

# PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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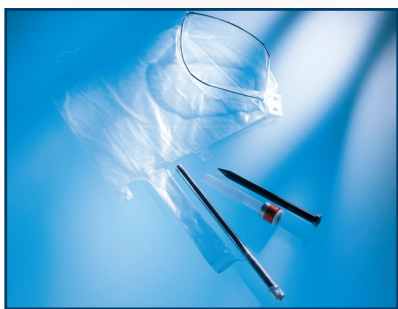
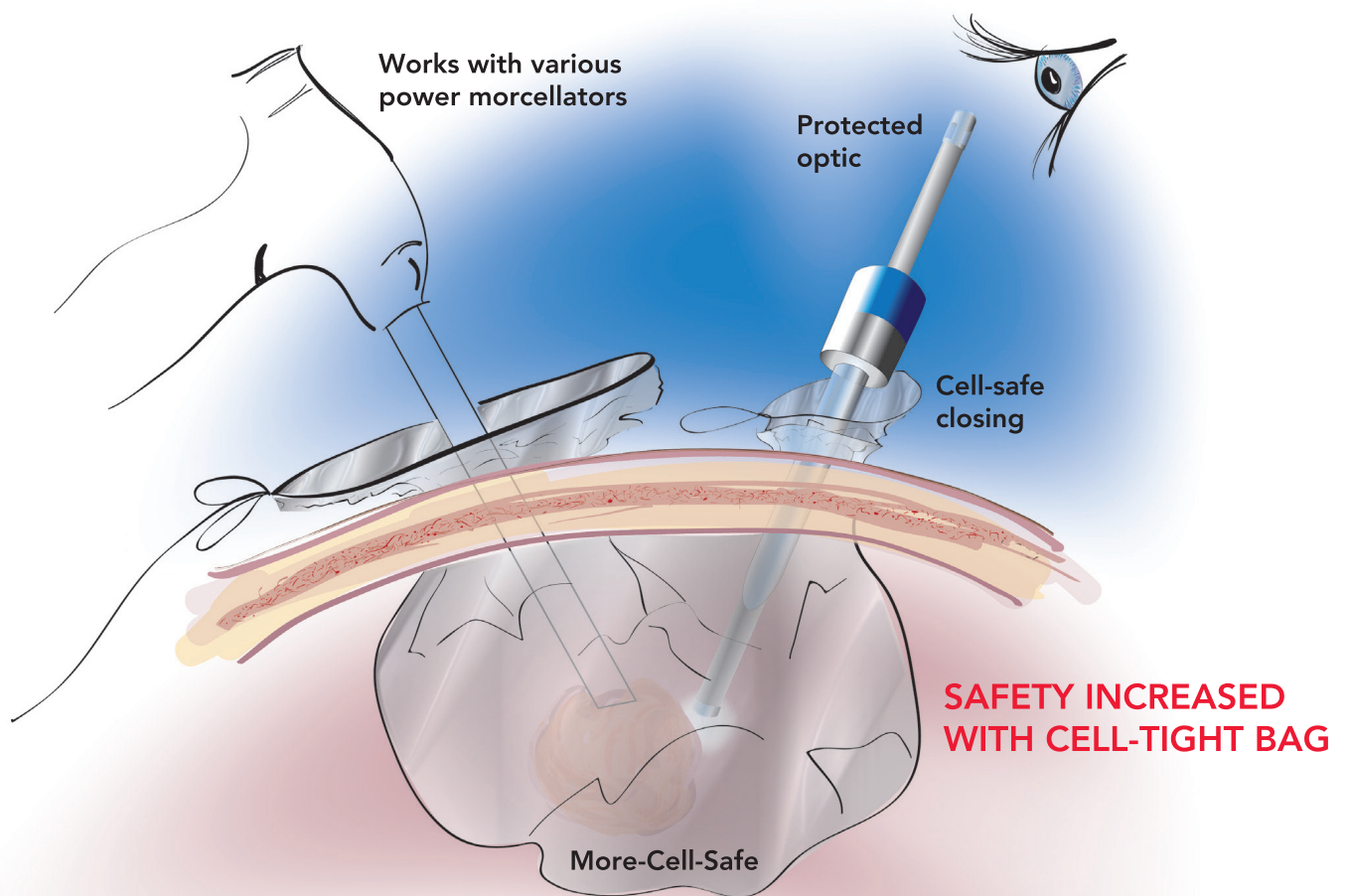


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# PELVIPERINEOLOGY

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## Towards a solution for obstetric fistula problems

I thank the Editors of Pelviperineology for this invitation to write an editorial as background to our **Interim Report on a new method for fistula surgery**, which was first proposed in this journal in 2015.

The background is that despite the efforts of the Millenium Development Goals and recent advances in maternal health across the world, far too many women are still dying in labour and many women are still getting injured.

The obstetric fistula is one of the most feared injuries and there are an estimated 2 million women across the world still waiting for treatment.

