionnaires: the questionnaires were validated properly, while the frontal interview verbal communication varies profoundly. The use of pelvic floor oriented and validated questionnaires is of great importance

for proper preoperative evaluation and therapeutic plan design. Among the frequently used questionnaires are the IIQ-7 and the UDI-6.[20]

9. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: PATHOPHYSIOLOGY

The causative process leading to pelvic floor supportive impairment yielding PHVVP, is presumed to be multifactorial: age, genetic connective tissue weakness, previous obstetrical trauma and poor surgical technique. Pelvic surgery is a major contributing factor for the occurrence of prolapse, but genetic factors, leading to connective tissue metabolism and biochemistry impairment, are important cofactors responsible to connective tissue weakening and POP formation. This explains the familial occurrence often seen with POP, and was demonstrated to be related to alterations with collagen total content and variants, cross linking, morphology and biodegradability. The female patient age is widely accepted as contributing to POP, especially with true procidentia. This age to POP correlation is mostly significant up to the sixth decade of life. This might be a result of estrogen deprivation at the menopause. Vaginal delivery is strongly attached to future POP as the pelvic supportive components, mainly the levator ani muscles and endopelvic fascial ligaments might be severely and irreversibly traumatized during the fetal journey through the birth canal. Previous pelvic surgery, especially retropubic colposuspension, is accepted to be associated to further apical and entero-rectocele formation, related to the change with vaginal longitudinal axis. When hysterectomy was previously performed, all the above mentioned conditions might be cofactor to the surgical damage caused at hysterectomy to the endopelvic fascial and ligamentary supportive architecture. Hysterectomy, vaginal more than abdominal, is often performed with preexisting pelvic floor relaxation at various degrees, frequently improperly addressed at surgery. Thus, an accurate indication, other than prolapse, should ground the indication for hysterectomy, especially with POP conditions, and uterine cervix sparing hysterectomy should be considered when adequate. These might contribute to PHVVP prevention by both avoiding surgical injury leading to herniation, and pelvic fascial, neural and vascular damage as well as preservation of the pelvic ligamentary architecture to be recruited for the reconstructive efforts. Previous pelvic floor reconstructive surgery was shown to increase by 12 the incidence of further prolapse reoccurrence necessitating reoperation, and it was unrelated to hysterectomy performed for non prolapse reasons. Others found that 12 months post POP reconstructive surgery prolapse recurred in 58% of the patients.[21-22]

10. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: ANATOMIC AND FUNCTIONAL OUTCOME ASSESSMENT

After completion of the therapy, the accurate outcome is to be properly assessed, especially on research setups and when adopting new techniques. The postoperative anatomical pelvic floor under Valsalva maneuver status should be assessed properly using an accepted prolapse quantification method as the Baden or the ICS POP-Q system. The patient is frequently reluctant to report dissatisfaction with the therapeutic results, considering that as impoliteness regarding the surgeon. Hence, the objective and independent patient self assessment validated questionnaires are an important tool for judgment of the accurate value of pelvic organ prolapse as for any other medical procedure. Thus, the accurate assessment of the various aspects of the pelvic floor relaxation related quality of life with validated questionnaires such as the IIQ-7 and the UDI-6 is essential.[23]

11. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: REDUCING FAILURE RATE

Proper training, skill maintaining and keeping good surgical technique are the keys for failure rate reduction. Proper mesh arms introduction to accurate points at SS (Sacro-Spinous) ligament & ATFP (Arcus Tendineus Fascia Pelvis) on one side and secure anchoring to the vaginal apex or preferably to the cervical ring if not removed earlier on the other one, are crucial for long lasting apical support. Proper mesh flattening and fixation to both lateral pelvic aspects prevent mesh shifting and further lateral supportive defects.

12. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: FAILURE MANAGEMENT

Vaginal vault prolapse reoccurrence might be due to detachment of the mesh arms from the anchoring points at the supporting pelvic ligaments or to vaginal vault, or to mesh shifting from lateral sidewalls. With either, should the failed surgical technique not be repeated but rather replaced by another technique. Thus, a failed vaginal procedure could be followed with an abdominal one and vice versa. As surgeons are generally familiar mainly with one single surgical method, referring the patient to an experienced colleague should be considered.

13. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: ADEQUATE PATIENT SELECTION

The only indication for supporting the prolapsed vaginal apex is clear diagnosis of such. Hence, only patients with true PHVVP should be appointed to apical reconstructive surgery. Relative contraindications might be previous pelvic irradiation, immuno-depressive state, active infection, systemic steroid use and poorly controlled diabetes. Some of these patients might be subject to other therapeutic and palliative modalities as pessary placement or colpoclesis operation. Adoption of these guidelines will promotes success and reduces avoidable failures.[24]

14. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: PATIENT INFORMED CONSENT

Patients enrolling for pelvic reconstruction must have informed consent. This consent should focus on the anticipated postoperative anatomical and functional prognosis including sexual activity and urine and feces storage and leaking problems. Patient's expectations from therapy, regarding each different aspect of physical function as well as quality of life improvement and impairment, arising from conditions related to pelvic organ prolapse and repair should be discussed. The post operative course including sexual and other physical activity restrictions, vaginal bleeding, discharge and pain, pointing the expected level and duration of each detailed feature should be pictured. The raw existing data concerning non-mesh against mesh implantation operations recurrence rate must be presented, as well as other data concerning mesh implantation, complications nature and rate, specific surgeon's training and experience and other commonly performed operations. All these will properly prepare the patient for the operation she is scheduled for, re-adjust her expectations and reduce unrealistic fantasies and improve satisfaction.

15. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: PREOPERATIVE MEASURES

The operation related morbidity was never proved to reduce with prophylactic antibiotics, enema, bowel preparation, lower extremities bandaging, indwelling urethral catheter and even vaginal antiseptic lavage. Nevertheless not supported by any solid data, these measures are widely used for theoretical preventive benefits.

16. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: INTRAOPERATIVE SAFETY MEASURES

Bladder drainage with urethral catheter was never proved as beneficial in terms of urethral and bladder injury reduction; some feel though that unemptied bladder provides better burdens anatomical identification, thus correct dissection and bladder protection might be facilitated with a filled bladder. The mode of anesthesia was shown to have no influence on cure rates and safety levels; intraoperative cough test was not proved to reduce the failure rate of the anti incontinence surgical steps. Some do feel that performing this non physiological diagnostic measure might contribute to elevation of postoperative bladder outlet obstruction rate. No data supports the routine use of anticoagulant medications, neither is performance of routine diagnostic cystoscopy, either prior to surgery or at completion of the operation, unless iatrogenic bladder injury is suspected. Rectal examination was advocated following posterior compartment mesh implantation, as rectal injury was reported with such. Vaginal routine tampon packing at the end of surgery never proved efficacy with improving cure or with postoperative bleeding reduction. On the other hand this is causing significant discomfort and even pain to the patient.

17. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: EARLY POSTOPERATIVE MEASURES

Pain management: the postoperative pain level is usually less that 5 according with a visual analog pain scale ranging 0 to 10. This is frequently dealt with oral analgesic medications repeated every 3 to 5 hours for 1 to 2 days. More effective analgesics are seldom indicated. Stool softeners are beneficial for easing defecation for the first postoperative week. Hospital stay varies between 24 and 72 hours after vaginal operations, depending on successful pain management. This is significantly longer after abdominal operation, as up to 7 postoperative hospitalization days are frequently then required. Recommendations regarding post operative activity restrictions refer mainly to refraining from sexual intercourse which is strictly forbidden for 6 weeks, in order to prevent dispareunia, suture break down and mesh exposure. Heavy lifting is usually advocated to be avoided as well as any other activities leading to increased intraabdominal pressure and local pressure applied the operative field before complete tissue healing is achieved. Follow up appointment is to be scheduled for the first and sixth postoperative month and yearly thereafter. At these, postoperative complications are to be looked for, including mesh exposure, granulation tissue formation, urine and feces storage and passage control impairments, sexual functions difficulties, vaginal or pelvic pain and various prolapse recurrence features.

18. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: CONTINUOUS POSTOPERATIVE THERAPY

Patient's quality of life after operation might be improved with some simple adjuvant therapeutic measures, as stool bulking and softening agents to facilitate defecation. Bladder overactivity symptoms, such as urinary urgency, frequency and urge incontinence, either preoperatively existing or de novo appearing since, should be considered to be dealt with by anticholinergic medications. Local or systemic estrogens could nicely reduce vulvovaginal itching and dispareunia, by improving surface tissue atrophy. Physiotherapy for pelvic floor muscles reinforcement might often contribute to improving patient's quality of life regarding pelvic floor functions reestablishment.

19. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: SURGICAL AND CLINICAL AVAILABLE DATA

Reviewing the literature for high level evidence concerning POP surgery reveals some important conclusions: The non-mesh operations anatomical and functional long term outcomes in terms of cure and complications are not well reported. This is true for vaginal hysterectomy for the cure of procidentia, for paravaginal and site specific prolapse repair, and for abdominal sacrocolpopexy as well. Nevertheless, vaginal sacrospinal fixation and abdominal sacrocolpopexy have remained the "gold-standard" for repair of vaginal apical suspension defects. Being less invasive, the vaginal approach is safer and is associated with fewer side effects, yet shorter lasting than the abdominal for the surgical cure of post hysterectomy vaginal vault prolapse repair. Similarly, the use of mesh was found to be justified in terms of postoperative prolapse recurrence and surgery related complications only for anterior pelvic floor reconstruction. Questions regarding the preferred mesh type, mesh for central and posterior pelvic floor compartment reinforcement and conservation of the prolapsed uterus remain improperly addressed and unanswered for the time being. As the relevant data referring to the various mesh armamentarium is rather poor as yet, the decision which mesh is to be used- if at all, depends heavily on individual surgeon's training and experience. This is obviously insufficient for properly supporting this decision, which should a clearly evidence based decision making process.[25-35]

20. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: WELL ACCEPTED RECOMMENDATIONS.

A Cochrane review, analyzing 22 trials, including 2368 patients, shows that abdominal sacrocolpopexy (SCP) yields lower rates for POP recurrence and dispareunia when compared with vaginal colpo-sacro-spineous fixation (VCSSF). On the other hand, the VCSSF is shorter in terms of operation time and recovery period. Mesh implants where found to reduce prolapse recurrence at the anterior vaginal wall reconstruction, and the vaginal approach was found to be superior to the transanal for posterior compartment repair. Many other authors acknowledged the relative shortage of relevant data needed for proper decision making regarding the operation choice for POP cure, including PHVVP and that the evidence available is not significant to guide practice. At the same time is recognized an unacceptable high rate of recurrence with the non-mesh POP reconstructive surgery. Thus, it is widely agreed that meshes implantation should be further investigated prior to withdrawal of solid recommendations regarding their usage. Simultaneously, despite relative lack of evidence-based information regarding long term efficacy and safety, is the use of grafts for POP vaginal reconstruction growing rapidly. The mesh implantation must be considered carefully for

each potential candidate, taking into account that the ultimate goal is QoL improvement, by correcting both the anatomical and functional derangements. For the time being there are not any data based guidelines recommendation for proper patient and surgery selection, perioperative management and surgeon's training. There is a considerable debate regarding the performance of vaginal hysterectomy in association with POP surgery, whether is it beneficial or not.[36-41]

21. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION: TRAINING THE SURGEON

The preferred potential trainee for acquiring POP surgery skills must be expected to perform more than 20 operations with any specific POP type operation yearly, otherwise skill maintenance would not be feasible. Preliminary requirements are thorough theoretical knowledge regarding general pelvic floor medicine and familiarity with advanced pelvic floor surgery. The candidate training should be done with a very experienced trainer, and should include 20 operations of any type of surgery, to overcome the requested learning curve. Thorough knowledge and awareness concerning complications, including prevention, diagnosis and management is essential.[39,41]

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Review

Complications of mesh application in the surgical treatment of pelvic organ prolapse

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Abstract: Mesh application has recently become popular worldwide. Despite considerable success in pelvic organ prolapse surgery, there is an increasing concern regarding mesh use. Although mesh use-related complications are minor and manageable during and after intervention in most cases, some of complications that seldom occur, such as bladder, bowel, and vascular injuries, may threaten life. According to International Continence Society and International Urogynecology Association, complications related to mesh application can be broadly classified as 1) vaginal complications (prominence-contraction, exposure-extrusion, and pain), 2) urinary tract complications (bladder perforation, urinary retention, *de novo* stress urinary incontinence, detrusor over activity, and vesicovaginal and urethrovaginal fistulas), 3) rectum or bowel complications (rectal or bowel injury, abscess and rectovaginal fistula), 4) skin and/or musculoskeletal complications, 5) patient compromise, and 6) infectious complications. This review describes underlying causes of mesh complications and their management.

Key words: Pelvic Organ Prolapse; Mesh application; Complication Management.

INTRODUCTION

Pelvic organ prolapse (POP) is a common condition, affecting women of all ages. A lifetime risk of prolapse or incontinence surgery is 7-19%.[1] Although there are many approaches to the surgical correction of POP, recently mesh kits have been developed because of high failure rates from traditional vaginal colporrhaphy and surgical suspension procedures using native tissue. Synthetic vaginal mesh was approved for use in the USA by the Food and Drug Administration (FDA) in 2004. According to the 2011 Society of Obstetricians and Gynecologists of Canada (SOGC) Technical Update on Transvaginal Mesh Procedures, anatomic cure from early case series and comparative trials using the first generation mesh kits ranged from 79 to 100%.[2] Despite achievement of appreciable success rate, concerns related to complications of mesh use among surgeons still remain. Complications commonly associated with mesh include cystotomy, bleeding, hematoma, mesh exposure/erosion, *de novo* stress urinary incontinence, dyspareunia, and pelvic pain. Upon more pronunciation of mesh complications, FDA published an article entitled "Public Health Notification and Additional Patient Information on Serious Complications Associated with Surgical Mesh Placed through the Vagina (Transvaginal Placement) to Treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI)" in 2008, which was updated in 2011.[3] The primary goals of this update were to inform that "serious complications with surgical mesh for transvaginal repair of POP are not rare" and "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk".

The present review intends to compile information on risks associated with mesh surgery.

