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PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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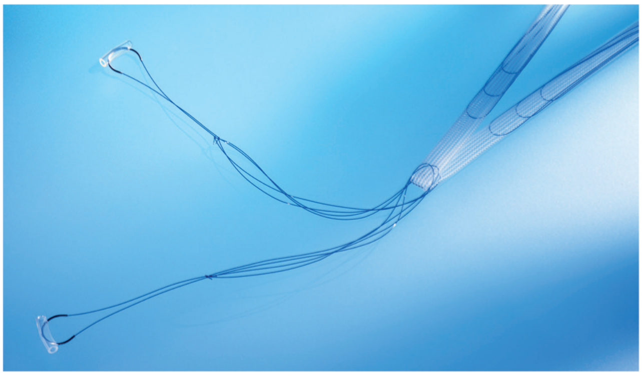
for Female Stress Urinary Incontinence

Q.: Who needs an adjustable sling?



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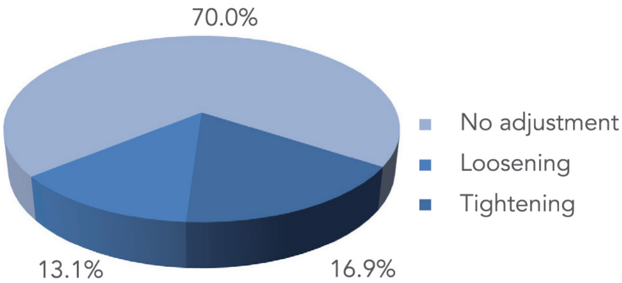
The results speak for themselves.

A.: About 30% of patients.

% of patients requiring adjustment



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90.3% completely dry
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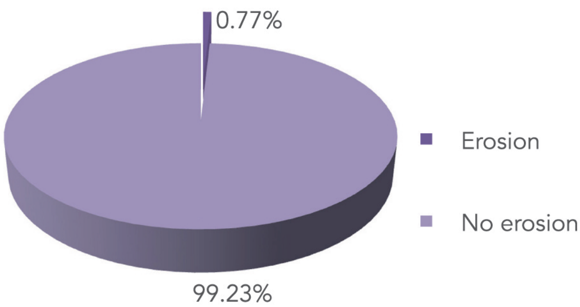
Low erosion rate



Advantages of Adjustment

- Resolves cases of persisting incontinence or urinary retention post-operatively with **no surgical reintervention!**
- Effective treatment for **high-risk groups** (e.g. combined SUI and voiding dysfunction), **severe SUI,** or patients with **previous failed treatment.**

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Original article

From polymer to optimal textile implants - A challenge for the engineer

ANDREAS MUELLEN, LINDA SCHLEWIT, BORIS OBOLENSKI

FEG Textiltechnik mbH, Juelicher Str. 338a, 52070 Aachen, Germany

Abstract: In some respects implants are like any other engineered device: they have to be designed carefully and must fulfill specific requirements according to their application. What makes the development of implants special is the necessity for close interdisciplinary cooperation. Good communication between physicians and engineers is essential. The physician should provide the engineer with the requirements; while the engineer has to translate those requirements into specific values and find the best compromise possible between conflicting requirements. This paper explains this concept by the means of two examples and gives an overview of the main questions which have to be considered when designing a new implant.

Key words: Polymer; Textile implants; Materials; Engineer.

I. INTRODUCTION

Engineering a new implant is not a trivial task. There is definitely not the one mesh of choice for every application. Different anatomic structures call for distinct textile structures (Figure 1).

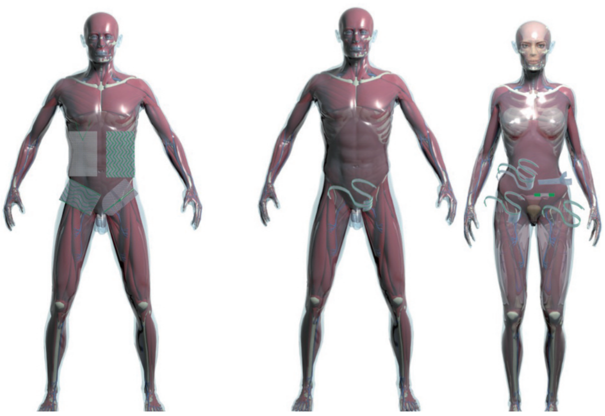

Figure 1. – Different mesh structures used for hernia repair (left) and m/f pelvic floor repair (right).

Therefore it is very important to define specific requirements for specific applications. An engineer calls this “compiling a requirement profile”. It is a huge challenge to comply with every requirement as there are many potential conflicts between them (e.g. sufficient stability vs. high effective porosity). An optimal implant always represents the best compromise possible. To determine necessary and desirable properties a close interdisciplinary cooperation is essential. Physicians provide engineers with either precisely worded requirements, specific values or autopsy specimens for testing. On the other hand engineers translate their requirements into specific values. To explain this concept we will exemplary have a look at meshes used for hernia repair or more precisely on three important requirements: stability, elasticity and porosity.

II A. EXAMPLE OF A REQUIREMENT PROFILE FOR AN INCISIONAL HERNIA MESH

To determine the tensile strength of the human abdominal wall, engineers used a simple analogous model for the human torso: a cylinder. The required stability can be calculated using the law of Laplace (Figure 2). With a maximum inner pressure of 20 kPa and a circumference of the abdomen of 100 cm the tensile force is 32 N/cm in transversal direction and 16 N/cm in longitudinal direction. [1]

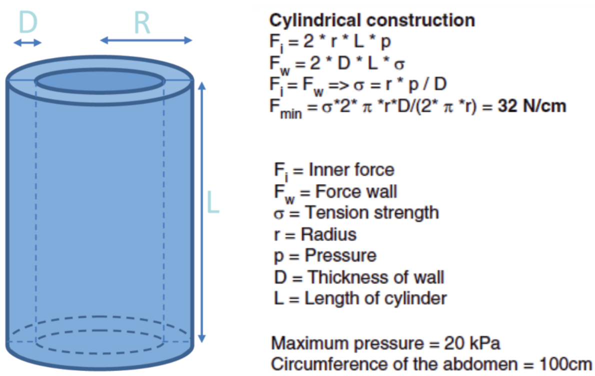

Figure 2. – Cylindrical construction for the human torso 1.

To determine the elasticity of the human abdominal wall, autopsy specimens were used. Figure 3 shows the experimental set-up. The results likewise showed a clear anisotropic behaviour of the human abdominal wall and a big difference between longitudinal and transversal direction (38 % to 20 % at max. tensile force)[1].

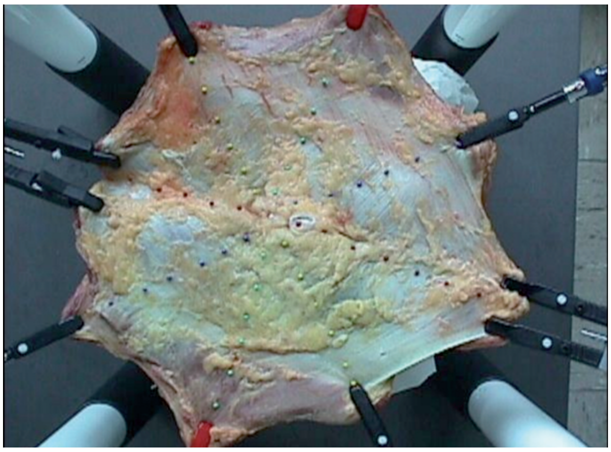

Figure 3. – Experimental set-up to measure the elasticity of explanted abdominal walls 1.

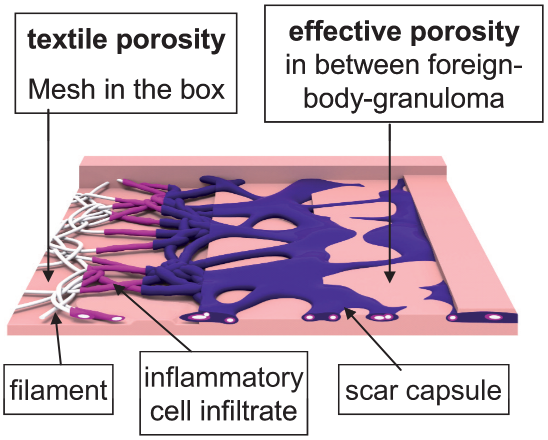

Figure 4. – Textile vs. effective porosity.

Figure 5. – Bridging limits for PP and PVDF.

Finally, the analysis of about 1,000 explanted meshes showed that a high porosity is essential for optimal incorporation. To avoid the bridging-effect (side by side granuloma leading to a continuous scar plate formation), the pore size must be bigger than 1 mm for PP and bigger than 0.6 mm for polyvinylidenfluoride in every direction (Figure 5)[2]. There is a major difference between "textile porosity" and "effective porosity". Textile porosity is the percentage of the mesh surface that is not covered by filaments including all sizes of pores; whereas effective porosity describes only the resulting pores which are available for tissue ingrowth after scar tissue formation (Figure 4).

A new objective system to measure the effective porosity was developed at FH Aachen University (Figure 6). A high resolution digital image is evaluated with graphical data procession. Only the pores with dimension over 1 mm in every direction (0.6 mm for PVDF) are taken into consideration[3].

Figure 7 shows the difference between textile and effective porosity through the example of three different mesh structures (class Ia and II according to Klinge et al)[4].

In summary: the close interdisciplinary cooperation between physicians and engineers led to a profound understanding of needed values regarding "stability", "elasticity" and "effective porosity" and a better understanding of hernia meshes and implants. The final requirement profiles are shown in figure 8.

This knowledge enables the textile engineer to construct an "optimal" hernia mesh for the repair of incisional hernias.

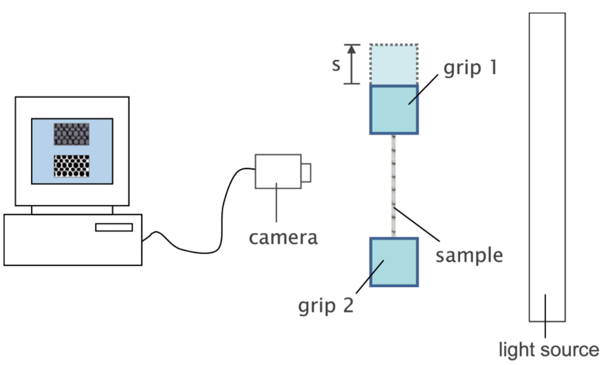

Figure 6. – Set-up for porosity measurement.

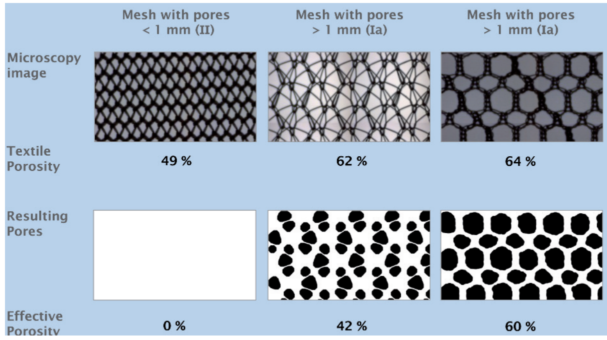

Figure 7. – Textile and effective porosity of different mesh structures.

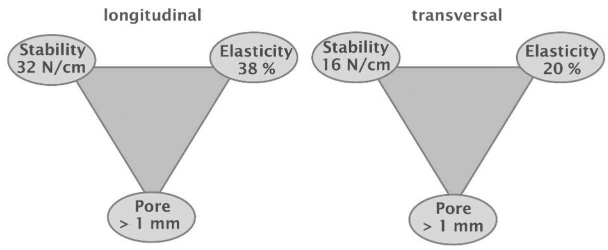

Figure 8. – Requirements for incisional hernia meshes in longitudinal and transversal direction.

II B. EXAMPLE OF A REQUIREMENT PROFILE FOR AN INCONTINENCE SLING

Compared to the anisotropic hernia mesh, slings for pelvic floor repair are clearly under uniaxial condition.[5] Almost tension-free when implanted, there is a certain force applied in longitudinal direction during implantation. This force is the minimal value required for structure stability. So far it has not been quantified. Measuring the tensile strength of explanted ligaments seems to be one option to determine a rough reference point for required stability.

A value of 2 N/cm with an elasticity of less than 10% has been suggested as rough estimates.[5] This estimate however is only sufficient for the implanted device. The pull-through force requires a greater stability during implantation (see figure 16). As foreign body reaction and scar tissue formation should always follow the same principles, the pore sizes indicated for hernia meshes can be used analogously (Figure 9)[5].

III. ENGINEERING A NEW IMPLANT (EXAMPLE INCONTINENCE SLING)

When starting to engineer a new implant, there are at least 3 main questions to consider:

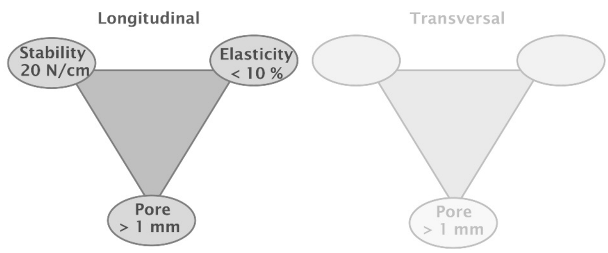

Figure 9. – Requirements for slings.

Which polymer should be used?
Which kind of threads should be used?
Which structure should be used?

1) Which polymer should be used?

The polymer choice depends on a variety of factors. Important properties for the use as implants are high biocompatibility, low evocation of foreign body reaction, high resistance to bacterial adherence, as well as stability under hydrolytic conditions.

Concerning biocompatibility it is also preferable if fewer additives are used. Table 1 shows a comparison between polypropylene (PP) and polyvinylidenfluoride (PVDF) with regard to main requirements. PP is the most commonly used material for pelvic floor surgery. PVDF has been the favoured material for cardio-vascular implants for decades and has also successfully been used in hernia surgery for the past ten years.

Table 1. – Comparison of PVDF and PP.

	PVDF	PP
Low foreign body reaction	++	-
Biocompatibility	++	+
Resistence to bacterial adherence	++	-
Stability	++	+
Long term stability	++	-
No necessity for additives	++	- -
Price	-	++

In several studies it was shown that PVDF induces much less foreign body reaction than PP[6,1]. An analysis of 100 explants showed that PP is not inert[7]. The inflammatory infiltrate as well as the foreign body granuloma are significantly reduced (Figure 10)[8].

Tests with different bacterial strains also showed that the bacterial adherence to PVDF fibres is smaller than to PP fibres or a combination of PP fibres and absorbable fibres (Figure 11). Consequently the risk of infection is reduced with PVDF[9].

The Young's modulus is a material parameter that describes the resistance of the material towards its deformation - the higher the Young's modulus the higher the resistance. It can be measured by the slope of the tangent of the initial, linear portion of the curve in a stress-strain diagram. The Young's modulus of PP varies between 1300 and 1800 N/mm², whereas the Young's modulus of PVDF varies between 2100 and 2900 N/mm². Hence PVDF opposes more resistance towards deformation than PP, which results in more stable fibres.

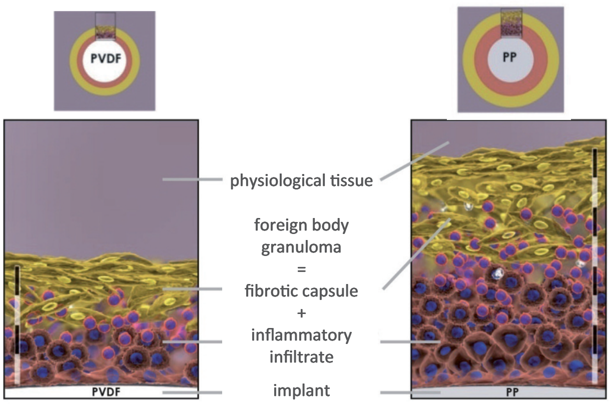

Figure 10. – Foreign body reaction of PVDF and PP[8].