There is a growing number of surgeons being trained and more women getting treated. But the surgery is not a guarantee of cure. Fistula patients vary considerably in the type of injuries they sustain and what type of surgery is needed to reconstruct the urinary tract, reproductive tract and gastrointestinal tract. Closing the defects is one thing and over 95% of women can have their fistula closed at the first operation by a skilled surgeon. However, up to 55% of patients will still have ongoing incontinence. This problem of ongoing incontinence has been underreported and even neglected. Many places just perform a dye test and if it is negative the patients are recorded as cured, *even if they are still leaking the same amount as before the operation*. The harder you look for the problem, the more you will find. It is the author's routine to examine all patients with a full bladder, get them to cough, walk and for the more severe cases quantify the loss with a one hour pad test. Accurate diagnosis is of critical importance. Those patients who remain wet become depressed, suicidal with little or no chance of having a normal life. Many, very many, live out their lives as outcasts from family and home.

There have been several different operations described to tackle the problem. The general principles of urinary incontinence in the west are not readily transferable as the pathology is different. The patients with ongoing incontinence invariably have had some damage of their urethra during the fistula formation, sometimes the whole urethra along with half the bladder has been destroyed along with the vagina and despite complex reconstructive surgery, they are still wet.

Some have tried tape slings, but with poor results and high erosion rates. Nearly all hospitals performing fistula surgery cannot afford synthetic slings anyway. Autologous slings, muscle or fascia are cheap and so are used more widely, but it is not the answer. For the most severe cases the cure rate is a pitiful 26%.

Our introduction of a skin flap to restore vaginal elasticity has shown a big jump in the success rates in women *that would have been labeled as having an extremely poor prognosis or even inoperable*. We could expect even greater outcomes in all patients with vaginal tissue loss.

This Interim Report is the endpoint of a classic scientific journey. Guided by the Integral Theory, an analysis was made of the pathogenesis; a hypothesis was formed, that the problem was scar-induced loss of vaginal elasticity. From this evolved treatment, application of a skin graft to improve tissue elasticity. This was tested in a small pilot study. Then the skin graft method was applied to the worst affected cases, the basis of our Interim Report. In summary, this technique marks the most exciting advancement in fistula surgery for many years and many thousands of impoverished women stand to benefit.

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# A review of the Integral Theory of Pelvic Organ Prolapse and proposed concept of repair: part 2 – the TFS ligament repair

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**Abstract: Aim:** To demonstrate how TFS site specific repair of the 4 main damaged ligaments (Part 1) restores the anatomy of patients' with cystocele, uterine/apical prolapse and high, mid and low rectocele. **Surgery:** The surgery is based on the TVT neo-ligament principle, shortening and reinforcing the ligaments: arcus tendineus fascia pelvis (ATFP) and cardinal (CL) to cure cystocele; CL and uterosacral (USL) to cure uterine/apical prolapse; USL and perineal body (PB) to cure rectocele; PUL to cure urinary stress incontinence. There is no vaginal excision. Which ligament to repair is guided by the Pictorial Diagnostic Algorithm, which uses symptoms to identify which ligaments are damaged. **Results:** The application of TFS for repair of only 4 ligaments has been found to be sufficient for repair of all three prolapses, cystocele, uterine/apical and rectocele. The 5th ligament, PUL, is essential for repair of urinary stress incontinence. There seems to be minimal recurrence of the prolapses in the longer term. Data from patients having total repair (all prolapses) indicates there is only a minimal fall in cure rate, from 92% at 12 months to 84% at 48 months. **Conclusions:** Suturing damaged tissue to damaged tissue creates scar tissue and more damaged tissue. With reference to the suspension bridge analogy, if the tensioning cables (ligaments) have collagenous damage, the collagen must be strengthened by tissue reaction from precisely implanted tapes. The one-way system at the base of the anchors allows the tapes to both shorten and reinforce the damaged ligaments, thus restoring anatomy and function: the directional muscle forces require a firm insertion point (ligament) to contract efficiently, according to Gordon's Law.

**Keywords:** ATFP; Cardinal ligament; Uterosacral ligament; Perineal body; Pubourethral ligament; TFS surgery.

## INTRODUCTION

This is the second of four related papers seeking to critically analyze the Integral Theory System and aims to introduce the TFS system of ligament repair.

The Integral Theory<sup>1</sup>, states that pelvic organ prolapse, bladder and bowel dysfunction and some types of pelvic pain, mainly derive, for different reasons, from laxity in the vagina or its supporting ligaments, as a result of altered collagen/elastin.

Surgery with the TFS tool has a simple basis: it shortens and reinforces damage in the 5 suspensory ligaments using the TVT neo-ligament principle first applied in 1990<sup>1</sup>. The same surgical methods apply for major prolapse or significant symptoms with minimal prolapse.

### Basic surgical principles

1. Ligaments provide suspensory strength<sup>2</sup>. They must be shortened and reinforced, preferably with a precisely located tape. This method is sufficient to restore all prolapses, apical, cystocele, rectocele and to restore the contractile force<sup>3</sup> of the pelvic muscles which control bladder and bowel function. Gordon's Law states that a striated muscle contracts efficiently over a small distance. Elongation of its insertion point also elongates the muscle and the muscle force decreases exponentially.