COMPLICATIONS OF MESH SURGERY

All complications associated with mesh surgery in POP have been reviewed and evaluated by International Continence Society (ICS), and International Urogynecology Association (IUGA) in 2011, which are summarized in Table 1.[4]

Vaginal Complications

Prominence-Contraction

Actual incidence of mesh contraction is not really known since these complications are not commonly reported. Most of the time accompanied by pain.[5] Mesh contraction may also cause vaginal shortening and tightening.[6]

Exposure-extrusion

ICS and IUGA offer to use exposure and extrusion of the mesh instead of erosion which is more commonly used in the literature. Graft erosion is one of the most common direct complications of graft materials used in urogynecologic surgery with an incidence of 10.3% (0-29%).[7] Exposures have been reported as early as 6 weeks and as late as 4 years after vaginal mesh surgery, but they usually occur during the first year.[8] Risk factors for mesh exposure vary by surgeons experience, high stage prolapses, smoking, and concomitant hysterectomy.[9-11] There are conflicting data about the age of the patients. Deffieux and colleagues found age over 70 to be a risk factor,[12] but Kaufman et al. reported that younger age and sexual activity were risk factors for mesh exposure.[13] Mesh exposure can be classified as early and late. Early mesh exposure usually is a result of the surgery itself, whereas late exposure may be a result of infections and recurrent trauma. ICS and IUGA suggest using time intervals as follows: T1: intraoperative to 48 hours, T2: 48 hours to 2 months, T3: 2 months to 12 months, T4: over 12 months.[4]

Vaginal discharge, odor, vaginal pain, and dyspareunia expressed by the sexual partner are some of the mesh erosion or extrusion signs. To minimize this type of vaginal mesh complication, the following suggestions have been proposed: making incisions as small as possible, using type I soft mesh, not using T incisions with hysterectomy, using hydrodissection, maintaining thick dissection plane, using pre and post-op estrogen, excising minimal vaginal epithelium and placing the mesh underneath the fascial plane.[14, 15]

Management of mesh extrusion or exposure is usually easy. Most of the time removal of the mesh is not necessary. Local estrogen and antiseptic agents are usually preferred. However, excision or total removal of the mesh and repetitive surgeries may be needed in some cases.[7] FDA highlighted that more than half of the women with erosions

from non-absorbable synthetic mesh required surgical excision in the operation room.[3]

Pain

Pain is an important complication of mesh placement, which will not be resolved even after mesh removal.[3] Pain after mesh surgery manifests itself as dyspareunia, vaginal pain, thigh pain, buttock pain or suprapubic pain. For POP, dyspareunia rate up to 38% has been reported with mesh use.[16] According to the literature, it is not accurate to denote that mesh use in urogynecology may increase dyspareunia or other pain syndromes.[14] To minimize the risk of pain with the use of mesh kits tension free surgical approach should be used as well as rectal and vaginal examination should be performed. Although women may develop pain syndromes without mesh exposure or extrusion, these two are important risk factors for pain syndromes.[8,14] Pain may also arise if the graft is placed too superficially or too close to the nerves. Often all or a portion of the graft requires removal. This can technically be difficult and may not resolve all pain issues. In the management of pain syndromes anti-inflammatory agents, vaginal estrogen, steroid injections, pelvic floor rehabilitation therapy may be used conservatively. In some instances surgical interventions to release tension, partial or total removal of the mesh may be needed.

Urinary tract complications

ICS and IUGA classified urinary tract complications as follows: A)Small intraoperative defect (e.g., bladder perforation), B) Lower urinary tract complication (other lower urinary tract complications or urinary retention), C) Uretheric or upper urinary tract.[4] Hung et al reported that compared to traditional methods, the mesh use in anterior prolapse surgery was associated with increased *de novo* stress urinary incontinence (10 vs. 23%).[17] de Landsheere et al. investigated 524 patients and they reported a 6.9% reoperation rate due to stress incontinence after vaginal mesh surgery in their retrospective study.[18] Detrusor over activity may be seen after urogynecologic operations. Milani et al reported 34% detrusor over activity rate after anterior vaginal repair with polypropylene synthetic mesh.[19] In the literature, the rate of *de novo* urgency after sling operations is reported to be as high as 25.9%.[20,21]

Vesicovaginal and urethrovaginal fistulas are two of mesh related urinary tract complications after vaginal surgeries.[22] Skala et al reported 2 vesicovaginal and 1 urethovaginal fistulas after vaginal tape operations in 179 patients.[23] There were also 62 (34.6%) cases of bladder outlet obstruction and 3 (1.7%) cases of intravesical graft extrusion. The overall rate of urgency was 45.3% and it was mostly seen after vaginal tape operations.[23]

Bladder injury is one of the other intraoperative complications, which is mostly occurring during needle insertion. Caquant et al reported bladder injury in 5 of 684 patients (0.73%).[6] Bladder perforation during needle passage may vary between 0.7 and 24% in retropubic sling operations.[20,24] Failure to recognize intravesical needle passage of mesh can lead to irritative bladder symptoms, pelvic and urethral pain, fistulas, recurrent urinary tract infections, and a return to the operation room. Erosion of mesh into the

TABLE 1. – New classification of mesh related complications.

	CATEGORY General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal:** no epithelial separation include prominence (e. g., due to wrinkling or folding), mesh fiber palpation or contraction (shrinkage)	**1A:** Abnormal prosthesis or graft finding on clinical examination	**1B:** Symptomatic e.g. Unusual discomfort / pain; dyspareunia (either partner); bleeding	**1C:** Infection (suspected or actual)	**1D:** Abscess
2	**Vaginal:** smaller ≤ 1 cm exposure	**2A:** Asymptomatic	**2B:** Symptomatic	**2C:** Infection	**2D:** Abscess
3	**Vaginal:** larger > 1 cm exposure or any extrusion	**3A:** Asymptomatic 1-3Aa if no prosthesis or graft related pain	**3B:** Symptomatic 1-3B(b-e) if prosthesis or graft related pain	**3C:** Infection 1-3C/1-3D (b-e) if prosthesis or graft related pain	**3D:** Abscess
4	**Urinary tract:** compromise or perforation including prosthesis (graft) perforation, fistula and calculae	**4A:** Small intraoperative defect e.g. Bladder perforation	**4B:** Other lower urinary tract complication or urinary retention	**4C:** Ureteric or upper urinary tract complication	
5	**Rectal or bowel:** compromise or perforation including prosthesis (graft) perforation and fistula	**5A:** Small intraoperative defect (rectal or bowel)	**5B:** Rectal injury or compromise	**5C:** Small or Large bowel injury or compromise	**5D:** Abscess
6	**Skin and/or musculoskeletal:** complications including discharge pain lump or sinus tract formation	**6A:** Asymptomatic, abnormal finding on clinical examination	**6B:** Symptomatic e.g. Discharge, pain or lump	**6C:** Infection e.g. sinus tract formation	**6D:** Abscess
7	**Patient:** compromise including hematoma or systemic compromise	**7A:** Bleeding complication including hematoma	**7B:** Major degree of resuscitation or intensive care	**7C:** Mortality*	
			TIME		
T1: Intraoperative to 48 hours		**T2:** 48 hours to 2 months	**T3:** 2 months to 12 months	**T4:** over 12 months	
			SITE		
S1: Vaginal: area of suture line		**S2:** Vaginal: away from area of suture line	**S3:** Trochar passage (except intra-abdominal)	**S4:** Other skin or musculoskeletal site	**S5:** Intra-abdominal

*Additional complication- no site applicable-S 0.

urethra can rarely occur, as well. In a retrospective series of transvesical tape, urethral erosion was reported in 0.3% of cases.[25]

Rectum or bowel complications

ICS and IUGA classified rectum or bowel complications as A) Small intraoperative defect (rectal or bowel), B) Rectal injury or compromise, C) Bowel injury or compromise (small or large bowel injury or compromise), and D) Abscess. These complications usually occur in posterior prolapses surgery. Dwyer et al revealed 1 case of rectovaginal fistula in 50 patients.[26] Erosion of mesh into the rectum is uncommon, but potentially a serious complication of this class of repair that can lead to rectovaginal fistula, and consequently the need for fecal diversion with colostomy construction and significant morbidity. Rectal perforation during the needle passage is usually self limited because the perforation site is frequently extraperitoneal.