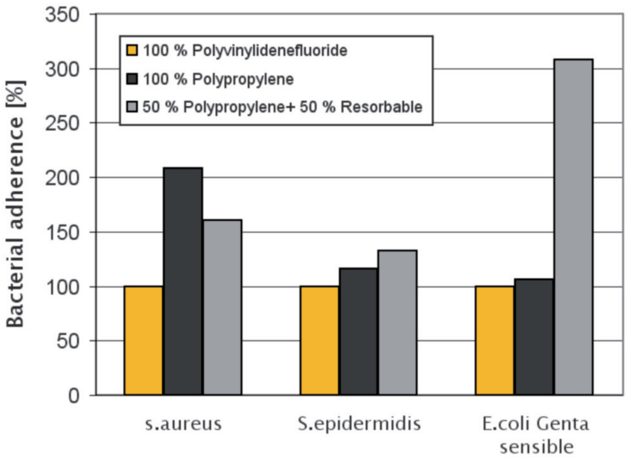

Figure 11. – Bacterial adherence on PVDF, PP and composite fibres.

A higher initial stability of PVDF coincides with a higher long-term stability[10]. Laroche et al. demonstrated during an in-vitro study over a period of 7 years that under hydrolytic conditions PP lost 46.6 % of its original tensile strength while PVDF only lost 7.5 % during the same period (Figure 12)[10]. In vivo studies confirmed the results[10]. Figure 13 shows SEM images of explanted PVDF and PP filaments. Only the PP samples show signs of surface cracking.

Another important advantage of PVDF over PP is that there is no need for operational additives such as diluents, stabilizers or antioxidants.

Like Polypropylene, PVDF can be coloured, but has furthermore the technological advantage of modifications regarding visibility in MRI[11,12] or bioactive coatings (Table 2) [13,14].

Table 2. – Additives used for PVDF and PP..

	PVDF	PP
Operational Additives	None	Diluents (softeners)
		Stabilizers
		Antioxidants
Optional Additives	Colorants for orientation	Colorants for orientation
	Particles for visible meshes	
	Bioactive coating	

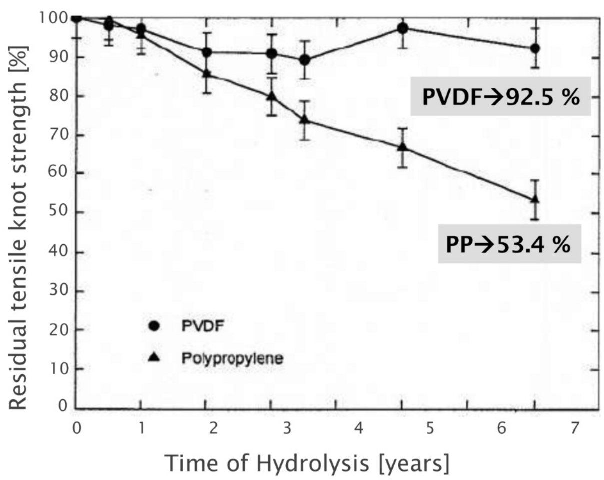

Figure 12. – Residual tensile strength of PVDF and PP sutures during exposure to hydrolytic conditions 10.

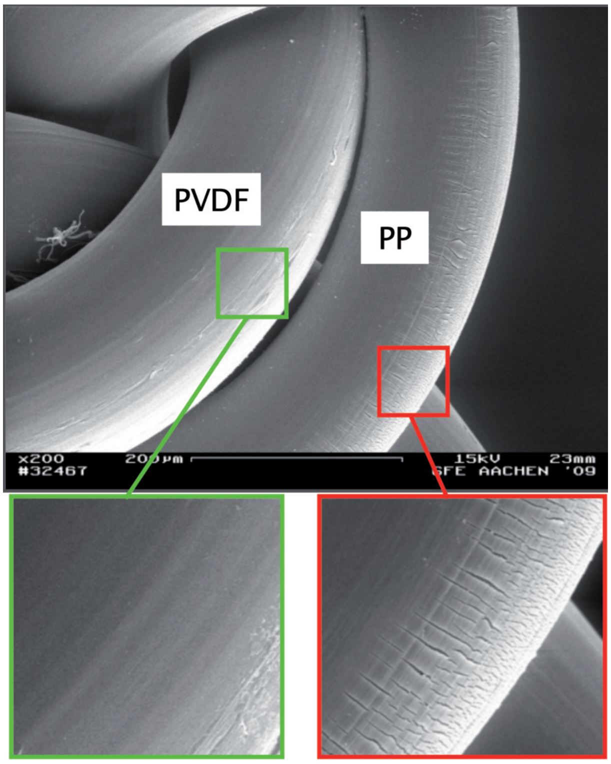

Figure 13. – Explanted PVDF and PP filaments, PP shows signs of surface cracking.

However, despite the superior properties of PVDF, it is still not the standard for pelvic floor implants. The reason for this is simple: higher costs and the fact that most manufacturers are unable to process this high-tech polymer. It is not processable on conventional spinning units for it contains fluorine which behaves aggressively during the process. Nevertheless the fluorine is advantageous in the final product for it provides long-term stability and elasticity even in fibres with a small diameter.

2) Which kind of threads should be used?

Figure 14 shows a schematic diagram of the melt spinning process. The properties of the filaments can be varied within wide limits but it is also a challenge to find parameters which ensure sufficient process stability and reproducibility.For most applications a multifilament – a thread composed of many small fibres – is advantageous as it offers a greater stability than a monofilament – a thread made from one single fibre. In a multifilament thread the different filaments buttress each other and inhomogenities can be balanced out. However, for the use in the human body a monofilament is preferable for it offers much less surface for bacterial adherence and foreign body reaction (Figure

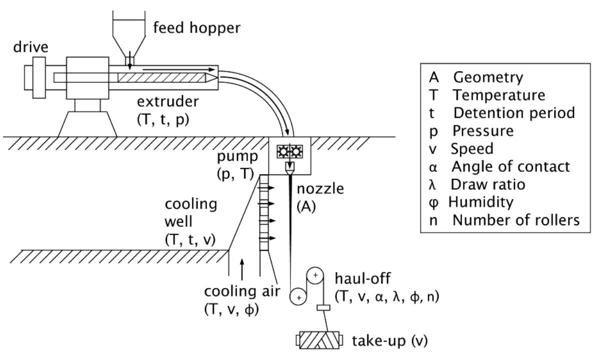

Figure 14. – Melt spinning machine.

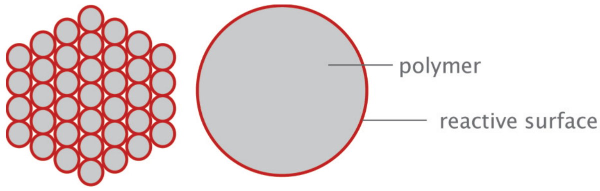

Figure 15. – Comparison of the reactive surface of multi- and monofilaments.

15). This coincides with the suspicion of many surgeons that multifilaments lead to increased infection rates.

3) Which structure should be used?

The structure of implants must be open-porous and soft but nevertheless stable. The edges should also be soft without sharp filaments sticking out ("saw-chain edge") to avoid tissue traumatization.

The structural stability for pelvic floor implants is especially important during implantation. An implant with insufficient stability can be deformed plastically which means the deformation remains even after the load has vanished. The plastic deformation is usually accompanied by a reduction of the effective porosity – the pores are elongated while their width is narrowed significantly ("collapse of pores"). This can turn a large pore class I structure into a small pore class II structure with an accumulation of foreign body material and an increased foreign body reaction and scar tissue formation. Insufficient stability can also lead to rolling-in which has the same negative effects as a material accumulation but can also lead to erosions when only the edges instead of a flat surface are in contact with sensitive structures like the urethra.

There are two technical options to prevent plastic deformation and the reduction of effective porosity during implantation. The first is a plastic sleeve around the implant which absorbs the tensile force and is removed after implantation. One disadvantage of this solution is the difficult handling during implantation. Subsequent repositioning after the sleeve has been removed is also impossible. Additionally the question of what happens after implantation remains. The second technical option is a stable structure. A well-engineered structure can absorb the tensile force without unacceptable deformation (Figure 16).

There are also two ways to avoid tissue traumatization with sharp edges during implantation. The first option is used most commonly because most of the implants are cut to fit and therefore have traumatic edges: a plastic sleeve around the implant which is removed after implantation.

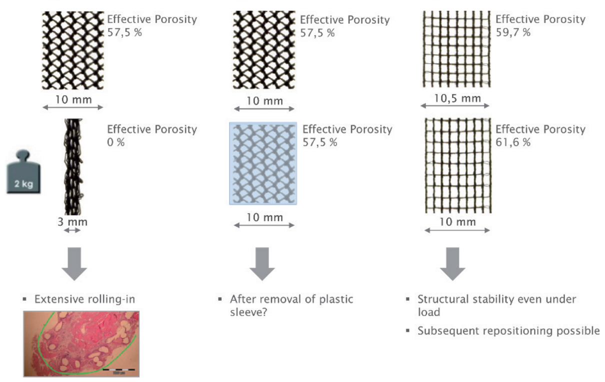

Figure 16. – a) unstable structure, b) unstable structure with plastic sleeve, c) stable structure.

But even though the extensive traumatization during pull-through is avoided, the filaments sticking out can still potentially harm surrounding tissue afterwards and lead to erosions.

The second option which avoids the complicated handling with plastic sleeves is a structure with soft, knitted edges (Figure 17).

IV. POST-MARKET SURVEILLANCE

To improve the knowledge of implants in the human body there is a need for intensified post-market surveillance with comprehensive registries as a basis. The benefits of registries over clinical studies are numerous. For one they provide a much greater data pool. They have a significantly longer follow-up time than studies and therefore can cover even delayed complications. Considering that usually only experts participate in studies, registries also represent the clinical reality much better. An accumulation of complications becomes apparent much quicker with registries so that potentially harmful devices can be identified and taken of the market earlier. However, so far the problem of data privacy remains. The solution is a fail-safe system for effective patient anonymization. In the long run, with registries providing more reliable data, patient safety and comfort will be ensured and improved which should convince even the sceptics.

Additionally a great option to support follow-up after implantation are MRI visible meshes[12]. They provide confirmation of the accurate implant position which gives optimal control of the healing process. This way, exposure to radiation (contrary to conventional x-rays) and unnecessary secondary interventions can be avoided. Figure 18 shows various visible meshes in MRI, figure 19 shows a 3D reconstruction of a visible mesh.

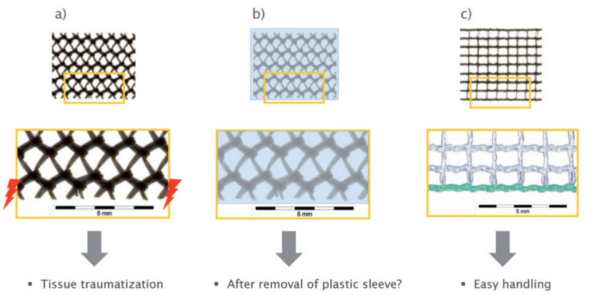

Figure 17. – a) “saw-chain” edge, b) “saw-chain” edge with plastic sleeve, c) soft, knitted edge.

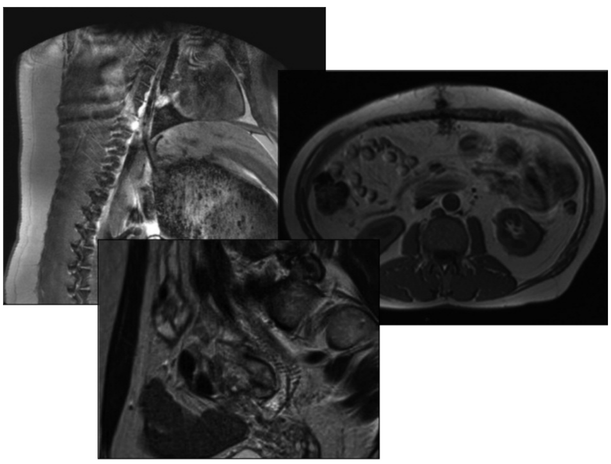

Figure 18. – Different visible mesh structures in MRI.

Figure 19. – 3D reconstruction of a hernia mesh.

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Giuseppe Dodi
ISPP President

Original article

Use of anal sling in the treatment of faecal incontinence

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Abstract: Fecal incontinence is defined as the recurrent uncontrolled passage of faecal material for at least 1-month duration. It affects people of all age and especially middle-aged women, nursing home residents and elderly. The evaluation includes a detailed clinical assessment with an appropriate physiological exam and imaging tests of the anorectum to provide information regarding the etiology and the severity of the problem. Before considering surgery, medical treatment, such as diet correction, fibers, transit delay, little enemas and rehabilitation must have failed. Selecting patients is critical in surgical treatment. In carefully selected patients with severe incontinence and rectal prolapse, who have not had acceptable improvement in symptoms the transobturator anal sling can be considered an alternative among the options. Implants for surgical treatment is a therapeutic option derived from experience by urogynecologists. Bioreabsorbing materials placed (tension free) along puborectalis muscle's line support pelvic diaphragm creating an elastic structure. The specific type of net for these applications is made by the monofilament of Prolene®, manufactured by Ethicon Inc.®, and diffused under the trade name of Net Polypropylene PROLENE®. In our personal experience 12 patients underwent surgery between 2006 and 2009. Intervention is feasible in early and advanced phase of fecal incontinence and rectal or pelvic prolapse.Even if this procedure is invasive, can be considered relatively simple and effective. None of patients had complications in subsequent follow-up.

Key words: Anal sling; Fecal incontinence; Surgical treatment; Prosthetic mesh.

INTRODUCTION

Faecal incontinence is the involuntary loss of rectal contents through the anal canal. It is defined as the recurrent uncontrolled passage of faecal material for at least 1-month duration. The prevalence varies from 2 to 18% depending on the definition of incontinence. Female patients predominate in most reports, but epidemiological studies show a more equal gender distribution. Anal incontinence is an embarrassing and debilitating problem that affects people of all ages and especially middle-aged women, nursing home residents and the elderly.[1] It significantly affects the quality of life, causing such a social embarrassment that those who suffer from it are reluctant to go out due to fear of social contact and therefore frequently become housebound.[2]

The variations of this condition encompass a wide spectrum, from mild to severe.[3] There are three subtypes: passive incontinence – the involuntary discharge of stool or gas without awareness; urge incontinence – the discharge of faecal matter in spite of active attempts to retain stool; and faecal soiling – the leakage of small amount of stool without awareness.[4]

The evaluation includes a detailed clinical assessment with an appropriate physiological exam and imaging tests of the anorectum to provide information regarding the etiology and the severity of the problem. There are several score indices to quantify symptoms for grading the severity of faecal incontinence and its impact on quality of life, such as the Fecal Incontinence Severity Index (FISI) and the Cleveland Clinic Incontinence Score (Wexner) that combines the loss of flatus, liquid, and solid stool, while the Fecal Incontinence Quality of Life Questionnaire (FIQL) and the SF-36 assess the quality of life.[5] Specific tests that can define the underlying physiopathology include anorectal manometry and anal endosonography.[6] These tools are used to assess the severity of symptoms and therefore are recommended to choose a strategy for treatment.

The treatment can be either medical or surgical. The first one consists in dietary changes, modification of fiber intake (either increase or decrease), bulking agents,[7,8] and bowel-habit training. Anti-diarrheal medications, such as loperamide, diphenooxylate, amitriptylineand bile-acid binders can be tried with caution. Self-management with rectal irrigation to keep the rectum empty and thereby preventing fecal incontinence has been successful both in the short- and long term.[9] Among non-invasive procedures both electrostimulation and biofeedback therapies are safe.[10]

Initially used for treatment of urinary incontinence, Sacral nerve stimulation has now become an established treatment for fecal incontinence.[11,12]

If medical treatments failed, patients can undergo surgery. Selecting patients is critical in surgical treatment to restore the anal aperture by repairing sphincter defects. Established injuries in symptomatic patients are treated by overlapping sphincteroplasty, which is usually done without creating a diverting stoma. If none of the previous options are feasible, adverting stoma remains an excellent alternative. Otherwise, in selected cases (for example when traumatic or neurogenic injuries are extensive) dynamic graciloplasty or an artificial anal sphincter can be tried.[13,14,15,16]

The purpose is to use a prosthetic mesh made of non-reabsorbable or partly reabsorbable that is applicable in a manner so-called "tension free", without that this mesh exerts a tensile force on the surrounding tissue, in contrast with the techniques of suspension already developed.