2. The uterus and vagina are conserved. The vagina has little structural strength<sup>2</sup>. Excision of vagina will shorten or narrow it and decrease its quantity of collagen and elasticity. The uterus functions like the keystone of an arch. All the suspensory ligaments directly or indirectly connect to the uterus. Hysterectomy, by division of the uterosacral and cardinal ligaments weakens the ligamentous insertions and predisposes to collapse of the vaginal walls as the patient ages. The effect of hysterectomy on structure and function becomes evident as collagen atrophies with age, especially after the menopause.

### Which ligament to repair?

The surgery is guided by the diagnostic algorithm, Figure 1.

Symptoms indicate which ligaments cause a particular prolapse and which symptoms are associated with damage in particular ligaments. The aim of the repair is to shorten and strengthen the ligament.

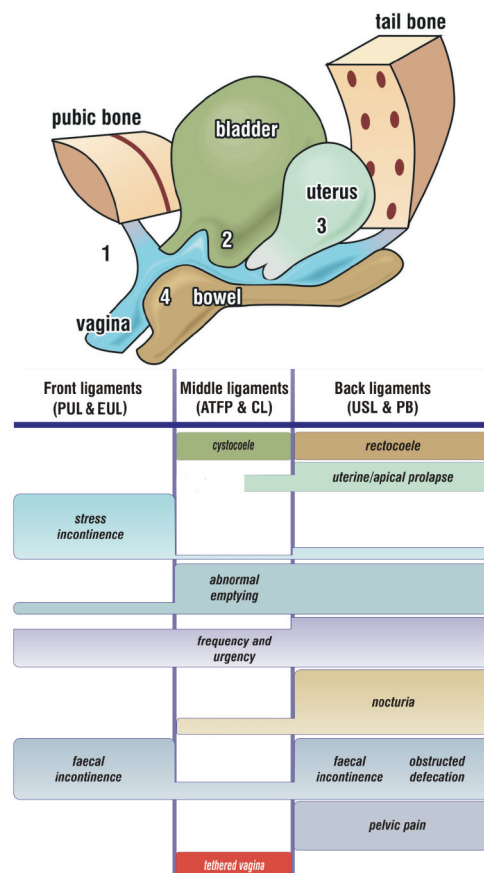


Figure 1. – Pictorial algorithm for diagnosis of pelvic organ prolapse. Symptoms indicate which ligaments cause a particular prolapse and which symptoms are associated with damage in particular ligaments.

**The TFS tools**

The TFS consists of an applicator, a non-stretch tape attached to two soft tissue anchors with a one-way adjustable mechanism for the tape which passes through the base. The tape is 7.5mm wide. It is a lightweight, non-stretch, individually knitted type I, lightweight, macropore, monofilament polypropylene mesh tape, Figure 2. At the base of the anchor is a system which allows one-way directional tensioning of the tape.

The anatomical fundamentals of how the TFS tools are applied are basically the same for each of the 5 ligaments. The vagina is incised. Bladder, rectum and enterocele are dissected to access the ligaments as required. The ligament is identified. A tunnel is made through the ligament with Metzenbaum scissors, or similar. The applicator is inserted into the tunnel to the required length. The anchor is deployed. The operation is repeated on the contralateral side and the tape is adjusted until tape looseness is removed and a resistance is felt. This resistance indicates a reciprocal return of muscle tone in the muscles which act on that ligament. The tape is cut and the vagina is closed.

**How the TFS works**

The TFS shortens and strengthens all 5 ligament structures, Figure 2. The TFS has minimal contact with the vaginal wall as it is applied transversely. Unlike large mesh sheets applied to the vaginal wall, the tapes do not inhibit the forward and backward movements of the muscle forces which are essential for opening, closure and tensioning of the bladder and rectum.

**Why is an adjustable tape necessary?**

The ligaments against which the pelvic muscles contract need to be of a specific length for the muscles to contract efficiently against them, as the contractile force of a striated muscle falls off exponentially if its insertion point is loose<sup>3</sup>. Closure and opening of the urethral and to a lesser extent

anal tubes (due to the ability of the rectum to contract independently) are also exponentially determined by the intra-urethral resistance of the tube: only a small change in radius may cause the patient to leak or be unable to evacuate. Because the organ function is subject to such exponentially controlled mechanisms, symptom control has very fine tolerances. Therefore any shortening and strengthening of a damaged ligament with a tape must be precise if a high rate of symptom cure is to be achieved.

**How does the TFS adjust the tape to the correct length?**

When the ligaments are loose, the striated muscles lengthen. As the tape is tightened, it removes the looseness in the ligament to the point where the striated muscle contractile force returns. The surgeon feels an increasing resistance to the tightening. At this point the tightening must stop there otherwise the anchor will pull out of the tissues. Each anchor has a pull out strength of 2.5 to 3kg.

**How the TFS binds the organs to hiatus and skeleton.**

The TFS tapes are inserted into the pubourethral, ATFP, cardinal (CL), uterosacral (USL), perineal body ligaments, Figure 2. The tapes create collagenous neoligaments which bind vagina, bladder, rectum to the hiatal muscles en route to the skeleton. The tapes limit the ‘ballooning’ of the hiatus so frequently seen in POP.