Reported bowel injuries usually occur within hours to days after performing the sling procedure. Most bowel injuries involve perforation of the bowel by the needles used during the procedure. Management of a bowel perforation at the time of sling placement usually covers resection of the injured segment and primary re-anastomosis, followed by a complete removal of the mesh.

Skin and/or musculoskeletal

Skin complications after urogynecologic surgery are rare but if occurs they are usually secondary to trocar entries or sinus tract, fistula formations. These are usually accompanied by infectious complications.

Musculoskeletal complications are more common after trans obturator tape (thigh pain), and abdominal or laparoscopic sacrocolpopexy (sacral pain, back pain). Anti-inflammatory agents are usually the first option in the management but in some cases these complications may persist even after mesh removal. Since these complications may be related to some other serious complications including pelvic abscess, fistulas, mesh erosion, and infections, detailed examination of the patients is necessary.[27,28]

Patient compromise

The severity of complication varies by the location of mesh placement and/or affected site as well as by the patient. Altman et al reported that compared with posterior repair, anterior repair was associated with a longer operating time, greater blood loss, and more frequent complications as well as a greater rate of vaginal hematoma (1.9%), despite similar patient characteristics.[29] This could be related to using four supportive arms in the anterior mesh, compared with two in the posterior procedure. Retroperitoneal hematoma is an important complication of urogynecologic surgery, Sivaslıo lu et al reported one case after abdominal sacrocolpopexy treated surgically with relaparotomy.[30]

Vaginal mesh surgeries may compromise life. FDA revealed that there were seven reported deaths associated with POP repairs. Three of the deaths associated with POP repair were related to the mesh placement procedure (two bowel perforation and one hemorrhage).

Infective complications

In the new classification of ICS/IUGA infectious complications are not categorized separately but used as a division of each category. Infectious complications after vaginal mesh surgeries may be accompanied by exposure, extrusion, urinary or bowel complications. The incidence of mesh-related infections and erosion ranges from 0 to 8%.[31] Mesh type, pore size, bacterial contamination, comorbid conditions (*i.e.*, diabetes mellitus and immune suppression) may affect infectious complications. Various types of infections have been associated with the use of vaginal mesh including retropubic abscess with cutaneous sinus, vesicovaginal fistula, rectovaginal fistula, pelvic abscess, perineal necrotizing infection, and vertebral osteomyelitis.[22,32,33] Common symptoms of infections are non-specific pelvic pain, persistent vaginal discharge or bleeding, dyspareunia, and urinary or fecal incontinence. Clinical examination can reveal tightening of the vaginal incision, vaginal granulation tissue, draining sinus tracts, and prosthesis erosion or rejection. A mesh-related infection can sometimes manifest as a pelvic abscess in the retropubic space, pararectal abscess, ischiorectal abscess, vesicovaginal fistula, rectovaginal fistula, abdominal fistula, sigmoid bowel-vaginal fistula, enterocutaneous or enteroperineal fistulas, and osteomyelitis.

In summary, synthetic mesh application has been replaced by conventional surgical intervention in POP surgery due its greater success. Synthetic mesh use-related complications are mostly minor and manageable. However, some of these complications, such as bowel and vascular injuries as well as uncontrollable infectious complications may risk the patient life in few occasions. To minimize complications, adequate surgery training and knowledge is needed and patients should be informed of possible complications. As more experienced surgeons are available and biocompatible materials with free-needles are developed, the risk of mesh-related complications will further decrease in the future.

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Case Report

Perioperative pelvic hemorrhage management in prosthetic sacrospinous ligament fixation for pelvic organ prolapse

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Abstract: Acute hemorrhage following pelvic reconstructive surgery is a complication requiring immediate evaluation and treatment. Many articles describe the perioperative morbidity associated with sacrospinous ligament fixation repair of pelvic organ prolapse; few studies on management of the perioperatve acute hemorrhage can be found. We report two cases of acute bleeding during prosthetic sacrospinous ligament fixation of uterus and vaginal vault, resolved with two different medical approaches. The current clinical problem of life-threatening hemorrhage during sacrospinous uterus and vaginal vault suspension is examined, and a management solution is defined.

Key words: Hemorrhage management; Pelvic floor reconstruction; Prolapse repair complication.

INTRODUCTION

Several mesh augmentation systems for pelvic reconstructive surgery have been recently introduced into the market using a variety of biomaterials with variable success rate. Initial reports from the manufacturer have included a 2.5% risk of postoperative complications, including a 1.75% of hematoma.[1] It is plausible that inherently weak or damages tissues in the pelvic floor need to be reinforced by a permanent support to avoid the high rates of recurrences commonly described using traditional suture techniques.[2] The potential for life-threatening pelvic hemorrhage exists during the transobturator technique and sacrospinous ligament (SSL) fixation procedure if the vessels posterior to the ligament are injured including the obturator vessels (and nerves) and the venous plexus within the endopelvic fascia.[3,4] Venous oozing can be controlled by pressure better than arterious bleeding. The problem is that this procedure is done blindly with finger-guide throughout each trocar's path in a zone (around the buttock hip) in which the vascular network is very rich and any movement risky.[5]

We report two cases of bleeding that occurred during a central-posterior mesh augmentation procedure, with SSL fixation,[6] which were successfully managed conservatively.

Case 1

A 44-years old women with symptomatic stage 3 uterus-vaginal prolapse, using the Pelvic Organ Prolapse Quantification staging (POP-Q score). The uterus and posterior vaginal wall prolapse at its greatest extent was 3 cm beyond the hymenal ring. General conditions of patients were good, preoperative examinations excluding haematologic and coagulative alterations. A light venous insufficiency of the legs was investigated with color Doppler. Preoperative preparation were: elastic stockings and low molecular weight heparin (4000 UI sc) for thromboembolic prophylaxis within 6 hours; bowel preparation consisted in 2 preoperative enemas. Metronidazole 500 mg i.v. was administered within 1 hour from the operation. The patient signed informed consent after a thorough discussion of potential risks of this conservative prosthetic surgery, including hemorrhage requiring blood transfusions, mesh erosion, and failure of the procedure. The patient underwent loco-regional anaesthesia. A Foley catheter was introduced into the bladder.