PERIOPERATIVE STEPS

In carefully selected patients with severe faecal incontinence and rectal prolapse, who have not had acceptable improvement in symptoms, the transobturator anal sling can be considered an alternative among the options.

Implants for surgical treatment is a therapeutic option derived from urogynecologists experience.[17,18] A prosthesis made of a partially reabsorbing nets used in the surgical treatment of prolapsed pelvic and faecal incontinence. It produces an increase in the production of connective tissue, creating a naturally elastic structure; this provides effective support and prevents the subsequent descent of the pelvic structures.

The technique consist in placing a bioreabsorbing or partially reabsorbing net along puborectalis muscle's line to support pelvic diaphragm creating an elastic structure that surrounds anorectal canal bilaterally in a tension free manner, that is without applying any traction of the surrounding tissues; it is suitable to be applied in correspondence of the obturator foramens (Figure 1, 2).

This Italian patent – not yet available on the market – includes the device and the "hammock" instruments to implant the prosthesis, which is formed by a central body of biological material and four ends in non-absorbing material to "suspend" the rectum and reposition it in its anatomical position (Figure 3).

Even if this procedure is invasive, it can be considered relatively simple and effective. There were no serious complication nor was ever necessary to explant the prosthesis.

This article describes the surgical technique used for the implantation and presents our personal experience in 12 patients who underwent surgery between 2006 and 2009. Intervention is feasible in early and advanced phase of fecal incontinence and rectal or pelvic prolapse. Symptoms resolution or alleviation reaches up to 85% of cases in the immediate postoperative phase. The Wexner score is about 10 points lower at a 3-month follow-up, and is reduced to 8 points 1 year after treatment. Changes to the relief of anal rectal manometry is about 12 mmHg squeeze pressure and 15 mm Hg resting pressure to follow-up to 1 year.

TECHNIQUE

The procedure may be carried out either under general or spinal anaesthesia, with the patient placed in the lithotomic position.

After putting the patient in a lithotomic position and disinfecting perineum and anus-rectal (and vaginal) cavities (after a suitable intestinal preparation), a vertical incision is made about 2-3 cm long, and a lateral one beyond 3 cm from anal coetaneous folds, on the left side of the patient at 3 hour (or on the right side in case technician is left-handed) (Figure 4). Once unglued subcutaneous tissue by an acute and rounded way, a tunnel is made by digitoclasy about anus-rectal channel, thus entering into a virtual space between rectum rear wall and ano-coccygeusraphe (Figure 5).

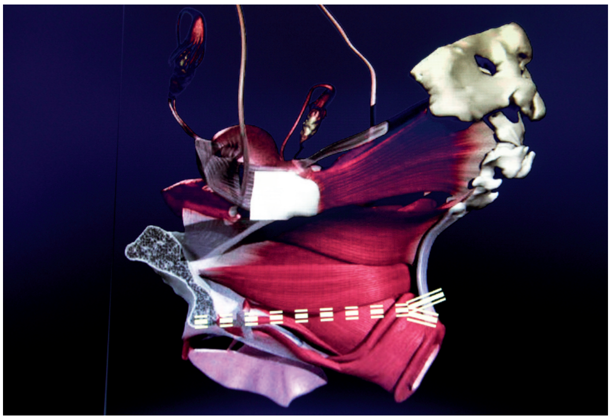

Figure 1. – Anatomy of the pelvis.

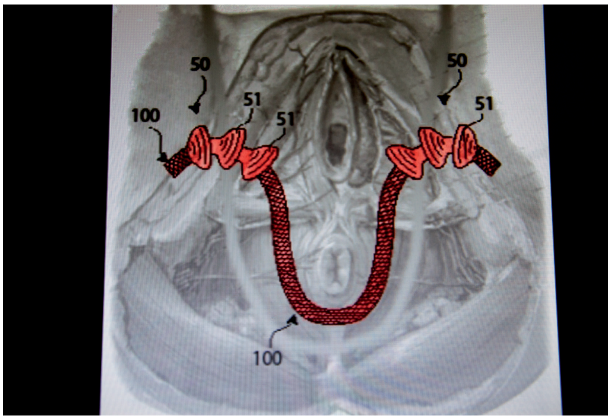

Figure 2. – Positioning of the prosthesis.

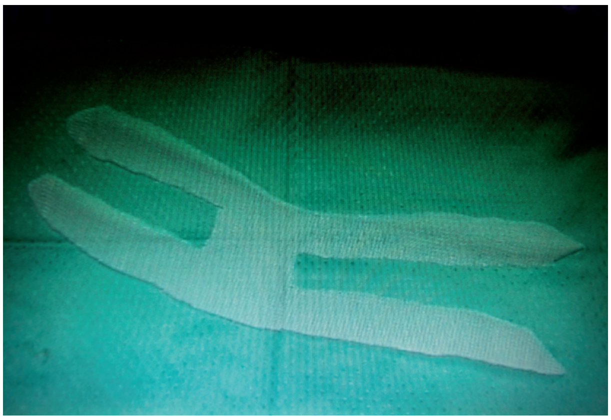

Figure 3. – Prosthetic mesh.

Figure 4. – Perineal incision and landmarks for engraving at the obturator foramina.

Figure 5. – Tunnel realized through digitoclasy between the rear wall of the rectum and the ano-coccygeusraphe.

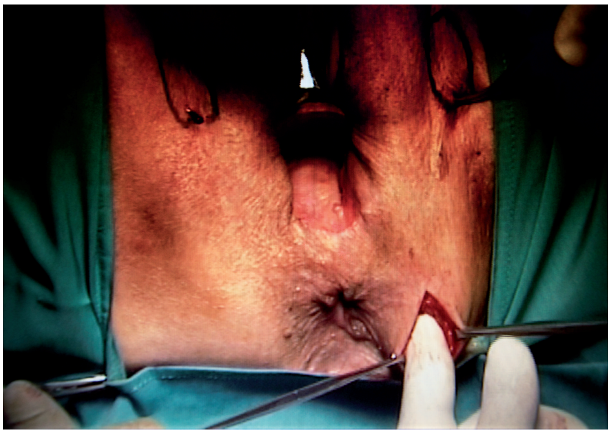

Figure 6. – Curved needle Hammock insertion through the obturator foramen coming out perineal incision.

Figure 7. – Leakage from the hammock loop to attach the prosthesis.

Figure 8. – Placement of prosthetic mesh in the loop.

Two point-shaped cutaneous incisions are made by lancet, at the level of the lower edge of obturator foramen, having as bilateral repere ischial tuberosities.

Afterwards, a curved needle is introduced, passing through obturator membrane, and thus it is brought by a combined action (through the vagina for a woman, through the rectum for a man) until exiting from the surgical opening already realized (Figure 6, 7).

It is hooked distal end of band exiting from skin (Figure 8, 9). This action is repeated from the opposed part, coupling needlepoint behind rectum wall (Figure 10).

Now, two arms of band are pulled by a combined action of hand index within anal channel in order to evaluate tension of central part of the same (Figure 11).

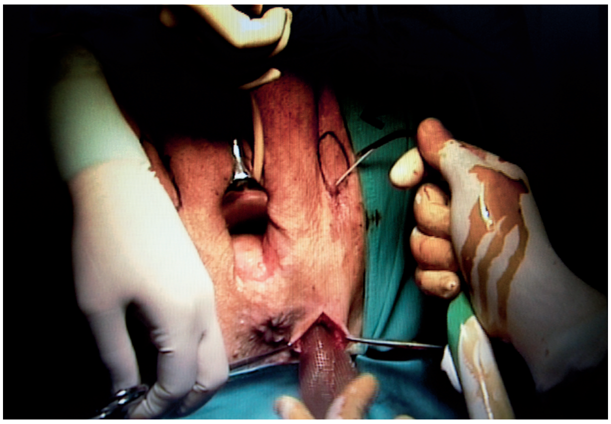

Figure 9. – Leakage by the skin of prosthetic mesh through the obturator foramen.

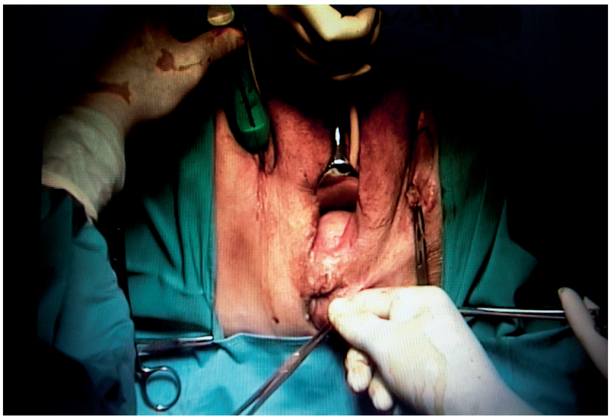

Figure 10. – Action repeated from the opposed part, coupling needlepoint behind rectum wall.

Figure 11. – Two arms of band are pulled to evaluate the traction of the central part of the prosthetic mesh behind the anal canal.

Now, it is considered the retraction condition of perineum in order to eventually loosening or pulling said band (Figure 12). Two band ends can be let free within subcutaneous tissue, thus exploiting the so-called Velcro effect of synthetic material, or they can be fixed by a quick hooking system, or anchored by two not-reabsorbing mono-filament suture stitches, or even self-support thanks to a silicone ogives or similar material system (Figure 13).

Cutaneous opening are closed after having cut the exceeding net.

DESCRIPTION OF THE PROSTHESIS

The main advantage of the prosthetic assembly of the

Figure 12. – Finding of prosthetic arms and repositioning of the anus in anatomic site.

Figure 13. – Final result and closing of the surgical accesses.

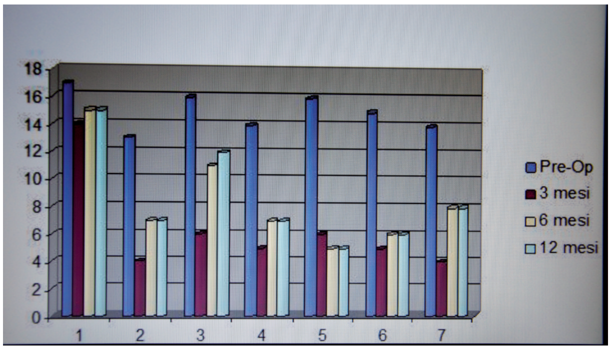

Figure 14. – Trend in the Wexner score at follow-up.

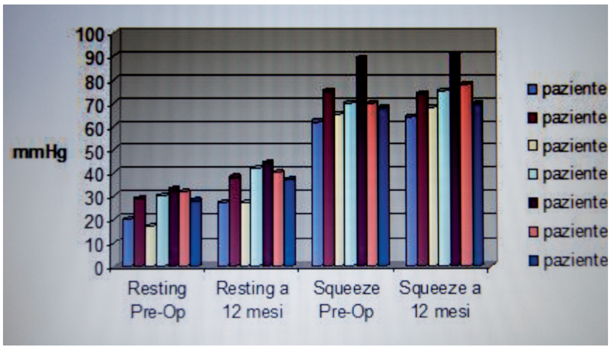

Figure 15. – Trend of anorectal manometry findings of squeeze pressure and resting pressure in the FU.

present intervention is an increase of production of connective tissue between surgically implanted net meshes, naturally creating a not-reabsorbing and elastic support which provides an efficient support and prevents a subsequent descent of pelvic structures subjected to prolapse. Furthermore, surgical application of said prosthetic assembly that can be carried out both in a premature or in an advanced phase of rectal prolapsed and in incontinence, correcting both of them.

The specific type of net for these applications is made by the monofilament of Prolene®, manufactured by Ethicon Inc.®, and distributed under the trade name of Net Polypropylene PROLENE®.

Said synthetic net, sterile and inert, has a bi-directional elasticity and a traction resistance higher than 10 kg/cm2, with a thickness between 0.5 and 0.9 mm, preferably about 0.7 mm. Transverse dimensions of meshes are between 1 and 3 mm, meshes has rhomboid shape. Each wire is a not-reabsorbing monofilament wire comprised of polypropylene $(C_3H_6)n$, particularly an isotactic stereoisomer of polypropylene.

CONCLUSION

Our experience on the twelve patients who underwent this procedure shows that the anal sling is a valid option among the existing ones for the treatment of some patients suffering from both fecal incontinence and rectal prolapse (Figure 14, 15).

The main advantages lie in the relative simplicity of the procedure and in its effectiveness.

None of the patients experienced subsequent complications, and none of them required an explants afterwards. Another set of patients has received the treatment, and the follow up results will be published when available.

CONFLICT OF INTEREST

The authors declare that have not receive any grants or financial support for the study and there is no conflict of interest.

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Case report

Pregnancy after advanced pelvic floor repair using CR-mesh (A.M.I.): a case report

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All authors declare that neither they have a financial interest or affiliation with any commercial organization.

Abstract: We report a case of a pregnancy of a young woman who previously underwent a transvaginal pelvic floor repair with mesh for pelvic organ prolapse. A 36-year-old woman with complete utero-vaginal prolapse, occurred after a vaginal birth complicated in a 4° degree perineal laceration, who underwent transvaginal complete advanced pelvic floor repair with CR-mesh (A.M.I.) to restore all the three DeLancey levels of support. After this operation, good anatomical and functional results were obtained. Then, she became pregnant culminating in elective caesarean delivery. During cesarian section no problem was reported in relation to the previous mesh implantation. The post-delivery follow-up after 2 years exhibited no prolapse relapse. In conclusion, pelvic floor reconstruction with vaginal meshes could have positive significance for young patients who desire uterine preservation for future pregnancies. However, further studies with long-term follow-up are warranted to determine whether it can be used in women planning future pregnancies.

Key Words: Pregnancy; Pelvic organs prolapse; Pelvic floor reconstruction; CR-mesh.

INTRODUCTION

Transvaginal pelvic floor repair using meshes are used all over the world and proved to be an alternative to the fascial surgery to reduce the risk of recurrence[1-4]. Whereas the meshes usually don't stretch significantly as the patient grows, often they are considered contraindicated for pregnant women or for women planning future pregnancies. Few articles in literature describe what happens if a patient encounters a pregnancy after a pelvic floor repair surgery with vaginal meshes[5,6]. Here, we presented a case of a pregnancy after a complete advanced pelvic floor repair with CR-mesh (A.M.I.)[7] and a successful delivery via caesarean section without recurrence of pelvic organ prolapse.

PATIENT AND METHODS

In November 2004 a 33-years-old woman was hospitalized at the Operative Unit of Obstetrics and Gynecology of Desio Hospital (Italy) at 41weeks 6 days of gestation of her second pregnancy. She had a history of a prior therapeutic abortion during the 17th week of her first pregnancy because of a fetal malformation (cystic hygroma). After a pharmacologic induction of labour by amniorexi and intravenous infusion of oxytocin and an uncomplicated labor she had an healthy baby weighting 3830 gr. During the delivery a median episiotomy was performed, complicated in a fourth-degree[8] complete perineal laceration, with a 1 cm total thickness rupture of the anal sphincter (internal and external) and of the front rectal wall. A reparation of the laceration was conducted with an introflecting double suture with reabsorbing stitches to repair the rectal wall and an overlapping using 4 prolene stitches, according Sultan,[9] to repair the external anal sphincter. The procedure ended with the reconstruction of deep and superficial perineal muscles, with final reconstruction of perineal body. No complications occurred in the postoperative period with a complete functional recovery.

Three years later, in October 2007, the patient was referred to our center complaining a protruding vaginal mass out of the vaginal introitus, anal incontinence (Incontinence Wexner Score = 8) and urinary frequency and urgency. She denied urinary incontinence.

Pelvic examination revealed stage IV pelvic organ prolapse, a total bilateral detachment of the pelvic fascia running for the whole white-line insertion with cyctocele 4° stage (presenting wrinkled surface indicating a lateral defect), hysterocele 3° stage, enterocele 2° stage and a rectocele 1° stage associated to signs of previous surgery, with a good persistent reconstruction of perineal body and of the anal-vaginal distance (4 cm) (Figure 1). The pelvic organ prolapse quantification (POP-Q) measurements were the follow: Aa +1, Ba +3, C +3, gh 4, pb 3, tvl 8, Ap -1,Bp -1, D +1. The cervix and vagina were smooth and soft without infection and decubitus ulcers. No uterine and ovarian abnormalities were found.