**The feasibility of Total POP repair**

The minimally invasive nature of the TFS allows all prolapses to be repaired at the same time. Essentially the same surgical technique is used to repair all 5 ligaments, PUL, ATFP, CL, USL, PB. The TFS sling is applied variously in up to 5 sites, Figure 2, depending on which ligaments are deemed to be damaged. The tape is applied into the body of the ligament, or directly adjacent to it. The tape creates a collagenous tissue reaction which strengthens the natural ligament<sup>1</sup>.

**Indicative structural results\* for Total POP repair by TFS.**

Inoue<sup>4</sup>, performed total repair for POP, cystocele, uterine/apical prolapse and rectocele, repairing all 5 ligaments as required. At 12 months, he reported 92.1% anatomical cure for all prolapses (n=278) p <0.001 falling to 84% at 48 months (n=50). Tape rejections for Cardinal, USL, ATFP, PUL were 1.1%. Sekiguchi et al.<sup>5</sup> reported 90% cure rate with total ligament repair (n=62) at 12 months with <3% erosion rates. Table 1.

\* Any protrusion from any compartment, 2<sup>nd</sup> degree POPQ or beyond, was considered an anatomical failure.

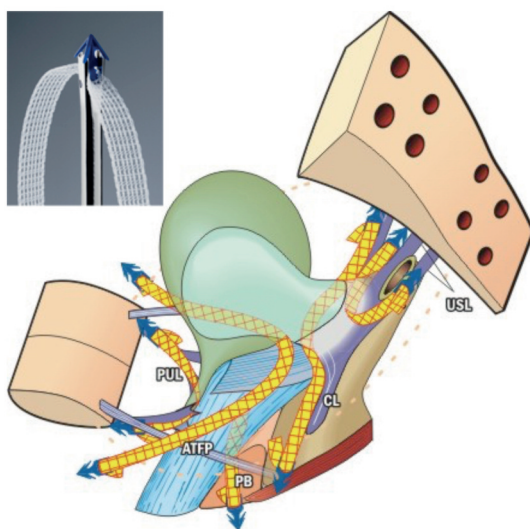


Figure 2. – TFS repair of 5 supporting ligaments - standing view. The tapes attach the organs transversely to the skeleton. The anterior vaginal wall is supported by ATFP and CL. The uterus is held up like the apex of a tent by USL and CL. The posterior vaginal wall is supported by USL cranially and PB distally. *Insert The TFS tool for creation of artificial collagenous neoligaments.* The TFS consists of an applicator, a non-stretch macropore tape attached to two soft tissue anchors with a one-way adjustable mechanism for the tape which passes through the base.

TABLE 1. Operative details CL/USL surgery 12 month data-1036 tapes in 278 patients, Inoue (4)

Variable	Value	Range
Mean operation time (min)	96.2	39-190
Mean estimated blood loss (ml)	75.1	7-280
Hospitalization after operation	0.7	0-7
Same day (38%)		
Mean days, Return to usual life	2.2	1-30
Mean tape per patient	3.5	1-5
Prolapse cure	92.1% (n=278)	<0.001 falling to 84% at 48 months (n=50)

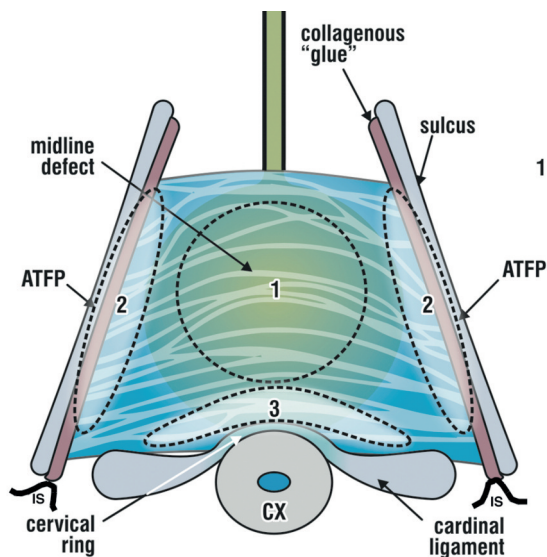


Figure 3. – Potential sites of anterior vagina damage. Schematic 2D view from below. Perspective: looking into the anterior wall of the vagina. 1. Midline defect (central part of PCF) caused by overstretching of vagina.

1. Central defect: overstretching of vagina usually part of defect 2.
2. Paravaginal or lateral defect: dislocation or stretching of the collagenous 'glue' attachment to ATFP.
3. High cystocele or transverse defect is the most common cause of cystocele, 80% in my estimate. *Causation:* dislocation of PCF attachment to the anterior cervical ring and cardinal ligament. Dislocation of the ATFP from its attachment to the ischial spines (IS) is usually seen; there is an associated shallow sulcus and downward rotation of the proximal vaginal wall on straining.