Surgical Technique

Central-posterior repair was performed with uterine sparing technique (Figure 1).[6] The posterior vaginal wall was infiltrated with 0.5% lidocaine and 0.25% epinephrine to assist with hydrodissection and hemostasis. A midline vertical posterior vaginal incision was made, the rectum dissected with fingers and the pararectal spaces reached. Identified by blunt dissection the ischiatic spine, the SSL and the levator ani, the prosthesis was inserted and fixed to the SSL with poliester suture 1/0 using an endostitch device (Tyco Healthcare, USA). Two small skin incisions were made 3 cm posterior and lateral to the anus, and a tunneller was introduced passing through the ischiatic fossa up to the para-rectal space to bring outside the 2 slings. The uterus was suspended to the sacrospinosus ligaments. The posterior colpotomy was closed with 3/0 continuous absorbable suture. Polypropylene prostheses (Gynemesh-Soft PS, 10x15cm-GyneMesh, Gynecare Ethicon) were used to reconstruct the recto-vaginal fascia, irrigated with antibiotic solution. The vagina was packed the gauze being removed on 2nd postoperative day. Intravenous antibiotics were continued for 48 hours. A significant blood loss (>500) was due to bleeding in the pararectal space that caused a 90 minutes operating time. Postoperatively a severe rectal pain was treated with ev infusion of ketorolac without relief. The hematocrit decreased from 25.2 in the first postoperative day to 20.2% in the third when a 5x7cm left pararectal hematoma was seen at transvaginal ultrasonography (Figure 2). Urine output remained satisfactory with intravenous fluid and no blood transfusion were considered necessary. The patient was discharged after 7 days with a bladder catheter, the micturition becoming spontaneous 20 days after the operation.

Case 2

A 64-year-old woman, with symptomatic POP-Q stage 4 vaginal prolapse (vault, cistocele and rectocele), and stress incontinence having had abdominal hysterectomy and bilateral annessectomy 16 years before, in good general conditions, excluded haematologic and coagulative alterations, signed informed consent, underwent total vaginal reconstruction and fixation to sacrospinous ligament, with loco-regional anaesthesia.

Surgical Technique

A Foley catheter in the bladder.

For an antero-central and central-posterior repair, two polypropylene prostheses (Gynemesh-Soft PS, 10x15cm -

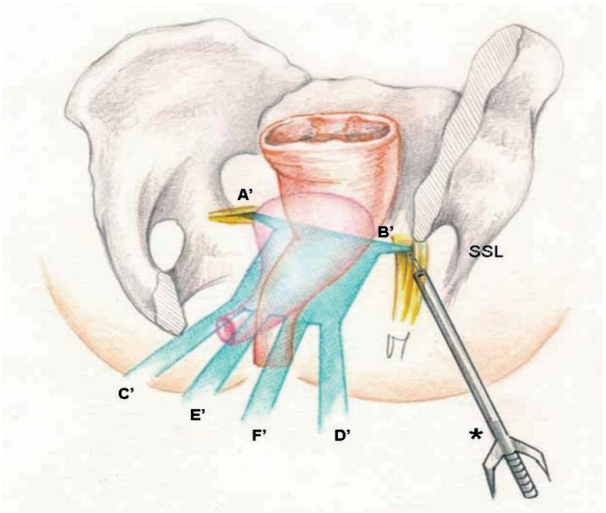

Figure 1. – Central-posterior repair: "uterine sparing techniques with Gynemesh-Soft PS and Endostitch".
Schematic representation of the posterior compartment repair. Red: uterus, brown: rectum, blue: prosthesis. *: endostitch device. SSL: Sacro Spinous Ligament. A', B': Points of fixation with the sacro-spinous ligament. C'-F': Arms used to insert the prosthesis during the transgluteal passages with the tunneller.

GyneMesh, Gynecare Ethicon) prepared cutting two "arms" from the initial mesh were used to reconstruct the pubo-cervix and the recto-vaginal fascia. The anterior vaginal wall was infiltrated with 0.5% lidocaine and 0.25% epinephrine. Trough a midline vertical incision 2 cm below the urethral meatus the bladder was dissected from the vagina and the paravescical spaces were reached. The tendineous arch of the pelvic fascia (ATFP), the ischiatic spine and the sacrospinosus ligament (SSL) were identified and the prosthesis was fixed to the SSL with poliester 1/0 suture using an endostitch device (Tyco Healthcare, USA) as a first level suspension for the vaginal apex.[7] Two small skin incisions were made in the genital-femoralis plica at the himenal level and 2 others 2 cm caudally and laterally for a tunneller that reached the vagina through the obturator foramen, membrane and internal muscle where the end of the sling was anchored. An opposite passage distended the leg of the prostheses, the procedure being repeated for all 4 arms and the cervix being brought into his natural position by the mesh. The bladder was therefore sustained by the four sling in a tension free fashion. The anterior vaginal incision was closed with a 3/0 continuous absorbable suture.[8,9]

In the central-posterior repair as described in the first case (Figs 1 and 2), a significant hemorrhage occurred during the sacrospinous ligament fixation of the vaginal vault, with a 1000 ml blood loss in the right pararectal space. Postoperatively the patient was shoked with a 19.2 haematocrit value, requiring 3 blood units. A 15 x 17 cm pelvic haematoma was visualized by CT scan. Two more blood units were transfused and an angiography confirmed the bleeding from the inferior gluteal artery injured during the sacrospinous fixation. Selective embolization stopped the hemorrhage (Fig. 4-5.) and the patient was discharged after 21 days.

DISCUSSION

Any surgical innovation requires caution in the interest of patient safety and to verify that the product is more efficacious and less invasive compared with other current methods. Despite limited evidence-based medicine concerning these procedures, they are being marketed widely, sometimes to surgeons not familiar with the pertinent anatomy. A Medline search on the English literature from 1996 to 2006 using the terms extraperitoneal, colpopexy, hematoma, mesh, Prolift failed to find reports of pelvic hematomas and bleeding resulting from mesh augmentation systems.

Two cases out of 82 patients undergone this innovative procedure are reported with a severe pelvic hemorrhage during and after a prosthetic sacrospinous ligament fixation.

In case of significant blood loss (> 500 ml) it is important to identify bleeding sites, arterial (obturator vessels, obturator-dorsal artery of clitoris, deep branches of internal pudendal, inferior haemorrhoidal artery) or venous (lateral attachment of pubocervical fascia, entering pararectal space, sacrospinous placement). The procedure is done blindly with finger-guidance throughout each trocar passage in an area very rich of vascular network.[5] The inferior gluteal artery is the vessel most likely to be injured during sacrospinous fixation, because of its location.[10] It commonly has six branches, two of which with important anastomoses around the sacrospinous ligament (main branch and coccygeal branch).[11] In the 25% of the women it arises from the posterior instead of the anterior branch of the internal iliac artery: in these cases the binding of the hypogastric artery to control of pelvic hemorrhage is useless as the posterior branch of the internal iliac artery is not involved.[10-12]

When the pudendal artery is damaged, the haemorrhage can be treated by surgical ligature of the hypogastric artery, because the pudendal vessels are rarely associated with a