She underwent then following exams:

Cough-test, after the replacing of prolapse: negative

Cistomanometry: no urodynamic signs of detrusor iperactivity

Uroflussometry: no urodynamic signs of defects in bladder emptying, negative bladder post-voidal residue and pressure-flow curve not obstructed

Dynamic defecography: presence of a static and dynamic enterocele and rectocele with internal mucosal prolapse, without intussusception.

Anal-rectal manometry: maintained the basal tone of external anal sphincter, and voluntary contraction of the same, even if with pressure values at lowest limit.

Trans-anal ultrasound with 360° 10Mhz rotating probe: a front median scar is highlighted into the anal sphincter (previous overlapping), the internal anal sphincter seems to have a normal thickness, with a minimal lack of homogeneity into the more cranial scanning and an adjacent lack of homogeneity of eternal anal sphincter that seems partially interrupted.

Figure 1. – Pelvic examination before CR-mesh operation: prolapse 4° stage.

Figure 2. – Anatomical result after transvaginal complete advanced pelvic floor repair with CR-mesh.

Latent period of pudendal nerve: signs of chronic sufferance of pudendal nerves, especially on the right side.

In June 2008 the patient, after a careful and complete informed consent about all the available therapeutic possibilities, underwent a complete advanced pelvic floor repair with CR-mesh (A.M.I., Austria)[7] associated with anal perisphincter infiltration with macroplastique (Figure 2). The CR-mesh technique suited the following concepts: 1. fixation of the anterior and of the posterior compartments to the De Lancey Level I apical support (by bilateral suspension to the medial end of the sacro-spinous ligament); 2. recreation of the De Lancey Level II lateral support (using transobturator and trans-ileococcygeus slings); 3. recreation of the De Lancey Level III distal support (by recreating bladder neck support and by reinforcing perineal body using superficial slings). The CR-mesh consists in a particularly soft macroporous monofilament polypropylene mesh, which has a weight of 19 g/m^2, less than other meshes used for the utero-vaginal prolapse, to minimize fibrosis and retraction after surgery and to permit good elasticity.

In the postoperative time an haematoma occurred, extended to the para-rectal space and to the left gluteal regions. This haematoma spontaneously resolved in one month. Another postoperative complication was urinary retention. The patient was discharged nine days after the operation with antibiotic and anti-inflammatory therapy, intermittent catheterism and daily ultrasound checks of post-voidal residue that normalized with value <100cc on the 13th day.

RESULTS

At 1-month follow-up the patient declared a complete satisfaction, she was asymptomatic, with normal bladder-urethral function and also a good control on anal-rectal function (Wexner score =2). She only still complained a light chronic pelvis pain (VAS=4) with occasional use of FANS. She presented a 1° degree POP-Q asymptomatic cystocele (Aa - 2, Ba -2), with an excellent suspension of central compartment (C -5, D -6) and maintained perineal thickness. No infection or rejection of the mesh occurred.

The patient underwent a check every six months with stable good results.

In September 2009, 15 months after the pelvic floor repair operation, she started her third pregnancy. During pregnancy obstetrical visits are scheduled monthly, with evaluation of POP-Q score and control of front and back mesh insertion; the results were:

– immodified vaginal profile during the whole pregnancy
– excellent flussimetric controls of uterine plexus and of placental, umbilical and fetal compartment;
– regular intra-uterine fetal growing curve

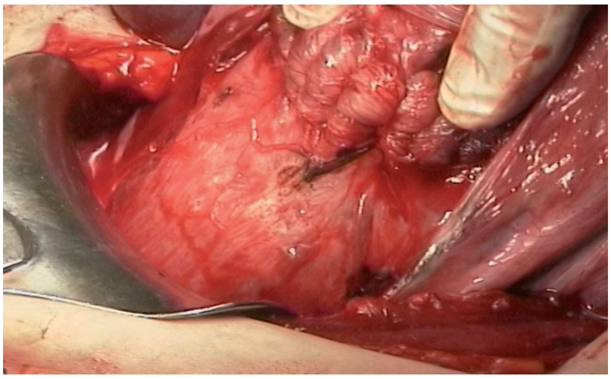

Figure 3. – Lower uterine segment during cesarean section, the peri-cervical mesh cranial insertion is never reached, even with a good preparation of the bladder-uterine space.

Considering her previous trans-vaginal operation, in April 2010, the patient had an elective cesarean section, with transversal incision using Pfannenstiel and extraction of an healthy baby weighting 3220 g. During the preparation and incision of lower uterine segment, the peri-cervical mesh cranial insertion (implanted in 2008) is never reached, even with a good preparation of the bladder-uterine space (Figure 3). The post-operative period was regular and the patient was discharged on the third day.

During the puerperal control on 30th day, the patient was asymptomatic, with an uro-gynecological objectivity unmodified in respect to the previous controls before pregnancy. She presented an asymptomatic cystocele second stage (POP-Q, Ba: -1). No relevant bladder-urethral or colon-proctologic symptomatology, only an occasional gas incontinence.

Her last visit about 2 years after caesarean section revealed that the mesh still remained intact and the suspension of the anterior and posterior vaginal walls and uterus was also maintained, without erosion of the vaginal wall or fornix.

DISCUSSION

Advanced pelvic floor repair using CR-mesh (A.M.I., Austria), described firstly by Bruce Farnsworth, involves comprehensive reconstruction of all three levels of pelvic support and the combination of this technique together with the new lightweight low density macroporous CR mesh results in very good outcomes for patients and a significant reduction in mesh related complications[10-11]. The characteristics of this ultra- light macroporous mesh, specifically designed to minimize fibrosis and retraction after surgery, permit to combine excellent strength, durability, surgical adaptability, sufficient porosity for necessary tissue ingrowth with a very good elasticity. This is very important in those patients who have pregnancy after the implantation of the mesh. During the pregnancy period the part of the body undergoes the most significant changes is the uterus, it increases to 20 times its original weight, and 1000 times its initial capacity and the ligaments supporting the uterus enlarge and elongate. On the other hand, vagina tissue soften with an increased elasticity of the pelvic floor's structures. As the CR-mesh create a sort of ring around the cervix and the two meshes are placed in the vesico-vaginal space and in the recto-vaginal space to support and repair the prolapsed vaginal wall during the operation, it must have sufficient strength while maintaining excellent elasticity.

The patient's successfully delivery via caesarean section without recurrence of prolapse proved that pelvic floor reconstruction with vaginal mesh could be a positive significance for young patients who desire uterine preservation for future pregnancies. However, data on long term follow-up for a large number of patients are lacking and further studies are warranted to determine whether the pelvic floor reconstruction surgery with vaginal meshes can be used in pregnant women or women planning future pregnancies.

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Original article

Laparoscopic implantation of neuromodulators for treating bladder and lower limb spasticity and promoting micturition in spinal cord injured patients

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Abstract: Introduction: Pelvic organ autonomic disorders and lower limb spasticity and atrophy are among the most important factors affecting morbidity and quality of life of thoracic spinal cord injured patients. Recently, the laparoscopic implantation of neuroprosthesis (LION) is figuring as a possibly more specific and selective treatment for these affections. *Objective*: evaluate the effect of the LION procedure at on bladder and rectal function and lower limb spasticity and contractility, to promote an alternative locomotion to thoracic spinal cord injured patients. Methods: we report our first case of a LION procedure. The patient is a 29 year-old man, with C7-Th1 (neurological Th3) car spinal cord injury since age 18 years, classified as grade B (ASIA), only due to rudimentary anal sensitiveness. Electrodes were implanted juxtaneurally to the pudendal, sciatic and femoral nerves. *Results*: at one month follow-up bladder spasticity was completely resolved and bladder capacity doubled (190mL pre-op to 380mL post-op). Moreover, the patient was able to extend the knee from postoperative day one. Thirty-two days after surgery, the right femoral nerve electrode was misplaced, requiring a reintervention and postponed the standing up training. At two-months follow-up thighs circumference increased from 38.5 cm (right) and 42 cm (left) to 40 cm (right) and 42 cm (left), he is showing some voluntary pelvic floor contraction, sensitivity improved on Th4 to Th11 and L2 to S4 dermatomes with the stimulator turned on and on Th4 and Th5 with it turned off. The stand up and walking training is planned to start at post-operative three months, in January. *Conclusion*: The LION procedure offers new target nerves for modulation and is a promising method for motor and urologic rehabilitation in spinal cord injured patients.

Key words: Bladder; Lower limb; Spasticity; LION; Neuromodulation.

INTRODUCTION

"Spinal cord injury (SCI) has been described as one of the greater calamities that can befall humans. Learning of the paralysis, bladder and bowel dysfunction, dependence on others, mobility limitations, and high risks of complications (such as pressure ulcers) that a spinal injury entails, most people who contemplate being forced to live this way cannot see anything but a life of low quality and conclude that they would rather be dead. Many individuals who actually incur an SCI indeed feel this way, at least initially. Some people with SCI very rationally decide to commit suicide, and others may do so during a period of depression and despair that is not uncommon after SCI. The suicide rate among individuals with SCI is about five times as high as the population at large and may be underestimated because of the "indirect suicides" achieved by prolonged self-neglect". (Paragraph fully transcribed from Dijkers, 2005).[1]

Pelvic organ autonomic disorders and lower limb spasticity and atrophy and their consequences (pressure ulcers, recurrent urinary infections, chronic renal failure etc.) are among the most important factors affecting morbidity and quality of life of thoracic spinal cord injured patients[2,3] and recovery of bladder and bowel function are the highest priority among para and tetraplegic patients.[4]

ELECTROSTIMULATION FOR THE TREATMENT OF NEUROGENIC BLADDER DYSFUNCTION

The first reported attempt to electrically stimulate the neurogenic bladder was reported in 1878, when Saxtorph MH described a catheter shaped electrode to work as a cathode – a method that showed acceptable results in treating bladder hypotonia in children[5], but not in spinal cord injured patients.[6] Poor results were also observed with direct detrusor stimulation, since the current intensity needed to achieve an effective bladder contraction was too high, causing pain and simultaneous urethral and pelvic floor muscles contraction.[7]

Attempts of deep spinal cord stimulation were made by means of a needle electrode implanted in the posterior horns, with up to 60% of the patients achieving satisfactory micturition (low residual volume), diminishing the incidence of lower urinary tract infections, increasing bladder capacity and decreasing the need for catheterization. On the other hand, the unspecific stimulation of the posterior horn had many undesirable effects like inducing detrusor-sphincter dyssynergia, autonomic responses (swheating, tachycardia etc.) and muscle spasms on the lower limbs. In this manner, despite the acceptable success rates, the high invasiveness and the 40% failure rate hindered the progress of this technique.[8]

Idealized by Brindley in 1977,[9] sacral nerve roots stimulation by means of a neuroprosthesis implantation showed good results and became commercially available (Finetech-Brindley Bladder System®, Finetech Medical® Ltd., Welwyn Garden City, UK), with more than 2500 procedures performed worldwide, reaching 20 years of follow-up.[10] The prerequisites for implantation were the integrity of the preganglionic parasympathetic neurons and a detrusor muscle preserved contractility.[11] Posterior rizotomy was performed at the moment of implantation, to treat the neurogenic detrusor overactivity and pain.[11,12] After the procedure, most of the patients became or remained continent, had their bladder capacity increased and managed to void with low residual (less than 30mL) without the need of self-catheterization, which drastically reduced the incidence of urinary infections.[13] Moreover, many reported electrically induced bowel movements and penile erection.[13,14]

The low success of this device was due to the necessity of a highly invasive, difficult and hardly reproducible procedure and to the irreversibility of the posterior rizo-

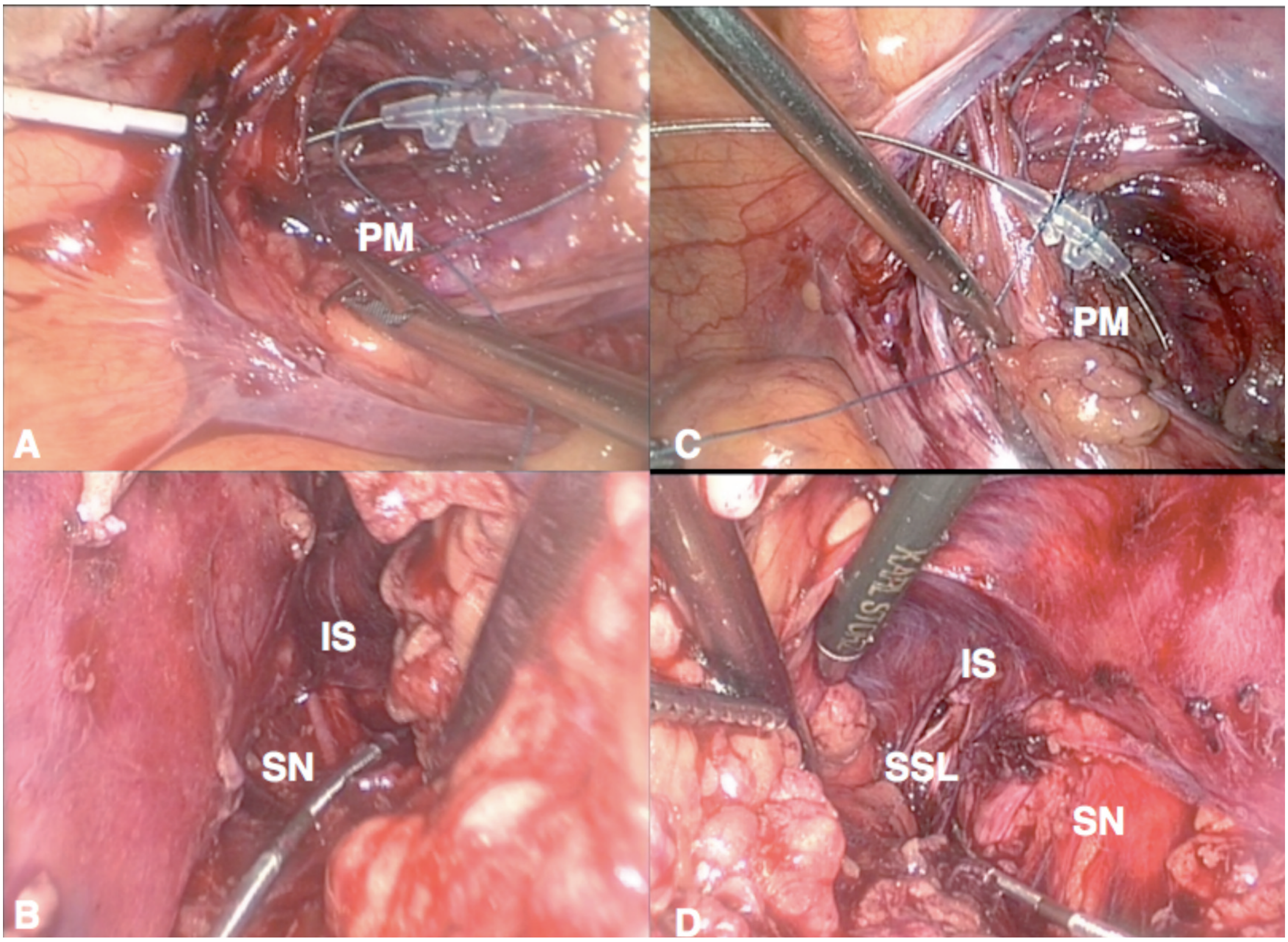

Figure 1. – Electrodes Placement: A - left femoral nerve; B - left sciatic and pudendal nerves; C - right femoral nerve; D - right sciatic and pudendal nerves (PM - Psoas Muscle; IS - Ischial Spine; SN - Sciatic Nerve; SSL - Sacrospinous Ligament).

tomy, which, in cases of partial success or failure would mean loss of reflex induced micturition, erection and bowel movements and the loss of residual perineal sensibility on patients with incomplete lesions.[7] The percutaneous implanted quadripolar electrode (Interstim®, Medtronic®, Minneapolis, USA) was developed in an attempt to overcome those difficulties. It has managed to increase bladder capacity in incomplete spinal cord injured patients[15-17] but with much inferior results in complete injury patients,[16-17] indicating that its main mechanism of action would be the modulation of the remaining spinal-bulbo-spinal paths.[18]

The laparoscopic implantation of neuroprosthesis (LION) has become possible through the Laparoscopic Neuronavigation (LANN) technique, which was developed in an attempt to preserve intrapelvic nerves during radical gynecological surgeries.[19-22] It consists of a series of nerve dissection techniques by using intraoperative neurostimulation to laparoscopically expose and identify the intrapelvic nerves, leading to a great evolution on the anatomic knowledge of the retroperitoneal spaces.[23]

The first LION procedures performed were rescue procedures after the explantation of a Brindley stimulator.[24] The patients had previously undergone a dorsal implantation of a Brindley stimulator and needed to have it explanted, due to cable or pulse generator infection or malfunction. Electrically induced micturition and defecation was obtained in six out of the eight patients. In the other two patients, irreversible damage to the nerve roots was observed.