### TFS cystocele repair

#### *Surgical anatomy and preliminaries*

Which operation, ATFP or cardinal? Correct diagnosis of which ligaments are damaged is an essential precondition for repair. The major cause of cystocele is dislocation of the anterior vaginal wall (PCF) and cardinal ligament from the anterior cervical ring attachment, ('transverse defect' or 'high cystocele') '3', Figure 3. Generally, vaginal rugae are present with such tears.

#### *Dislocation from cervix.*

The vagina prolapses downwards lateral to the cervix 'CX', usually on both sides, Figure 4. The presence of rugae indicates it is a pure CL dislocation. In patients with prior hysterectomy, the ligaments prolapse lateral to the hysterectomy scar. The CL TFS operation, Figure 5, is sufficient to restore even major cystocele. If the distal vagina continues to bulge after the CL TFS operation, the ATFP TFS ('U-Sling') is performed, Figure 5.

### TFS cardinal ligament operation (Figure 5)

This tape 're-glues' PCF to cervix and re-suspends the cervix and ATFP (if dislocated from the spine) to the pelvic side wall.

Even with lateral/ central defects, the cardinal ligament is always repaired first. Under tension, a transverse incision is made at the vesico-cervical junction, usually 1-1.5 cm above the cervix or hysterectomy scar. Under tension, the bladder is dissected off the cervix or hysterectomy scar taking care to dissect it laterally off the vagina to the pelvic side wall. This is to protect against perforation during the application of the tape. Using a gently curved Mayo scissors,

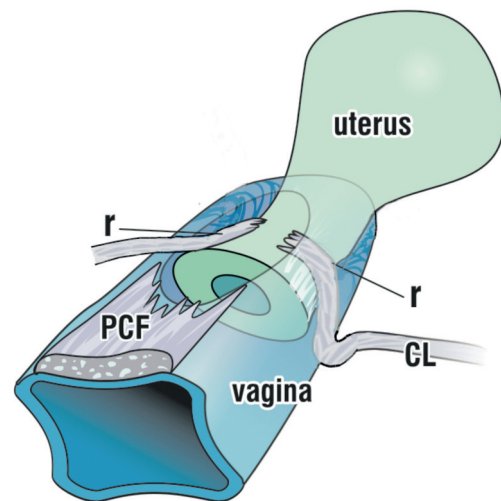


Figure 4. – The cardinal ligament (CL) extends anteriorly to fuse with the cervical ring (r) and the pubocervical fascia (PCF) of vagina. A break in CL and PCF attachments to the cervical ring during labour ring may cause the anterior vaginal wall to rotate downwards like a trapdoor to form a 'high cystocele' or 'transverse defect'. In this situation, the cardinal ligaments also prolapse downwards lateral to the cervix to form the characteristic prolapse ('drooping') of vagina lateral to the cervix or hysterectomy scar.

with tips always pressed towards the vaginal mucosa, a channel is made to the side wall. A finger is inserted to further define the channel. The TFS applicator is inserted into the channel until the fascia is perforated at the side wall. The anchor is released, tugged laterally to embed the prongs, then checked to ensure it has gripped. The procedure is repeated on the contralateral side. The tape is now tightened until a resistance is felt, an indication that reciprocal muscle activity has returned. The vagina is sutured. No

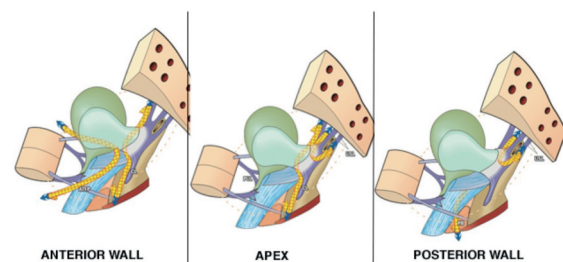


Figure 5. – Cardinal ligament and ATFP USL and PB TFS operations. Schematic view 3D view, patient in standing position. The tapes support the vagina in the manner of ceiling joists supporting a ceiling plaster board.

*Anterior vaginal wall* The (horizontal) cardinal (CL) tapes attach the proximal half of the anterior vaginal wall to the skeleton, re-create the cervical ring and re-attach a detached anterior vaginal wall to the cervical ring. The distal tape (TFS U-sling) reinforces the existing ATFP structure. It provides structural support to the distal half of the vagina, supports the central defect and re-attaches a dislocated PCM to the symphysis.

*Apex* The cardinal TFS tape re-attaches the dislocated CLs 2cm above and forward of the ischial spine. This automatically re-attaches an ATFP torn from the ischial spine (IS) to the side wall. The tape reglues the dislocated PCF attachments to the cervical ring. The USL tape shortens and reinforces elongated or damaged USLs and "reglues" the USL ligaments to cervix posteriorly.

*Posterior vaginal wall* The posterior vaginal wall is re-attached cranially by the TFS USL operation and distally by the TFS PB (perineal body) operation.

attempt is made to excise any vaginal mucosa however lax it may appear.

Cystoscopy is performed at the end, taking care to observe ureteric function.

#### TFS ATFP repair, U-Sling operation (Figure 5)

In the 20% of patients where a bulging persists after CL TFS surgery, the TFS ATFP (U-Sling) operation is performed.