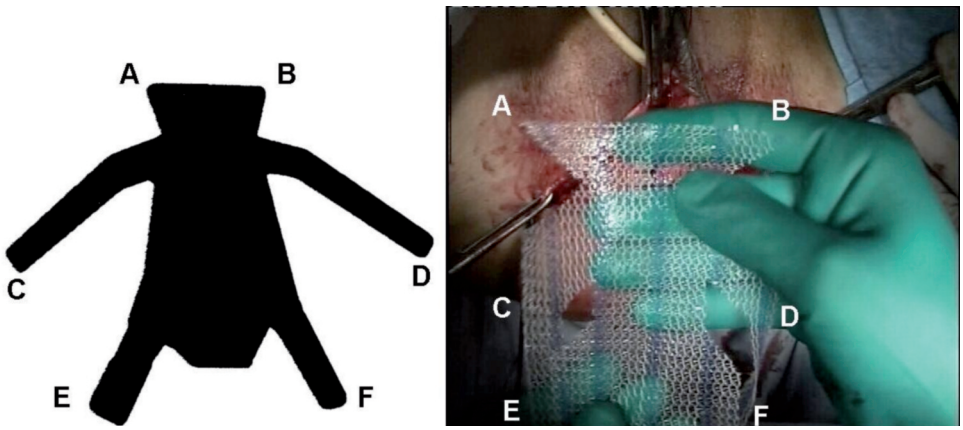

Figure 2. – Prosthesis shape: schematic representation and manual confectioning during surgery. A, B: Points of fixation with the sacrospinous ligament. C-F: Arms used to insert the prosthesis during the transgluteal (posterior compartment reconstruction) or transobturator (anterior compartment reconstruction) passages with the tunneller. E-F arms to insert the prostheses for third level reconstruction (perineal body), these arms are left tension-free.

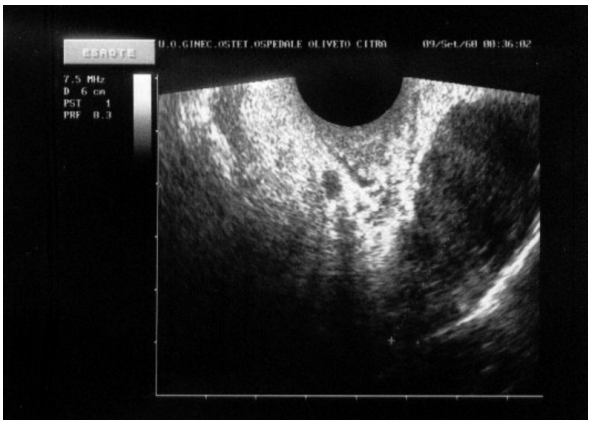

Figure 3. – Transvaginal ultrasonography: left pelvic pararectal haematoma 5 x 7 cm with a moderate mass effect on the bladder.

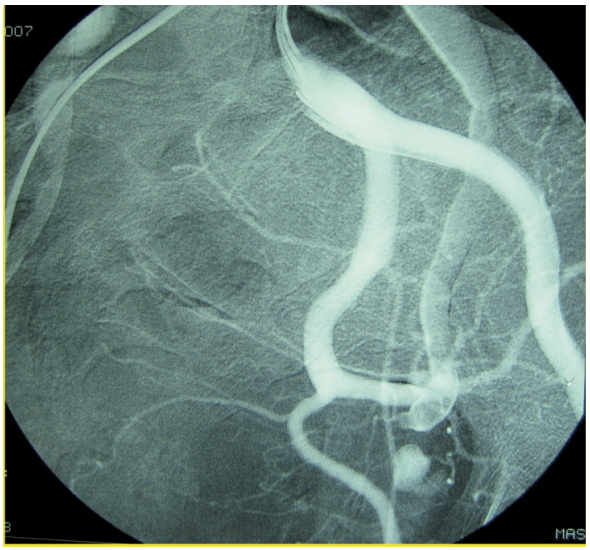

Figure 4. – Right transfemoral approach was gained using a 4 Fr introducer sheath (Radiofocus Introducer II, Terumo, Tokyo - Japan), and a 4 Fr Simmons 1 angiographic catheter (Radiofocus Glidecath, Terumo, Tokyo - Japan) was advanced over a 0.035" J tipped 180 cm long hydrophilic guidewire (Radiofocus Glidewire, Terumo, Tokyo - Japan).

collateral circulation. In all other circumstances the resulting haemorrhages are particularly difficult to control due to anastomoses between the hypogastric, vertebral and circumflex femoral arteries. In these cases, prolonged compressions with dressing gauzes and direct clipping of injured vessels is the first-choice treatment, while arterial embolization is an alternative treatment. In some cases surgical packing and clippings are not sufficient to stop the bleeding and different operations can be necessary. Management of important bleeding during pelvic surgery are: anticipating the entity of bleeding with blood transfusion preparation and support, minimise operating time and tissue trauma. If general conditions are restored with fluid replacement and blood transfusion, it means that bleeding sites are certainly venous, otherwise it is extremely important early intervention with angiography, as described in our two cases.[13]

No commercial associations or disclosures may pose, or create any conflict of interest with the information presented in this article.

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Figure 5. – The left internal iliac artery was selectively catheterized and a preliminary Digital Subtraction Angiography (DSA) confirmed the presence of contrast media extravasation at the distal tract of what appeared being an anatomical variant of the superior vescical artery originating from the common trunk of the hypogastric artery.

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Book review

As announced in the Editorial by Bruce Farnsworth (Pelviperineology 2011; 30:5) this is the sixth of a series of articles highlighting the different sections of the book "Pelvic Floor Disorders, Imaging and a Multidisciplinary Approach to Management" edited by G.A. Santoro, P. Wieczorek, C. Bartram, Springer Ed, 2010.

Pelvic organ prolapse

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The *sixth section* of the book "Pelvic floor disorders - Imaging and Multidisciplinary Approach to Management" is entitled "Pelvic Organ Prolapse" and consists of sixteen chapters. This section is divided into two main subsections describing investigation and management of pelvic organ prolapse.

In the first subsection "Investigation" authors describe various imaging techniques and their importance for the evaluation of pelvic organ prolapse. Pelvic organ prolapse (POP) represents a significant health and economic problem worldwide and has a deleterious impact on a woman's quality of life. The etiology of prolapse is very complex, thus it is very important to determine precisely the anatomy of pelvic structures and severity of damage to their support.

In the first chapter titled "Imaging as a Key to Understanding the Causes of Pelvic Organ Prolapse" Clive Bartram states that imaging modalities such as evacuation proctography, cystocolpodefecography, dynamic MRI, and ultrasonography (US), are valuable to quantify and define pelvic floor support and allow to establish the extent and severity of POP. Very often they may be more extensive than clinically apparent. Author believes that imaging is an important key to our understanding and management of POP.

The second chapter titled "Endoluminal Ultrasonography" by G.A.Santoro, A.P.Wieczorek, M.M.Woźniak and A.Stankiewicz highlights the role of ultrasound in diagnostics of pelvic floor disorders (Figure 1). It has several important advantages over other imaging modalities: absence of ionizing radiation, relatively easy to perform, minima discomfort, cost-effectiveness, reduced time requirement, and wide availability. The authors describe precisely the role of high-frequency endovaginal US in the assessment of the anatomy of pelvic floor structures in patients with POP. It enables detection of defects of the connective supporting structures, visualizes subclinical cystoceles, or multicompartmental damage.

In the third chapter titled "Translabial Ultrasonography" H.P. Dietz presents the role of this the most commonly used imaging method in the investigation of women with lower urinary tract symptoms and POP. Translabial US enables recognition of two types of cystoceles with different functional implications: cystourethrocele associated with above-average flow rates and urodynamic stress incontinence and a cystocele with intact retrovesical angle associated with voiding dysfunction and with levator trauma (Figure 2). The author presents the role of this method also in the diagnostics of rectocele. Moreover, it enables postoperative evaluation of mesh position, and injectables, and may uncover complications such as dislodgment of anchoring arms.