The next obvious step was to use the LION as the primary procedure, since laparoscopy is a minimally invasive approach, as opposed to the posterior laminectomy and posterior rizotomy of Brindley's procedure. The proposed operative plan was to modulate the S2 and S3 nerve roots, femoral and pudendal nerve, with the objective of treating bladder and inferior limb spasticity and allowing for function recovery regardless of the absence of remaining spinal-bulbo-spinal paths. In all patients, bladder capacity was substantially increased and electrically induced micturition micturition was achieved, leaving them free of self-catheterization; lower limb spasticity was achieved; in the two men, electrical induction of a satisfactory, sustained, erection was also possible; and, at last, at 3, 6 and 9 months postoperatively, patients were able to stand up by means of an electrically induced contraction of the quadriceps.[25]

History has taught that the more peripheral (i.e. the more specific) electrodes are implanted, the better are the results. We are now conducting at our institution a randomized controlled trial with implantation of electrodes on the femoral, sciatic and pudendal nerves (Figure 1) with the objective of controlling bladder and lower limb spasticity and allowing for standing up and some limited walking. The preliminary results of this promising study are to be published on the next two years.

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The Tissue Fixation System workshop was held in Yokohama as part of the annual meeting of the International Society for Pelviperineology (October 23rd 2012).

Introduction to the TFS Workshop ISPP 2012 Yokohama

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The workshop began with brief presentation of pelvic floor anatomy, in particular, the role of connective tissue by Bernhard Liedl, and function and dysfunction by Peter Petros. This was followed by the reporting of results for the TFS by Drs Sekigichi, Inoue, Haverfield and Liedl. The presentations are in the form of abstracts.

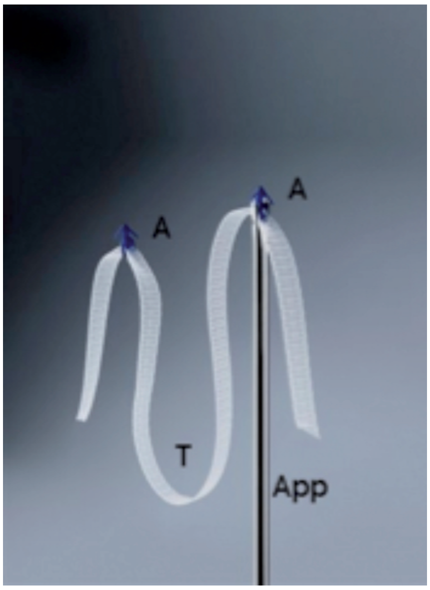

Figure 1. – The current Tissue Fixation System (TFS). Applicator (App) tape (T) and anchor (A). The tape is 7mm wide type 1 macropore polypropylene. There is a one way tensioning system at the base of the anchor.

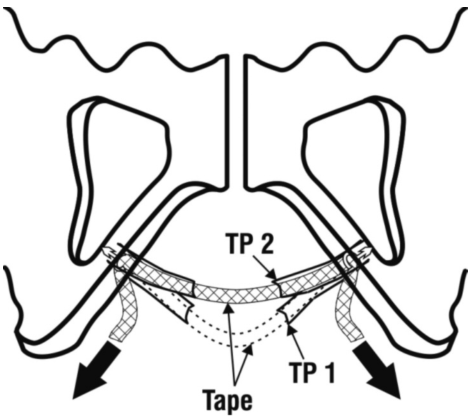

Figure 2. – Schematic view of repair of prolapsed and laterally separated perineal bodies. The perineal bodies are elevated and approximated by the one-way tensioning action of the Tissue Fixation System sling. TP1= prolapsed deep transverse perinei muscles attached to posterior surface of the descending ramus of the pubis. TP2 is the restored position of deep transverse perinei.

The Tissue Fixation System (TFS Surgical, Adelaide, Australia), is a universal minimally invasive single incision tensioned tape system designed to reinforce damaged pelvic ligaments/connective tissues (Figure 1). It reinforces the perineal body, (Figure 2), and 4 main suspensory ligaments, pubourethral, (Figure 3), ATFP, cardinal & uterosacral (Figure 4).

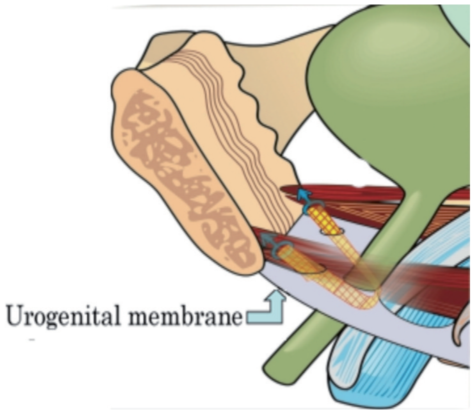

Figure 3. – The TFS midurethral sling. The anchors penetrate the urogenital membrane ("perineal membrane") and attach below the Space of Retzius into the insertion point of the pubourethral ligaments.

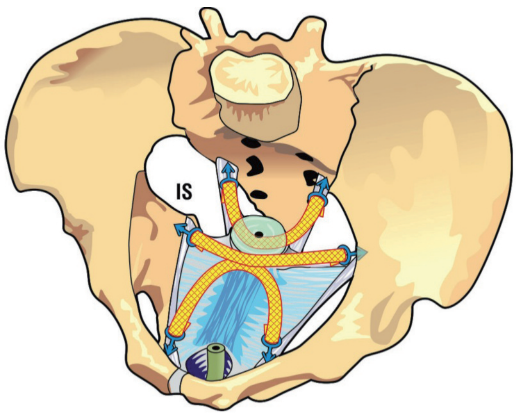

Figure 4. – Site and position of the slings. From front to back: TFS U-Sling tape for repair of central and lateral defects, TFS cardinal ligament tape for repair of transverse defect (high cystocele, uterine/apical prolapse) and TFS uterosacral ligament tape for repair of uterine/apical prolapse, enterocele and high rectocele. Perspective: Patient in standing position, looking into the pelvic brim. The U-Sling is inserted medial to the obturator fossa, and more cranially than a TOT sling. The cardinal ligament TFS penetrates the ATFP 2cm above and distal to the ischial spine (IS) and inserts into the muscles adjacent to the ATFP. The uterosacral ligament (USL) sling inserts into the USL approximately 2cm distal to its insertions into the sacrum.

Connective tissue of the pelvic floor: definitions and topografic anatomy

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INTRODUCTION

My lecture today aims to demonstrate the topografic anatomy on which the Integral System of pelvic floor repair is based.

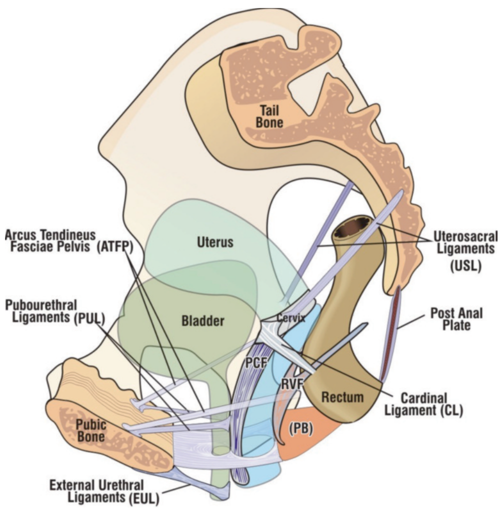

Figure 1. – The principal suspensory connective tissue structures of the vagina, sagittal view, standing position.

The principal suspensory connective tissue structures of the vagina structures are Extraurethral ligament (EUL); Pubourethral ligament (PUL); Arcus tendineus fasciae pelvis (ATFP) Cardinal ligament (CL)/Cervical ring; Uterosacral ligament (USL); perineal body (PB). In addition, we have the anterior vaginal wall represented by suburethral vagina (hammock), fibromuscular layer of upper wall (PCF) and posterior vaginal wall, whose fibromuscular layer is represented by RVF (Fascia of Denonvilliers).[1]

The Pictorial Algorithm, (Figure 2), relates symptoms to damaged pelvic floor connective tissue structures. The 3 zones of the Algorithm are natural divisions of the ligament groupings and their causality of symptoms.

ANTERIOR ZONE (urethral meatus to bladder neck)
Extraurethral ligament (EUL)
Hammock
Pubourethral ligament (PUL)

MIDDLE ZONE (bladder neck to cervix)
Pubocervikal fascia (PCF)
Arcus tendineus fasciae pelvis (ATFP)
Cardinal ligament/Cervical ring (CX Ring)

POSTERIOR ZONE (cervix to anal canal)
Uterosacral ligament (USL)
Rectovaginal fascia (RVF)
Perineal body

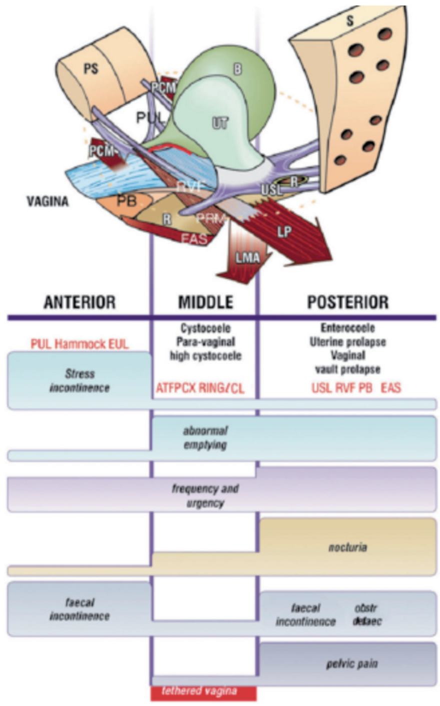

Figure 2. – Connective tissue alterations at pelvic floor which can be surgically cured as per the Integral Theory "laxity in the vagina or its supporting ligaments".[1] The "Hammock", Pubocervical fascia and Rectovaginal fascia represent the fibromuscular layer of the vagina.

ANTERIOR ZONE

The anterior zone extends from the urethral meatus to bladder neck. It comprises 3 main structures , all of which impact on the urethral closure mechanisms.

Extraurethral ligament (EUL)
Suburethral Vaginal Hammock (H)
Pubourethral ligament (PUL

PUL is the principal ligament for continence during effort. EUL and the suburethral vaginal hammock also assist in closure during effort, but their main function is sealing the urethra

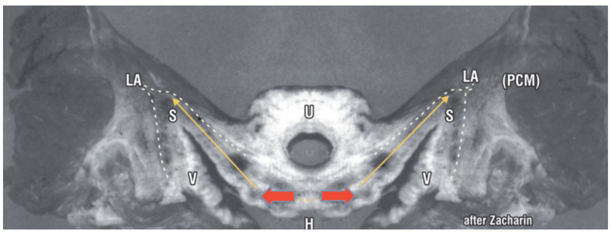

Figure 3. – Coronal section of the suburethral vaginal hammock S = sulcus - the attachment to the LA (anterior pubococcygeus muscle section "PCM"); U = urethra; V = vagina. The arrows indicate the dirctional movements of the muscle closure forces.

From Robert Zacharin[2] by permission.

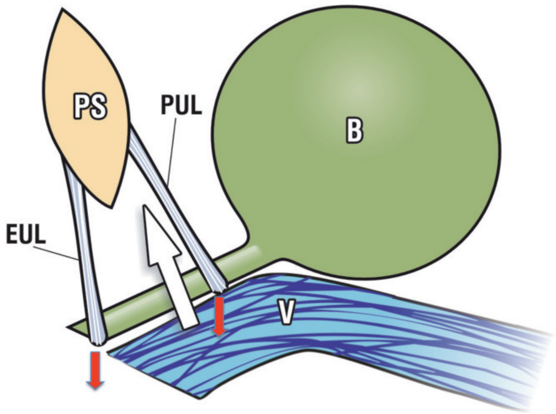

Figure 4. – The anterior zone structures sagittal view- sitting position EUL suspends the vaginal hammock to the anterior surface of pubic bone and PUL suspends the hammock to the posterior surface. The large arrow indicates how the PCM, figure 3, stretches the hammock forwards to close the distal urethra.[3]

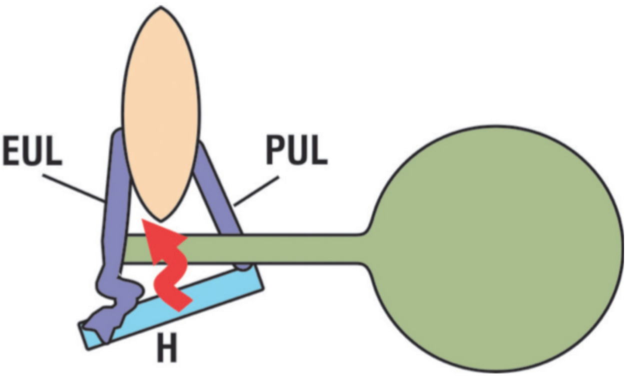

Figure 5. – A lax EUL prevents sealing of the urethra, so that even in patients who have been cured of urinary stress incontinence with a midurethral sling, urine can leak out insensibly. The hammock "H" falls open like a trapdoor. The classical symptom of EUL/hammock laxity is urine loss on sudden minor movement usually associated with a feeling of a"bubble" escaping.[4]

MIDDLE ZONE
The middle zone extends from bladder neck to cervix.
It comprises 3 connective tissue structures.

Pubocervikal fascia* (PCF)
Arcus tendineus fasciae pelvis (ATFP)
Cardinal ligament/Cervical ring (CX Ring)
PCF is the musculofascial layer of the anterior vaginal wall. The vaginal epithelium has very little strength.

* The existence of RVF is controversial. Like the PCF, it can be viewed as the musculofascial layer of the posterior vaginal wall.

POSTERIOR ZONE

The posterior zone extends from the cervical ring to the perineal body. It comprises 3 structures.

Uterosacral ligaments
Rectovaginal fascia* "RVF" (Denonvilliers).
Perineal body
CL = Cardinal ligament. This diagram is not quite correct as it does not show the important reflection of CL to the anterior surface of the cervix. The Uterosacral Ligaments are shown inserting between S2 and S4 and into the posterior ring of cervix.

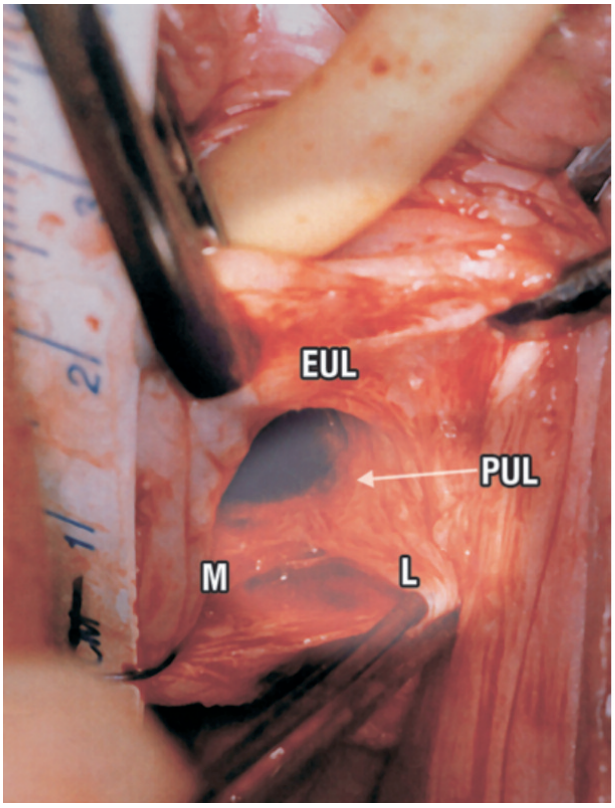

Figure 6. – Live anatomy of the anterior zone- paraurethral incision.[5] The EUL is seen attaching the external urethral meatus to the anterior part of the pubic bone. PUL descends from behind the pubic symphysis to divide into 2 parts, medial, attaching to the midurethra and lateral attaching to m. puboccygeus.