The ATFP tapes support the vagina in the manner of ceiling joists supporting a ceiling plaster board (vagina). Like a ceiling plaster board, a damaged vagina has little structural strength. The U-Sling pulls the distal vagina forwards to re-attach it to the origin of ATFP at the symphysis. Because the pubococcygeus muscle inserts into the distal vagina, it, too, is re-attached to the symphysis.

A separate full thickness vertical incision about 5 cm long is made, beginning 1cm behind the bladder neck. The bladder is dissected off the vagina as per a standard native tissue repair sufficiently to create a channel for the tape. A channel is made with dissecting scissors behind the descending ramus, ascending towards the insertion of ATFP at the pubic bone. The applicator is inserted into the channel, the anchor released and checked for grip. This procedure is repeated on the contralateral side and the tape is tightened until a resistance is felt. The vagina is sutured. No attempt is made to excise any vaginal mucosa however lax it may appear.

Cystoscopy is performed at the end, taking care to observe ureteric function.

#### TFS Uterosacral ligament (USL) operation (Figure 5)

##### *Surgical anatomy and preliminaries*

The uterosacral and cardinal ligaments are related. It is evident that with any degree of uterine or apical prolapse, the cardinal ligaments are also elongated, so they should always be repaired at the same time as the USL. In the standing position, the USL is some 3cm higher than the sacrospinous ligament. The TFS uterosacral ligament (USL) operation is therefore more anatomically accurate than insertion in the sacrospinous ligament and will result in a longer vagina. Furthermore, it does not cause any unilateral deviation of the vagina maintaining a normal anatomical axis.

The CL/US Ligament complex is the insertion point of the LP/LMA muscle vectors: accurate tightening is critical for relief of posterior zone symptoms, Figure 1. The USL's attach to the lateral wall of rectum. A lax USL will predispose to intussusception and with straining produce anal mucosal prolapse and haemorrhoids. If the USL tape is too loose, the result of the procedure for all posterior zone symptoms, Figure 1, will be suboptimal.

##### *TFS Surgery for USL repair*

Under tension, a full thickness transverse incision 5cm wide is made approximately 3-4 cm below the cervix or hysterectomy scar. If the prolapse is 3<sup>rd</sup> or 4<sup>th</sup> degree, the incision is made 1-2cm below the cervix, as the tape will need to shorten a longer length of USL. Any enterocele is dissected to allow access to the USLs. The vagina is stretched to tension the USLs so they can be more easily located. Look for them at 2 and 10 o'clock. These are grasped with Moynihan/Littlewood forceps. The direction of the USL's is determined an important aspect for creation of the tunnel and tape insertion. A small bleb of local anesthetic is injected into the ligament to enlarge it. A vertical incision is made in the superior border of the USL. Still under tension, a

fine Metzenbaum scissors or similar, is inserted into USL to create a tunnel for the TFS which extends to 1cm short of the sacrum. Direct palpation of the ligament (rectally or vaginally) during this manoeuvre can be helpful. The procedure is repeated on the contralateral side. Traction on the vaginal apex is relaxed by removal of the forceps to allow shortening and the tape is tightened and checked to ensure the anchor has gripped. The vagina is closed.

For apical prolapse Petros *et al.* reported symptomatic cure by 30 patients (86%), and improvement in two (6%). Three patients were classified as failures. There were two tape rejections, one associated with operative failure. The cure/improvement rate in the examination group was 87%<sup>7</sup>.

#### TFS surgery for perineal body (PB)

##### *Surgical anatomy and preliminaries*

There are two perineal bodies connected by a central tendon. The PBs are attached behind the descending ramus at the junction of the upper 2/3 and lower 1/3, Figure 3, by the deep transversus perinei 'muscle' (DTP) \* (Figures 6a, 6b). During childbirth, the tendon is stretched and the two PBs are displaced laterally, allowing protrusion of a rectocele. Diagnosis of laterally separated perineal bodies can only be made definitively by rectal examination.

\* The DTP is whitish in colour and except for the presence of some striated muscle fibres, it has the classical histological appearance of a ligament, collagen, smooth muscle, elastin, nerves, blood vessels.

*Surgical principle:* For a correct anatomical restoration, the perineal bodies need to be re-attached to the posterior surface of the descending pubic ramus, at the junction of the upper 2/3 and lower 1/3 by penetration of the deep transversus perinei ligament by the TFS tape. The model in figures 6a, 6b represent TFS repair of the descending perineal syndrome. It shows how the TFS shortens, reinforces, elevates and centrally restores loose, elongated, laterally displaced ligaments, in this instance, perineal bodies. The deep transversus perinei ligaments attach the perineal bodies to the descending ramus.

*Indications for PB repair:* Rectocele with assisted defecation, descending perineal syndrome, anterior rectal wall intussusception, obstructed defaecation, faecal incontinence. The perineal body functions as a unit with the uterosacral/cardinal ligaments. It is therefore standard practice to repair USLs at the same time as PB repair.