In the fourth chapter "Cystography and Defecography" V.L. Piloni describes the usefulness of conventional radiological examinations. Despite of an increasing role of MRI and US imaging in urogynecology, the author claims that cystography and defecography still have enduring and pertinence value in some conditions, such as: diagnosis of distortion of the mucosal anal infolding, tears, postoperative strictures, and depiction of the internal opening of perianal fistula.

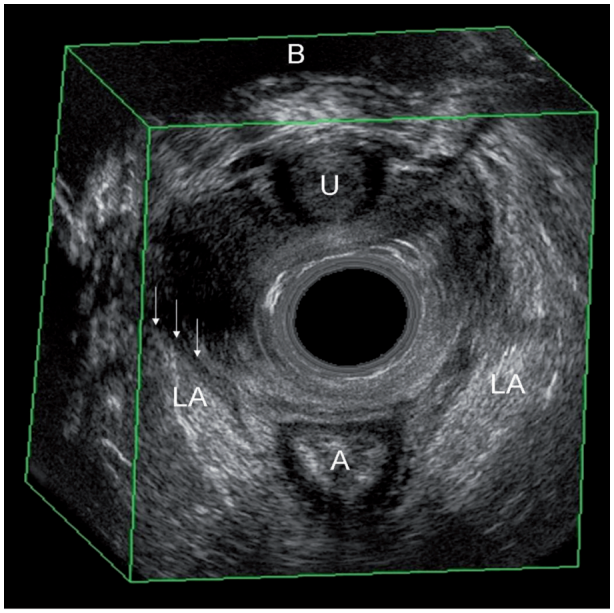

Figure 1. — Endovaginal ultrasound with rotating probe, showing a damage of levator ani (LA) on the right side (arrows).

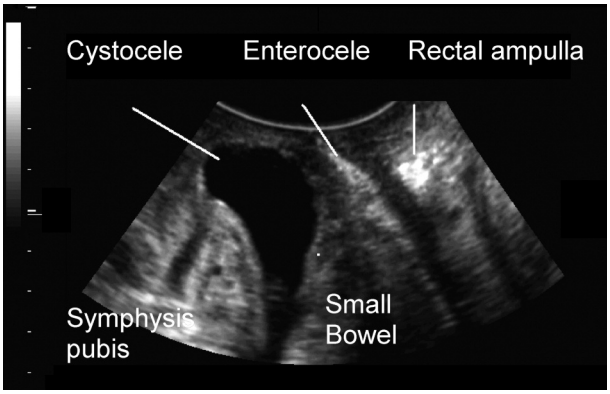

Figure 2. — Translabial ultrasound with convex probe, showing multicompartimental pelvic organs prolapse.

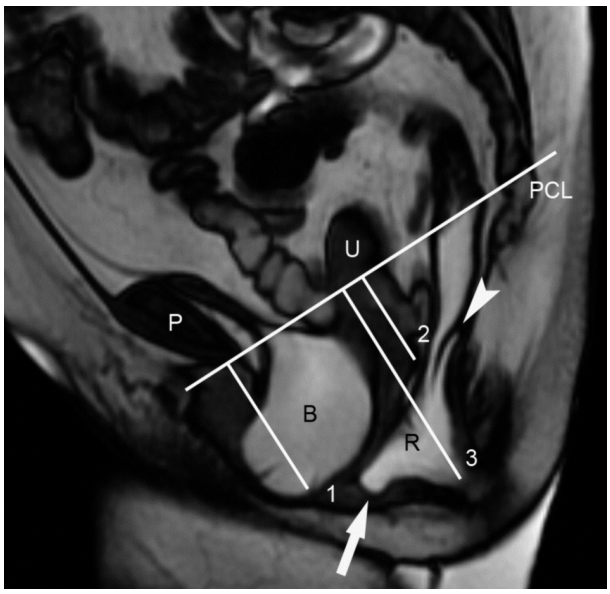

Figure 3. — Midsagittal balanced steady state free precession T2-weighted MR image obtained during maximal straining shows a bulging of the whole pelvic floor with a moderate descent of the anterior compartment (1: 5.5 cm) and the middle compartment (2: 4 cm) and a large descent of the posterior compartment (3: 8 cm). In addition, a small anterior rectocele (arrow) and intussusception of the posterior rectal wall (arrowhead) are seen. P=symphysis pubis, B=bladder, U=uterus, R=rectum, PCL=pubococcygeal line.

The chapter fifth "Magnetic Resonance Imaging" by D. Weishaupt and C.S.Reiner describes role of MRI in diagnostics of POP and outlet obstruction. It presents dynamic MRI features of various findings that may be observed in these patients and discusses criteria, which are used to grade pelvic floor relaxation and organ prolapse (Figure 3). Dynamic pelvic floor MRI is valuable for selecting candidates for surgical treatment and for choosing the appropriate surgery.

In the sixth chapter entitled "Anorectal Manometry" F.Pucciani presents the role of anorectal manometry in individuals with POP who have defecatory symptoms or fecal incontinence. Manometric evaluation provides functional anorectal data in patients who suffer from posterior prolapse, as anal sphincter activity, rectal compliance, and rectal sensation may be tested. Moreover, manometric signs of defective anal sphincter function or impaired anal relaxation may be also detected, depending on concomitant rectal pathologies. Manometry can only identify those patients whose outlet obstruction is sustained by concomitant anorectal dysfunction.

In the second subsection "Management" authors describe various surgical and conservative treatments of pelvic organ prolapse. In the seventh chapter "Management of Pelvic Organ Prolapse: a Unitary or Multidisciplinary Approach?" G.Dodi, L.Amadio and E.Stocco focus on the necessity of a multidisciplinary approach to pelvic floor disorders, due to frequent coexistence of dysfunctions in all three compartments. It is known that, of patients treated for anal incontinence, 53% and 18% respectively complain of urinary incontinence. The authors state that only combined urologic, gynecologic and colorectal reconstructive procedures can safely be undertaken during the same surgical session, with no increase of morbidity. Additionally, there is a good possibility of an enhanced success rate, and shortened recovery time when all pelvic floor dysfunctions are treated in the same operative session.