Perineal body

The perineal body is 4-5 cm long. It separates the posterior vaginal wall from the anterior rectal wall and anus. It is composed of a central fibromuscular portion and two lateral portions attached to the central portion medially, and anterior and posterior parts of the descending pubic ramus laterally.

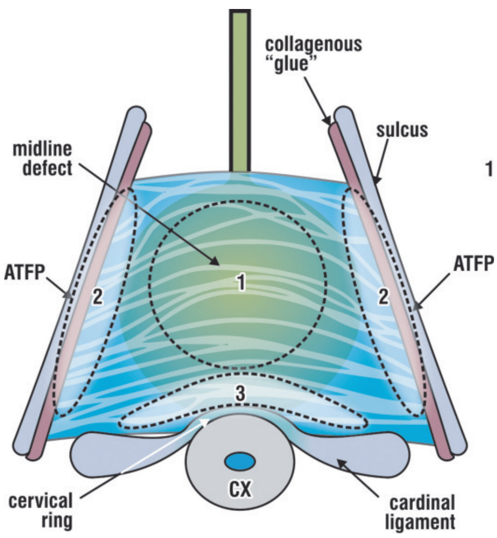

Figure 7. – The anatomy of the middle zone- schematic view into the anterior vaginal wall.[6] The cardinal ligament is seen inserting into the anterior part of the cervical ring; The vagina is attached proximally to the cervical ring "3", and laterally attached to ATFP (sulcus) "2". CX = cervix. Broken pubocervical fascia causes a central or midline defect "1".

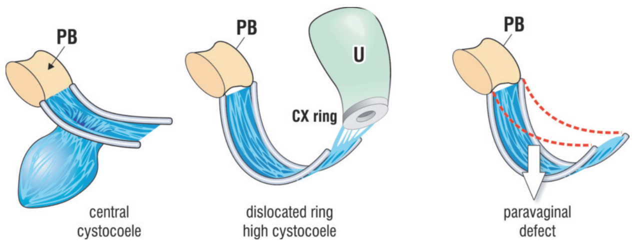

Figure 8. – The 3 types of cystocele. Schematic 3D sagittal view, from left to right, central defect, caused by overstretching of the PCF so that the bladder stretches the extended membrane downwards; dislocation of PCF and cardinal ligaments from the cx ring so that the vaginal wall dislocates downwards like a trapdoor "high" or "transverse" cystocele (transverse defect); damaged ATFP or more likely, lateral vaginal attachment to ATFP, "lateral defect". This is almost invariably associated with a central defect.

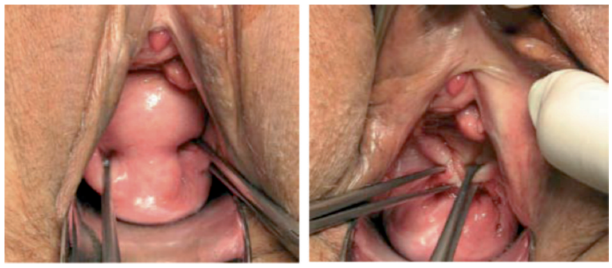

Figure 11. – Proof of causation of cystocele by dislocated cardinal ligaments by 'simulated operation'.[6]

Left 3rd degree cystocele, Allis forceps applied to dislocated cardinal ligaments (CL) which are identified as a "drooping" of the vagina on the lateral walls of the cervix. Right: Allis forceps brought to the midline, at the same time, reducing the cystocele. This maneuver demonstrates the essential role of the CL in supporting the proximal vagina as it inserts into the anterior cervical ring.

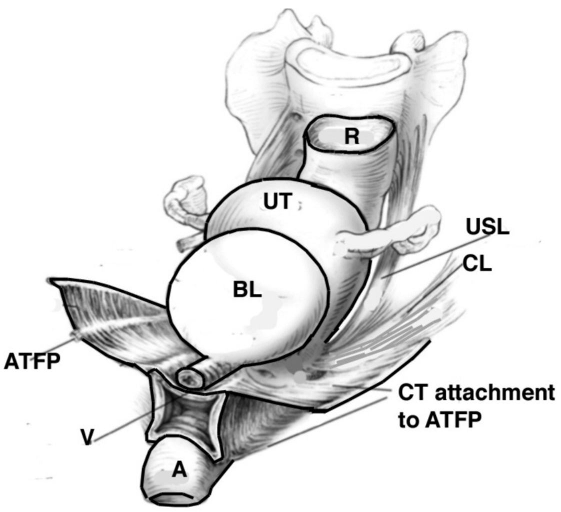

Figure 9. – Schematic 3D view of the middle zone pelvic connective tissues from in front and above. The paracolpium attaches the anterior vaginal wall to ATFP. Rupture causes the lateral defect. Also the attachments of cardinal (CL) and uterosacral (USL) ligaments are shown. V = vagina; R = rectum; A = anus; UT = uterus. (after Corton 2009)[7]

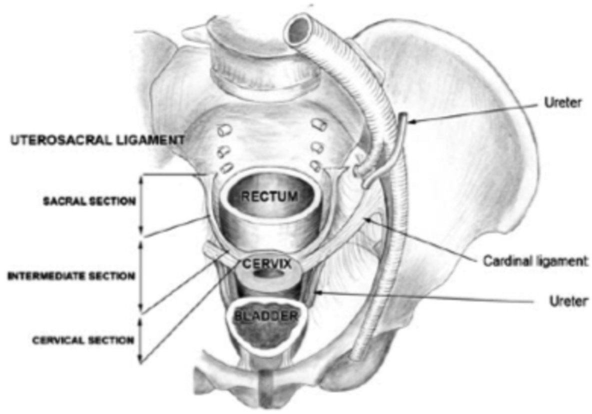

Figure 12. – 3D view of the organs from an anterior perspective to show the cardinal and uterosacral ligament (from Vu et al. 2010).[8]

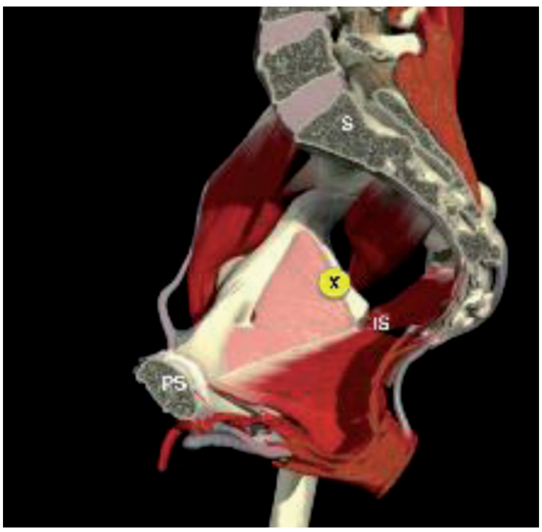

Figure 10. – The insertion point 'X' of cardinal ligament 2cm above the ischial spine 'IS'. Sagittal view into the left hemipelvis. The cardinal ligament is best felt rectally: stretch the cervix towards the introitus; identify the ischial spine with a finger tip; the cardinal ligament is felt 2cm above the ischial spine as a horizontal band extending from the lateral pelvic wall medially.

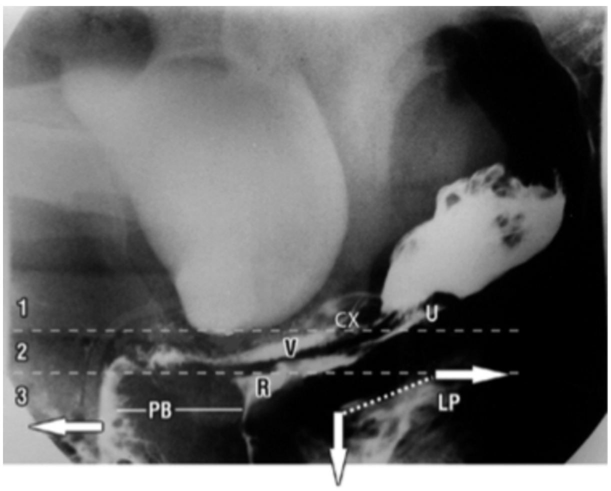

Figure 13. – Perineal body (PB) saggital perspective. Arrows represent directional striated muscle forces acting on the pelvic organs. V = vagina; R = rectum; U = insertion of USL. 1,2,3 represent levels of organ support.

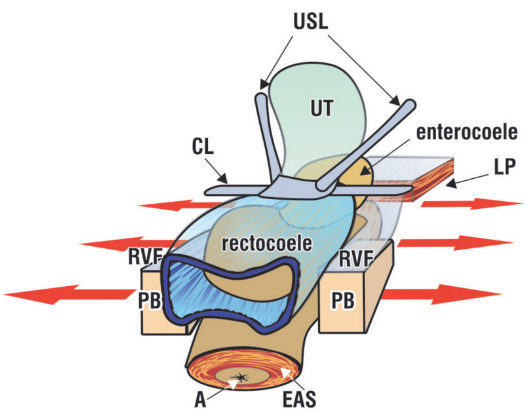

Figure 14. – Pathogenesis of rectocele Schematic 3D view of the vagina and perineal bodies from the introitus.[6] The perineal bodies (PB) have been separated allowing the rectocele to protrude. The uterosacral ligaments have also been separated allowing protrusion of enterocele and high rectocele. The rectovaginal fascia (RVF) attached to PB, USL and levator plate muscles (LP). A = anus; EAS = external anal sphincter.

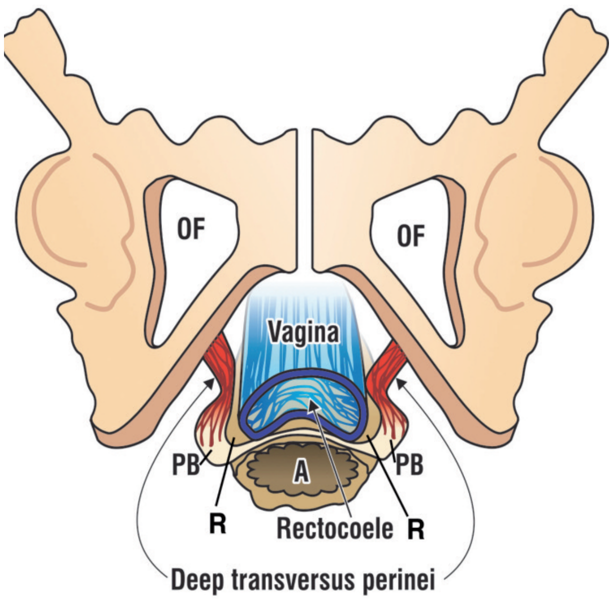

Figure 15. – The anatomy of low 3rd degree rectocele "perineocele".

The rectum "R" everts forward and spreads laterally to attach densely to the laterally displaced perineal bodies "PB". The arrows indicate the deep transversus perinei, the principal attachment of PB to the posterior surface of the descending ramus. In the surgical operation, anchors attached to an adjustable sling penetrated the "deep transversus perinei" muscle: one-way tensioning elevated both "PBs" and brought them closer to the midline, obliterating the rectocele herniation.

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Stress urinary incontinence, urgency, abnormal emptying and nocturia caused by connective tissue laxity

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"Stress, urge and abnormal emptying are mainly caused by lax suspensory ligaments inactivating striated pelvic muscle forces".[1,2]

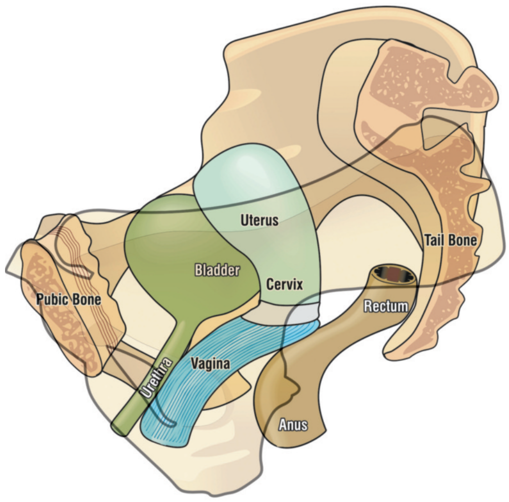

Figure 1. – Figure 1. Bladder, Uterus and Rectum function as storage containers.
•Urine •Foetus •Faeces
Their outlet tubes are •Urethra •Vagina •Anus

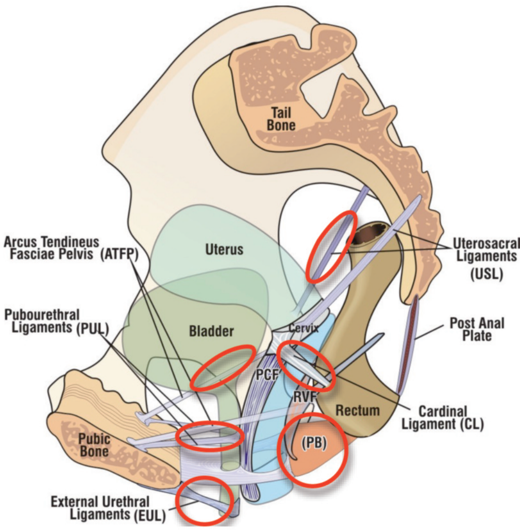

Figure 2. – Five Ligaments suspend the organs from above and perineal body supports them from below.[3]
External urethral ligaments attach external meatus to anterior surface of pubic bone. Pubourethral ligament attach midurethra and pubococcygeus muscles to pubic bone. ATFP supports the anterior vagina. Cardinal ligaments insert into the anterior cervix, also supporting anterior vaginal wall. Perineal body supports posterior vaginal wall, anterior rectal wall and external anal sphincter. The anterior vaginal wall which supports the bladder/urethra. The posterior vaginal wall which supports the anorectum.

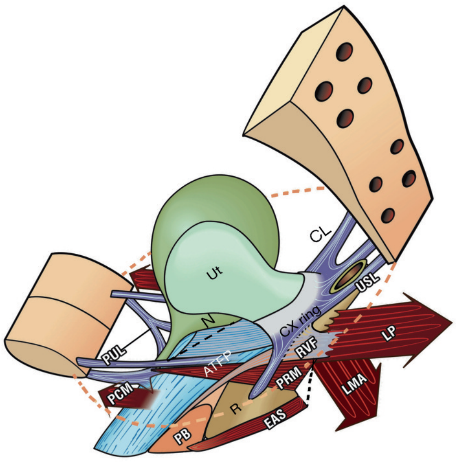

Figure 3. – Three Muscle forces pull against the suspensory ligaments.
External striated muscles (arrows) pull against the suspensory ligaments PUL and USL to close and open the urethral and anorectal tubes (broken lines). Any laxity in the ligaments translates to weaker closure forces[4] (incontinence), or weaker opening forces (evacuation difficulties).
Suspensory ligaments PUL = pubourethral; ATFP = arcus tendineus fascia pelvis; CL = cardinal; USL = uterosacral; PB = perineal body.
Striated muscles PCM = m. pubococcygeus; LP = m. levator plate; LMA = conjoint longitudinal muscle of the anus. B = bladder; N = stretch receptors; Ut = uterus; R = rectum; RVF = rectovaginal fascia; cx = cervix.