##### *Surgery*

Under tension, a posterior vaginal transverse incision 5cm wide is made just behind the hymen. The vagina is dissected off the rectum and the laterally displaced PBs are identified. The PB is whitish in appearance. On stretching, it is important to confirm that it inserts into the descending ramus\*. Using a strong curved needle on a No1 vicryl suture, the PB is 'dug out': the needle is placed into the PB and it is lifted up and grasped with a strong forceps. Using Metzenbaum scissors, a tunnel is made into each PB, through the deep transversus perineus, penetrating its insertion to just behind the descending ramus. The scissors need to be horizontal. Any downward angulation may injure the pudendal nerve as it exits Alcock's Canal. The applicator is inserted, the anchor is released, checked and the procedure is repeated on the contralateral side, stopping when a resistance is felt. The incision is closed.

The pubococcygeus is situated close by the DTP. It is a deep red colour. On pulling it can be confirmed that it inserts just behind the inferior border of the pubic bone.



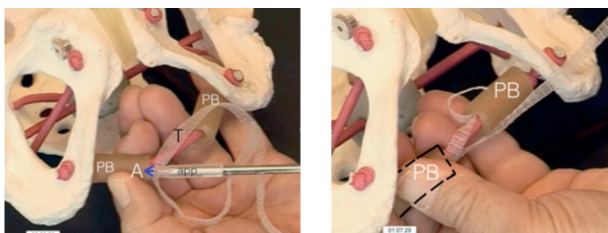


Figure 6. – TFS PB operation for descending perineal syndrome. *Left figure* The laterally displaced perineal bodies (PB) are attached behind the upper 2/3 and lower 1/3 of the descending ramus by the deep transversus perineus ligament. A tunnel 'is made through PB and the ligament penetrating behind the ramus. The TFS anchor 'A' is inserted bilaterally. Note downward angulation of the PBs. *Right figure* Tightening of the tape The PBs are elevated as the tape is tensioned. This, reverses the 'descending perineal syndrome' anatomy; a 1.5-2cm gap is left between the PBs. This fibroses in time to form a new central ligament.

### TFS PB operation for descending perineal syndrome (Figure 6)

#### Results of TFS PB surgery for descending perineal syndrome

Thirty patients with 3<sup>rd</sup> degree rectocele, symptoms of obstructive defecation and manually assisted defecation underwent TFS USL and TFS PB surgery. At 12 months follow-up, cure of symptoms of manually assisted defecation and prolapse was achieved in 27 patients (90%) of patients<sup>8</sup>.

### TFS repair of pubourethral ligaments

#### Surgical anatomy and preliminaries

There may not be significant distal vaginal prolapse with PUL laxity. The main symptom is urinary stress incontinence, (USI), but also, urgency when associated with USI and fecal incontinence when associated with USI. A midurethral sling is applied to shorten and reinforce damaged pubourethral ligaments. The technique is retropubic. Like the TVT, the TFS creates a neoligament in the exact position of the pubourethral ligament.

#### TFS Surgery for repair of PUL

The first part of the TFS mid-urethral sling is almost identical to that of the TVT

Under tension, a full thickness incision approximately 2cm long is made between mid-urethra to within 0.5cm of the external meatus. Under tension, pointing towards ipsilateral shoulder, dissecting scissors create a tunnel until a resistance is encountered, the perineal membrane. The scissors is guarded with a forefinger, and a 1.5-2cm perforation is made. The applicator is guarded, inserted, the anchor released and checked for grip. The procedure is repeated on the contralateral side. A No. 8 Hegar dilator is inserted into the urethra during tightening of the tape to prevent urethral constriction by the tape. The tape is then tightened until a resistance is felt. The bladder is filled and cystoscopy performed to ensure there is no perforation of the bladder. If urine continues to leak after removal of the cystoscope, it indicates that the tape is too loose. The Hegar is inserted and the tape is tightened. The tape should never be tightened without a Hegar in the urethra.

#### Repair of distal closure mechanism\*

The hammock/external urethral ligament (EUL) are now repaired. With a Foley No. 18 catheter in-situ, a continuous suture is inserted: first into one EUL, fascial layer of the vaginal hammock, first on one side, then the other and the suture ends by insertion into the contralateral EUL. The suture is gently tightened over a No. 18 Foley catheter. The vaginal epithelium is now closed with interrupted sutures.

\* The external urethral ligament attaches the external meatus to the anterior surface of the pubic bone. The vaginal 'hammock' is densely adherent to the distal half of the urethra and therefore to PUL. Laterally it is attached to the forward vectors pubococcygeus muscle, ('pubovaginalis').

#### Rationale for EUL and distal vaginal repair- the urethral sealing mechanism.

The main function of the distal mechanism (hammock and EUL) is sealing of the urethral mucosa rather than closure during effort. The vagina is pulled forwards towards the bone by the anterior portion of pubococcygeus muscle pulling against the external urethral ligament (EUL) and the pubourethral ligament (PUL). Laxity in EUL, PUL or vagina may invalidate the closure force by the muscle. Symptoms are insensible urine loss, often accompanied by "a feeling of a bubble of air escaping".