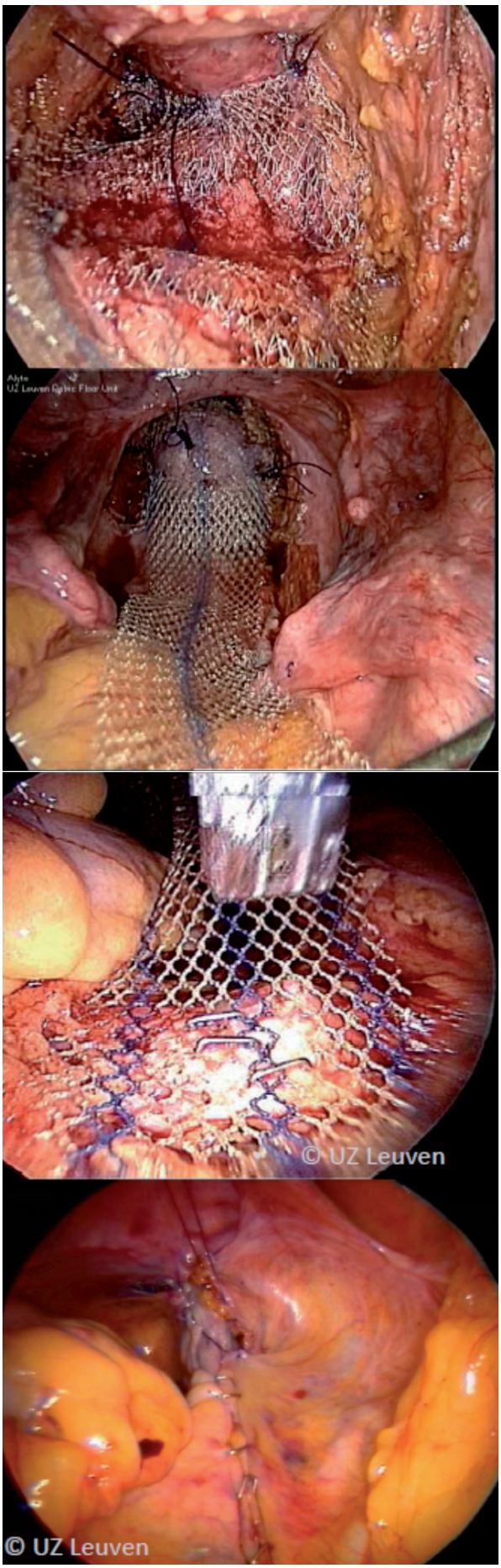

Figure 4. – Abdominal approach to uro-genital prolapse.

The eight chapter "The Abdominal Approach to Urogenital Prolapse" by D.H. Kim and G.M.Ghoniem presents various surgical techniques for the treatment of urogenital prolapse. The choice of operation must be made after careful consideration of a series of factors related to the patient's anatomy, medical history, and goals of surgery. The vaginal approach can be used to repair prolapse through all compartments – anterior, apical, and posterior. An abdominal approach, is required if concurrent intra-abdominal pathology exists that needs to be addressed. Moreover, this chapter reports available data and highlights more specifically the consequences of surgery with mesh reinforcement (Figure 4).

In the ninth chapter "The Perineal Approach to Urogenital Prolapse" T. Rechberger presents the anatomical principles of surgical repair and the importance of tissue tension in the restoration of both structure and function. Perineal operations are safer than abdominal ones but carry a higher likelihood of recurrence of the prolapse.

In the tenth chapter "The Laparoscopic Approach to Pelvic Floor Surgery" E. Werbrouck, F. Claerhout, J. Verguts, J. Veldman, F. Van der Aa, D.De Ridder and J. Deprest reports that, compared to open procedures, laparoscopic operations are associated with reduced postoperative pain, earlier recovery, and shorter length of hospital stay, despite a longer operative time and higher direct costs. In addition laparoscopy offers great exposure and surgical detail, and reduces blood loss.

In the eleventh chapter "Total Pelvic Floor Reconstruction" P.P. Petros presents the new operations modalities of tissue fixation system for pelvic floor reconstruction. The TFS is a new minimally invasive technique using a different bioengineering support principle for pelvic organ prolapse (Figure 5).

In the twelfth chapter "The Abdominal Approach to Rectal Prolapse" by S.M. Murad-Regadas, R.A. Pinto and S.D. Wexner are described in details the most commonly used abdominal techniques for rectal prolapse. The surgical options can be summarized as suture or mesh rectopexy with or without sigmoid resection. Choosing the optimal repair for rectal prolapse involves the contemplation of patient's health and the preexisting bowel function related to a history of constipation or fecal incontinence, also compromise of the sphincter muscles at the anorectal evaluation. Among the abdominal procedures, suture or mesh rectopexies are the option for patients with normal or increased bowel function or atonic sphincter. Resection rectopexy is preferred for constipated patients or with normal sphincter tonus. Abdominal approaches are associated with low morbidity rates, even among elderly patients, and lower long-term recurrence rates compared to perineal approach.

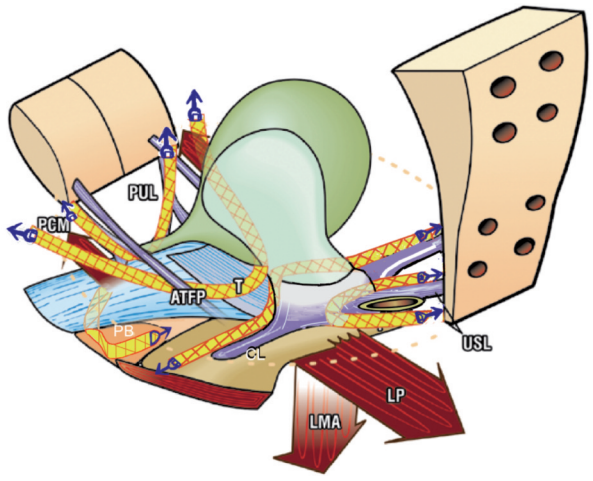

Figure 5. — Tensioned TFS minisling tapes approximate and tension laterally displaced ligaments and their attached fascia., pubourethral (PUL) ATFP, cardinal (CL) uterosacral (USL), perineal body (PB).

The thirteenth chapter entitled "The Perineal Approach to Rectal Prolapse" written by M. Trompetto and S. Cornaglia reports available data and highlights in details the most used perineal procedures (Delorme's and Altemeier's operations) for rectal prolapse. Perineal operations are safer than abdominal ones but can have a higher possibility to bring to a recurrene of the prolapse. Functional results probably depends more on the initial severity of the disorder than on the type of operation.

The fourteenth chapter "The Laparoscopic Approach to Rectal Prolapse" written by J.R. Karas and R. Bergamaschi presents the current opinion on the impact laparoscopy may have on the outcomes of complete rectal prolapse, with insight on laparoscopic surgical technique, and an overview of the literature dealing with this specific subject. The laparoscopic approach for suture rectopexy is feasible. The laparoscope provides the surgeon with a magnified vision deep into the pelvis with the added benefit of a relatively weak fixation of the rectal fascia to the sacrum.

The fifteenth chapter entitled "Pelvic Floor Muscle Training in Prevention and Treatment of Pelvic Organ Prolapse" by K. Bø and I.H .Brækken describes the four randomized controlled trials on the effect of pelvic floor muscle training (PFMT) to treat POP and symptoms of prolapse. The results of all trials show that significantly more women in the PFMT group improved one POP stage compared to the control group. In addition, the study demonstrated significant reduction of POP symptoms (heaviness and bulging) and bladder and bowel symptoms.

In the sixteenth chapter "Medical Treatment of Irritable Bowel Syndrome, Constipation and Obstructed Defecation" P.F. Almerigi, M. Menarini and G. Bazzocchi described in details non-operative therapies that can be successfully used in posterior compartment disorders, including antidiarrheals, dietary modifications, fiber supplementation, bulking agents, osmotic laxatives, tricyclic antidepressants, and antispasmodics. Moreover, the description of new agents, which effect is currently being researched (agonists and antagonists of serotonin receptors, adrenergic modulators, chloride channel activators, probiotics, and others) is also presented. The treatment of slow transit constipation may feature therapy of the comorbidities that may result in constipation. Dietary suggestions, lifestyle changes, correction of bowel habits, and laxatives are fundamental, but new agents should be also taken in consideration. Obstructed defecation can be treated by aiming to decrease the consistency of the stool and facilitate rectal evacuation.

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