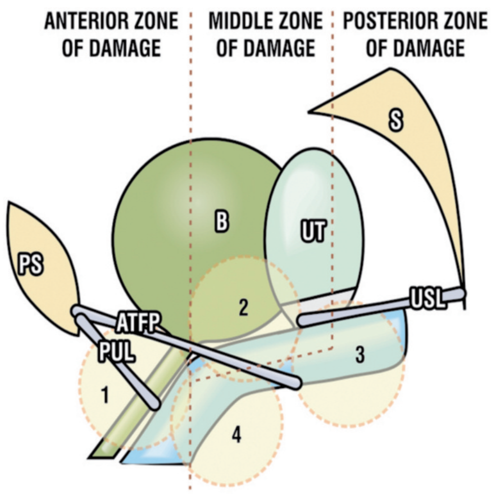

Figure 4. – Pathogenesis of pelvic organ prolapse.[5] The circles represent the foetal head stretching the ligaments and perineal body as it descends down the birth canal.
1. PUL damage= stress incontinence; - 2. ATFP/CL damage = cystocele; 3. USL damag e= uterine prolapse, enterocele; 4. perineal body damage= rectocele.
Multiple injuries may occur, some subclinical, explaining subsequent prolapses.

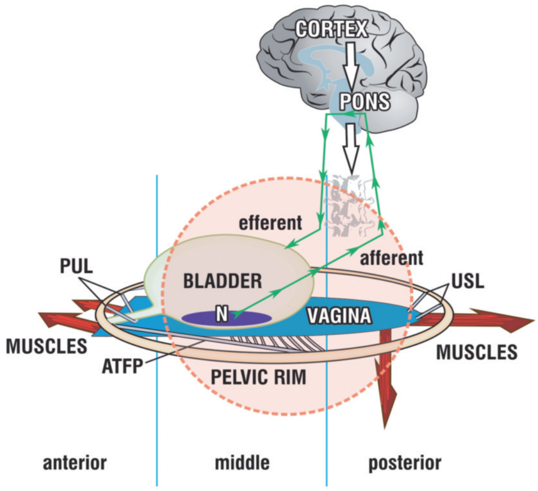

Figure 5. – Pathogenesis of bladder overactivity.
If the foetal head overstretches the vagina and ligaments, the ensuing laxity may not allow vagina to stretch and support stretch receptors "N". N fires off prematurely,[6] activating the micturition reflex, resulting in urgency, frequency, nocturia.

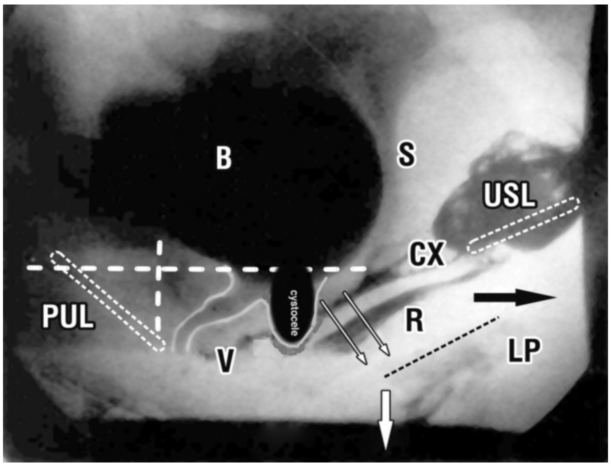

Figure 6. – Pathogenesis of bladder evacuation problems Cystocele and lax USLs inactivate the posterior vector forces (arrows) which open out the posterior urethra during micturition. As the internal resistance to flow is inversely proportional to the 4th power of the radius (5th power with non-laminar flow), even a minor laxity may cause significant evacuation problems.

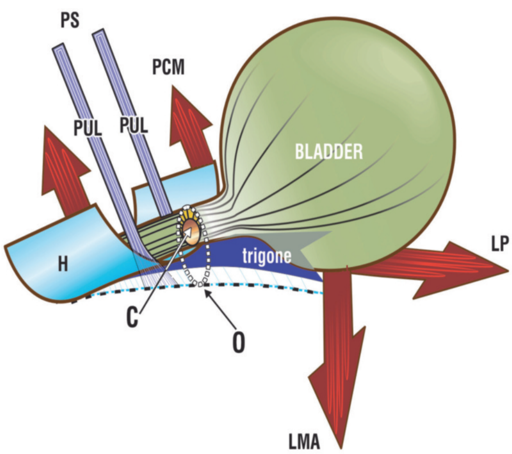

Figure 7. – Pathogenesis of urinary stress incontinence.[7]
A loose pubourethral ligament (PUL) means that PCM muscles cannot "grip" to immobilize the suburethral vaginal hammock "H". LP/LMA pull open the posterior urethral wall vastly decreasing the internal resistance to flow. Urine may leak with effort-stress urinary incontinence.

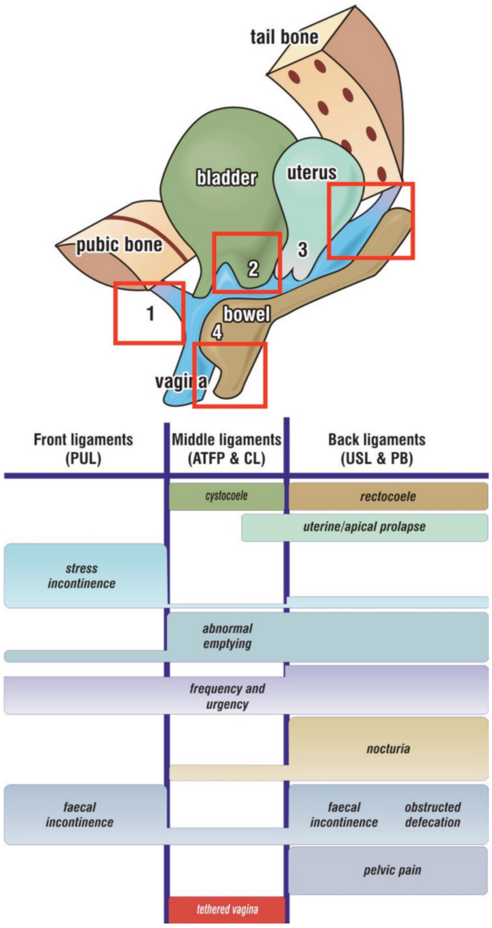

Figure 8. – Diagnosis-Simplified Pictorial Diagnostic Algorithm.[5]
Relates specific symptoms to lax (damaged) ligaments as seen in figure 4. Labelling as in figure 4.
Where there are multiple sources of abnormal symptoms, symptom grouping is used to assess site of ligament damage. All etiologies are laxity related except for the "tethered vagina syndrome", where excessive tightness in the bladder neck area of vagina (iatrogenically induced scar tissue) tethers the opposite muscle forces, so that the stronger posterior forces, overcome the anterior forces (PCM) to stretch open the urethra, much as occurs in USI, figure 7. The characteristic symptom is sudden massive urine loss immediately on getting out of bed in the morning.[3,5]

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Mid-urethral TFS sling operation for urodynamic SUI in an outpatient clinic: 3 year results

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INTRODUCTION

The TFS (Tissue Fixation System) was reported in 2005 by Petros PE.

Like the TVT, the TFS works by creating a foreign body collagenous tissue reaction which reinforces weakened puburethal ligaments. However, TFS has very low risk of bladder or intestinal perforation and hematoma in the retropubic space.

The 4 pronged anchor has a mode of action like a grappling hook, while at the base, a one-way tensioning has the unique quality of restoring laterally displaced ligaments and fascia to the correct anatomical position.

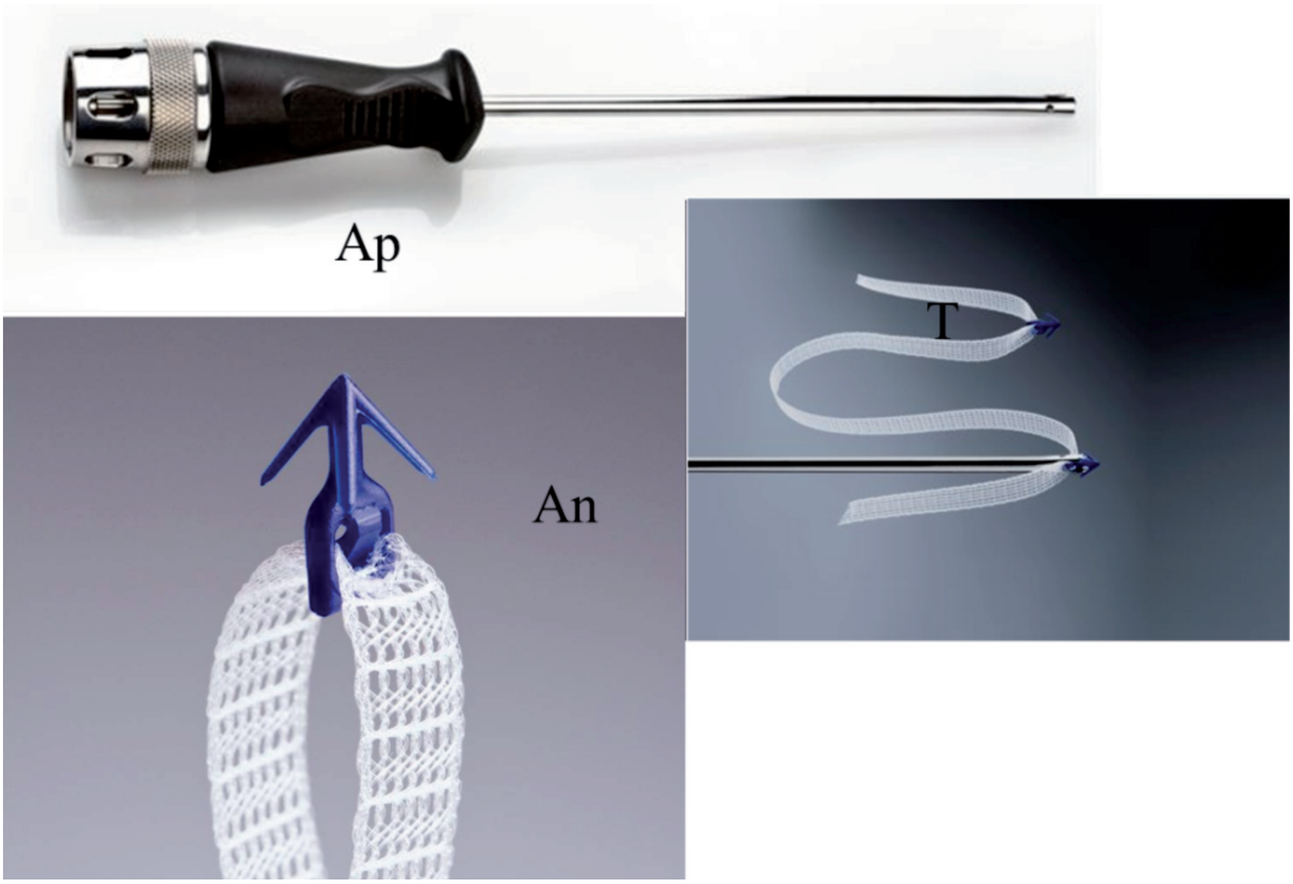

Figure 1. – The TFS (Tissue Fixation System): the applicator (Ap), anchor (An) and lightweight non-stretch TFS tape "T".

AIMS OF THE STUDY

To test the feasibility of using the TFS to perform a mid-urethral sling on a middle-term basis for urodynamic SUI in a free-standing outpatient facility.

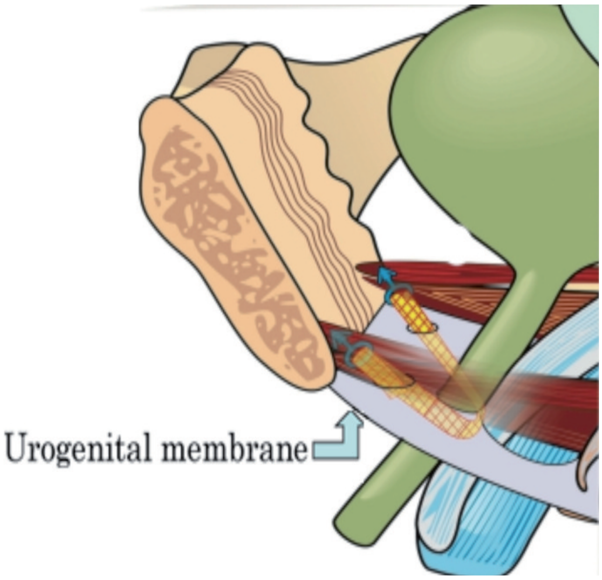

Figure 2. – The TFS midurethral sling. The anchors penetrate the urogenital membrane and attach below the Space of Retzius into the insertion point of the pubourethral ligaments immediately behind the perineal membrane.

MATERIAL AND METHODS

We performed 44 mid-urethral TFS sling operations between December 2006 and March 2008.

All patients had positive cough stress tests, and residual urines were less than 10 ml. We evaluated the patients at 1year after the operations.

Pre-operative data

	Mean	± SD
Age	58.2	+/- 11.9
24 hr pad test	108 gm +/-	259 gm

- Average BMI is 23.57±12.03.
- Menopause rate is 61.4%.
- They had no previous urogynecologic surgery and no pelvic organ prolapse.

Pre-operative Urodynamic data

	Mean	± SD
ALPP (abd leak pt pressure)	81.5 cm H_2O ± 34.1 cm H_2O	
MUCP (Maximum urethral closure pressure)	33.1 cm H_2O ± 15.7 cm H_2O	

- There was no detrusor overactivity recorded on urodynamic testing.
- The definition of ISD：
  ALPP <65cmH2 0 or MUCP<20cmH2 0.

According to this definition,
15(34.1%) pts. were diagnosed as ISD
out of 44 pts.

Operating data

Mean operating time include local anesthesia	24.5 min ± 7.7 min
Mean blood loss	17.7 m l ± 21.7 ml
Mean staying time in the clinic	5.56 hours ± 1.06

Five patients discharged with indwelling catheter but voided with no difficulty within 2 days.

RESULTS

Outcome after 1 year

Success (90.9%) – 40/44 cases
Failure (9.1%) – 4/44 cases

Success was defined as negative stress test and 24 hour pad test results less than 3gm[1]

Outcome after 3years

Success (84%) - 37/44 cases
Failure (16%) - 7/44 cases

In failure 4 cases at the first year, we re-operated on all 4 patients with another TFS midurethral sling.

- All 4 patients became continent after re-operation.
- Among 3 patients who were new failure cases, 1 patient had a re-operation and became continent after re-operation.

The change of operation (1)

- We have changed volume of local anesthesia after an experience of anchor entry into bladder for enough liquid abruption.
- 0.25% xylocaine 70 ml
  ⇒0.15% xylocaine 130 ml

The change of operation (2)

- Two failure cases were included in the first 5 cases. Therefore the learning curve of mid-urethral TFS operation may reach a sufficient level at about 5 cases.
- After that, We met a failure case every 20〜30 cases.
- Then we checked the length of urethra before operation and placed under the mid-urethra accurately.

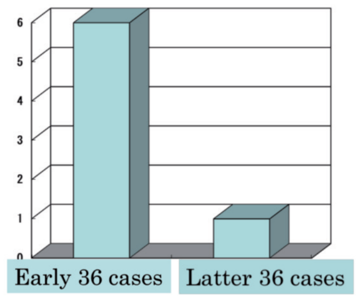

Figure 3. – The number of failure cases between the early and the latter phases: the success rate is improved from the early 36 cases to the latter 36 cases.

CONCLUSIONS

The 3 year success rate is almost as same as the TVT.

The TFS mid-urethral sling operation is a simple, safe, and effective operation, and can be done without difficulty in a free standing clinic as an outpatient procedure.

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Tissue Fixation System (TFS) sling to repair pelvic organ prolapse: complications and outcome

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INTRODUCTION

There is rapid ageing of the Japanese female population. In September 2008, women age 65 and older accounted 16.35 million in Japan. In September 2012, women age 65 and older accounted 17.59 million, an increase of 7.6% in 4 years. Because of the ageing process, an increasing number of patients are developing pelvic floor laxity. Because of the presence of many collateral health problems, all of which vastly increase the risks of surgery, minimally invasive operations are required for safety and quality of life. In 2005, a new minimally invasive universal system for repair of pelvic organ prolapse (POP) and urinary stress incontinence (USI) was reported. For the first time, a high cure rate was reported for both POP and a wide range of pelvic floor symptoms by repairing 4 main suspensory ligaments, pubourethral (PUL) ATFP, cardinal, uterosacral and perineal body.[1-4] The basis for these operations was the Integral Theory and its diagnostic and surgical applications.

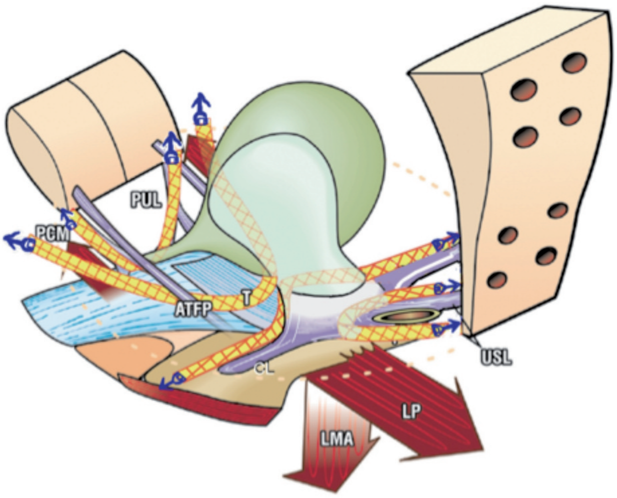

Figure 1. – TFS repair of 4 main suspensory ligaments, pubourethral (PUL) ATFP, cardinal (CL), uterosacral (USL) and perineal body (PB).

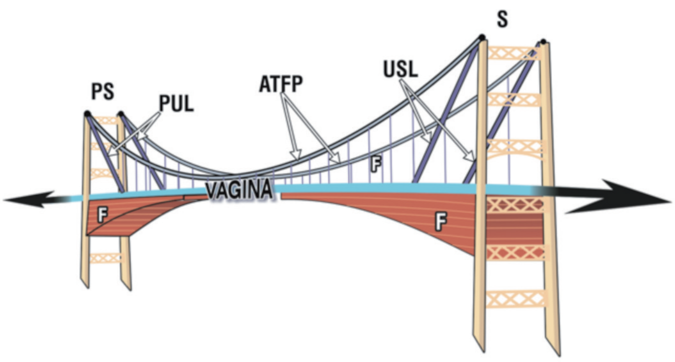

Figure 2. – The ligaments support the pelvic floor in the manner of a suspension bridge.
The muscle forces (arrows) stretch the vagina against the suspensory ligaments which attach to bone (PS = pubic symphysis; S = sacrum). The TFS strengthens the ligaments thereby restoring the muscle forces which support, open and close the organs.[5]

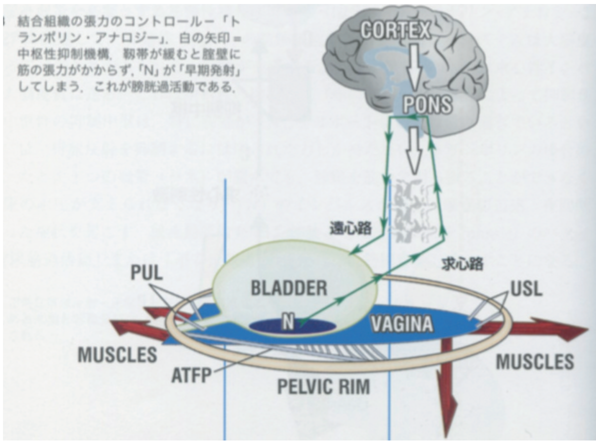

Figure 3. – The muscles stretch the vaginal membrane against competent ligaments to support the stretch receptors 'N', thereby controlling urgency. Lax suspensory ligaments may not allow the muscles to tension the membrane; 'N' fires off prematurely sending afferent impulses to the cortex which are perceived as urgency.[5]

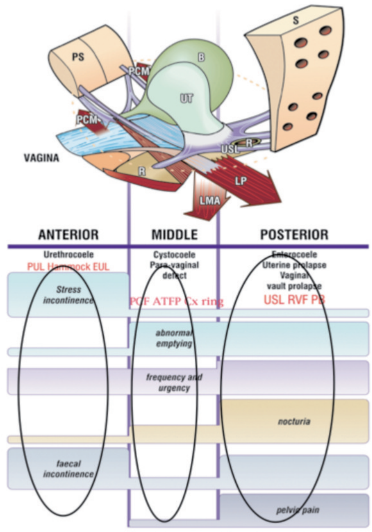

Figure 4. – The pictorial algorithm uses specific symptoms to indicate which ligaments/connective tissue structures have been damaged.[6]

THE FIRST SURGERY OF TFS IN JAPAN

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

Advantages of the TFS sling

1. Antero-posterior elasticity is largely maintained
2. Less risk of erosion, fistula, or organ adherence
3. The one-way sling allows lax ligaments and fascia to be tightened, an essential step for restoration of abnormal symptoms and function.

AIM OF THE STUDY

To evaluate the effectiveness ,complication and safety of Tissue Fixation System (TFS) surgery in women with pelvic organ prolapse.

MATERIALS AND METHODS

Operations using the TFS anchor system were performed on 337 women aged between 36 to 85 year (average 68.3) for grade 3 or 4 pelvic organ prolapses (301 uterine prolapses and 37 vault prolapses) between October 2007 to July 2012 inclusive. In this operation, the TFS applicator® was used. This instrument has two polypropylene plastic anchors attached to an adjustable non-stretch multifilament (from October 2007 to December 2008) and monofilament (from January 2009) polypropylene mesh tape. The TFS sling operations, (since modified), were originally performed as reported by Petros & Richardson. The TFS sling was applied in 5 main sites, (U sling for ATFP, Cervical sling for cardinal ligament repair, USL-sling and Perineal body sling). In this operation, the TFS applicator® was used. This instrument has two polypropylene plastic anchors attached to an adjustable non-stretch multifilament (from October 2007 to December 2008) and monofilament (from January 2009) polypropylene mesh tape, Table 1.

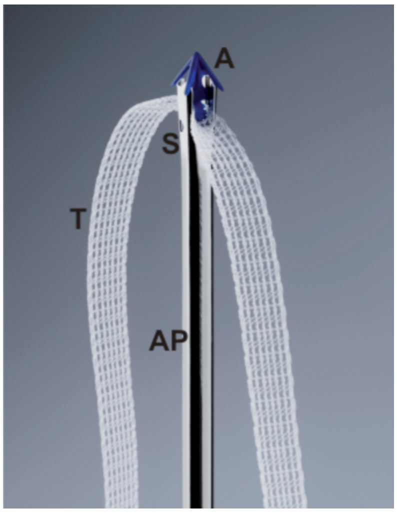

Figure 5. – The TFS applicator (AP) and anchor (A). T = macropore monofilament tape. At the base of 'A' is a system which allows one-way directional tensioning of the tape.

TABLE 1. – TFS patients (337 persons): demographics.

Characteristic	Mean	Range
Mean age (range)	68.3.0	36-85
Mean BMI	24.6	18.3-33.2
Parity mean(range)	2.8	1-6

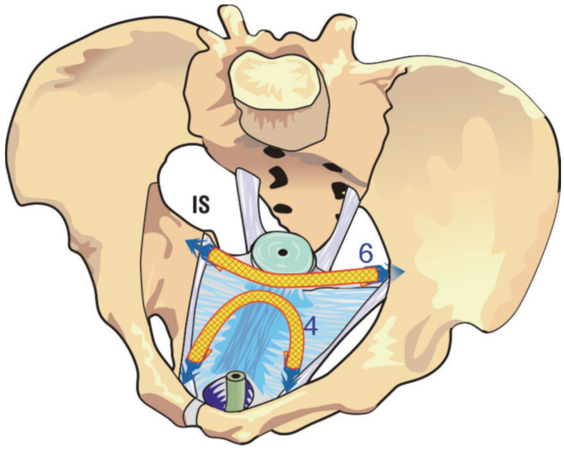

Figure 6. – Repair of cystocele with TFS Cardinal ligaments sling and U-Slings.
TFS Cardinal ligament sling. A tape is placed 1 cm above the fold of the bladder, and insert into the fibromuscular tissues beyond the sulcus 2cm above the ischial spine.
TFS U-Sling. A tape is placed approximately 3 cm above the fold of the bladder. The anchors penetrate the collagenous tissue near the insertion of ATFP.
In both, the tapes are tightened to support the anterior vaginal wall much in the manner of a ceiling joist.

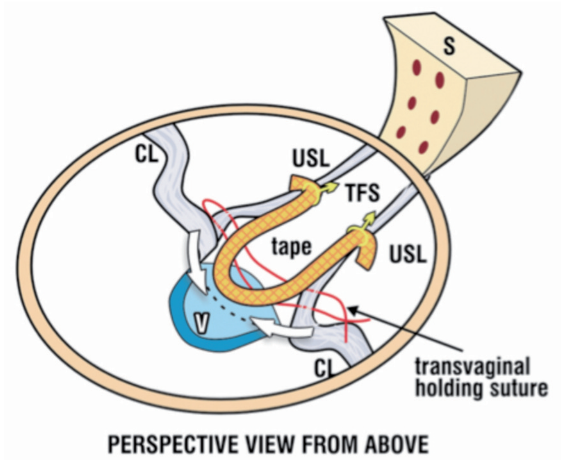

Figure 7. – Posterior USL sling. The anchors penetrate the USL approximately 2cm distal to the sacral bone insertion and tightened . This action shortens and reinforces USL and closes the enterocele.

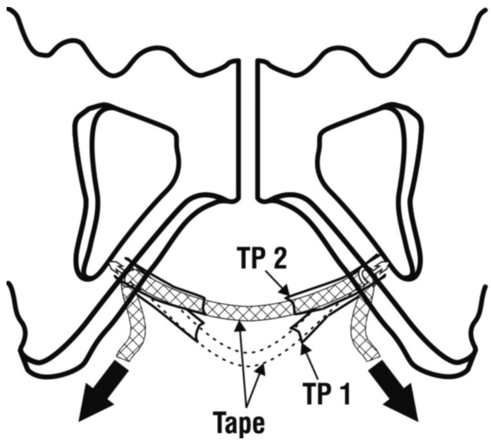

Figure 8. – Perineal body (PB) TFS sling. The anchors penetrate the deep transversus perinei which inserts exactly at the junction of the upper 2/3 and lower 1/3 and the tape is tightened. This action elevates the prolapsed perineal body from position TP1 to TP2.

RESULT

1156 tapes were used in all patients. 303 U slings for lateral/central anterior vaginal wall defects, 301 posterior slings (USL-sling) of the uterosacral ligaments, 314 Cervical sling for cervical ring defects, 234 perineal body slings for defect of the perineal body and 4 anterior slings for SUI (ISD) were performed. 1156 tapes were used in all patients.

TABLE 2. – 1156 tapes were used in all patients.

Variable	Value	Range
Mean operation time(min)	89.0	39-190
Mean estimated blood loss(ml)	71.2	7-378
Hospitalization after operation	0.7	0-3
Same day (42%)		
Mean days, Return to usual life	2.2	1-10

TABLE 3. – Cure rate of symptoms (337 patients) from 2007/10 to 2012/7). All patients had uterine prolapse with grade 3 or 4 according to the Pelvic Organ Prolapse Quantification (POPQ) standard scoring system.

Variable	no	cure rate
SUI	160/174	91.9%
Urgency	156/171	91.2%
nocturia	78/129	60.5%
Day time frequency	152/179	84.9%
Dragging pain	54/76	71.1%
Fecal continence	43/52	82.7%

All patients were followed up for a minimum of 3 months (3-57). There were no intraoperative complications and two post-operative complication: ileus due to tape in abdominal cavity and adhesion of the mesentery and USL mesh, 3 and 4 month after operation and treated operatively.

The average rate of rejection or erosions in 1156 tapes was 3.2%. 38 mesh tapes of 36 patients were rejected and partial excision of meshes was performed. However, this figure included a disproportionate number of perineal body slings. The rate of tape rejection or erosions was 0.7 (3 meshes)% in U slings, 1.0% (3 meshes) in Cervical sling, 1.0 (3 meshes) % in posterior slings (USL-sling), and 12.8 (30 meshes) % in perineal body slings, respectively. Rhere was no rejection in anterior (midurethral) slings. The rate of rejection or erosions in 1156 tapes was 3.2%.

TABLE 4. – Tape rejection or erosion. 337persons from 2007/10 to 2012/7; complications (FU 3-57months).

Variable	no	%
U-sling	2/303	0.7
Cervical sling	3/314	1.0
USL(posterior) sling	3/301	1.0
Perineal body sling	30/234	12.8
Total	37/1156	3.2

DISCUSSION

The rate of tape rejection or erosions in perineal body slings was better after improving the procedure. The first improvement was the the position of the anchors. We changed the position of the anchors from in the perineal body (not beyond) to beyond the posterior surface of the descending pubic ramus. And then, the rate of tape rejection or erosions in perineal body slings was improved after the changing from one layer closure to 2 layers closures and washing with sterile normal saline 100ml before closure, 20.5% in 2007 and 2008, 23.5% in 2009, 4.3% in 2010, 6.6% in 2011 and 2.6% in 2012, respectively. We hypothesize that the insertion of the anchor into the peritoneal cavity was caused by a fault in the method of insertion. Having located and grasped the uterosacral ligament (USL), the anchor was inserted from lateral to medial, instead of penetrating the USL and directing the anchor laterally, away from the rectum and Pouch of Douglas. We now penetrate lateral to the USL.

CONCLUSIONS

The TFS procedure delivers satisfactory results for pelvic organ prolapse (vault prolapse and uterine prolapse repair). The rate of mesh tape rejection and erosion was low, but we think that the rate will be lower because our operation techniques were improved.

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ERRATA CORRIGE

In the article "A simplified biomechanical perspective of the Integral Theory System", by F. Wagenlehner, B. Liedl and P. Petros (Pelviperineology 2012; 31 (4): 101-106), figures 9a and 9b the figures are erroneously the same.

Here and in the online version the correct sequence.

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 7, 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.

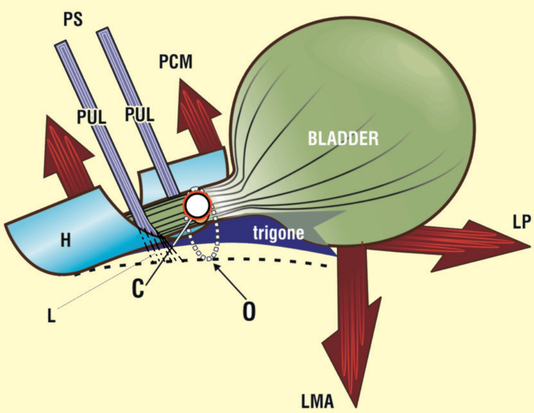
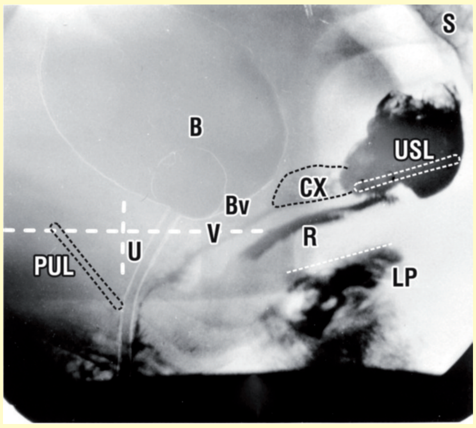


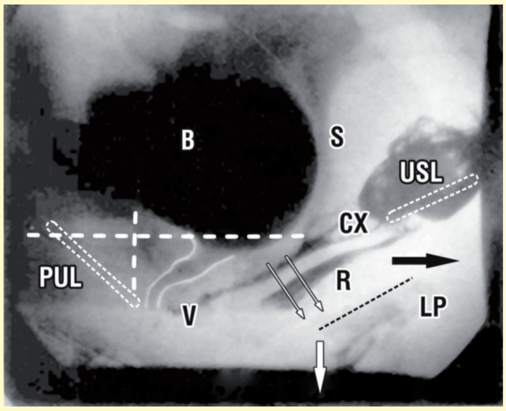
Figure 8. — How a lax ligament may cause urinary stress incontinence. O = open position of urethra; C = closed; L = excessive length of the pubourethral ligament (PUL). The contractile strengths of PCM, LP and LMA are weakened by a lax PUL.

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'.



9a



9b

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

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