#### Results -TFS repair of PUL

Using a local anesthetic technique, Sekiguchi et al.<sup>9</sup> reported 91% cure of USI including the 40% of patients who had ISD. Petros et al reported 80% cure at 3 years, plus another 6.5% with a > 70% improvement<sup>10</sup>. In a 5 year RCT, Sivaslioglu<sup>11</sup> reported 89% cure for TFS and 78% for TOT. Urinary retention (n=2/40), groin pain (n=12/40) and mesh extrusion (n=1/40) were noted in the TOT group, but not in the TFS group. In the TFS group there was no urinary retention or significant postoperative pain. There was one anchor displacement (left side) in 1 patient. The anchor was removed. The patient remained continent.

### CONCLUSIONS

Suturing damaged tissue to damaged tissue equates to more damaged tissue. Damaged ligaments have to be reinforced with precisely placed tapes. The one-way system at the base of the anchors allows the tapes to both shorten and reinforce the damaged ligaments, thereby restoring anatomy and function: the directional muscle forces require a firm insertion point (ligament) to contract efficiently (Gordon's Law). The neo-ligaments created appear to have longevity. Four year data in patients having total repair (all prolapses) shows mild deterioration with the TFS for POP, from 92% cure rate at 12 months to 84% at 48 months.

### CONFLICTS

There are no financial conflicts.

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# Prevention and cure of post vesico-vaginal fistula repair incontinence by insertion of skin graft in the bladder neck area of vagina. Update on hypothesis and interim report

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**Abstract:** *Background:* There are 2 million women who suffer from vesicovaginal fistula (VVF), and more than 130 000 new cases develop each year in Africa alone. Though the cure rate for the VVF itself is more than 90%, up to 45% of patients continue to leak heavily after successful VVF closure. *Aim:* To present an interim report of the testing of a hypothesis which states that the major cause of post fistula repair incontinence is tissue necrosis consequent upon obstructed labour which leads to scarring in the bladder neck area of the vagina and invalidation of the closure mechanisms. *Methods:* The hypothesis was tested by application of a skin-on Singapore graft to the bladder neck area of the vagina, both prophylactically and in patients with ongoing incontinence following successful VVF repair surgery. *Results:* The flap has been used in 24 cases with severe day/night ongoing incontinence after fistula closure. Some cases had been operated on 9 times before and deemed incurable. After dissection and releasing of the tethered anterior vagina on average there was a 2cm gap created in the anterior vaginal wall that needed to be covered. With urethralisation, sling and the flap 71% of cases were completely dry and 29% improved, often satisfied with their improvement or dry using a urethral plug. The average standard ICS one hour pad test on these patients was 224ml in one hour before the operation and 29ml afterwards with a range of 0-176ml. The same method of urethralisation and sling without the flap yielded a 26% dry rate on the most severe cases of ongoing incontinence with multiple previously failed procedures. Using the graft as a primary repair (n=41), for Goh type 4, 46% with the flap were completely dry as against 19% without. *Conclusions:* The skin flaps restore the closure mechanisms and continence as hypothesized. We believe the initial results from the graft technique are sufficiently convincing to announce this as a significant advance in fistula surgery. Nevertheless, more data is being assembled to complete a statistically valid comparative analysis of the new methods with the old.

**Key words:** Vesicovaginal fistula; Post-fistula repair incontinence; Singapore graft; Tethered vagina syndrome.

## INTRODUCTION

In 2015 we published a hypothesis<sup>1</sup> which originated from preliminary studies at the Addis Ababa Fistula Hospital (AAFH) where the “Tethered Vagina Syndrome” concepts from the Integral Theory of Female Urinary Incontinence<sup>2</sup> were applied to the problem of post vesicovaginal fistula repair incontinence. Our hypothesis stated that a major cause of post fistula repair incontinence is neither a loose pubourethral ligament nor an overactive bladder. Rather, it is tissue necrosis consequent upon obstructed labour which leads to scarring in the bladder neck area of the vagina. This “tethers” the stronger posterior vectors to the weaker forward vectors, figures 1 & 2, overcoming them, so that the urethra is opened out instead of being closed on effort and, in severe cases, at rest. In the normal continent patient, Figure 1, PCM vector (m.pubococcygeus) stretches the distal vagina forwards against the pubourethral ligament (PUL) to close the distal urethra. The backward/downward vectors, levator plate (LP) and conjoint longitudinal muscle of the anus (LMA), stretch and rotate the proximal urethra backwards and downwards around PUL to close the bladder neck. Adequate elasticity in the bladder neck area of vagina, “zone of critical elasticity” (ZCE) (Figure 1) is required for this to occur. With significant scarring at ZCE, the vector forces (backward arrows, Figure 2) are directly transmitted via the scar to overcome the weaker forward PCM vectors. In consequence, the posterior urethral wall is forcibly pulled open, resulting in a sudden rush of urine typically on straining or getting up off a chair. With coughing, there may be little or no urine loss, as there may be just sufficient elasticity for the rapid opposite motion of the fast twitch fibres. This explains why post VVF incontinence patients often leak when downward pressure is exerted with a speculum in the vagina. This action removes any remaining elasticity in ZCE. In

women, such as many of those from AAFH who wet constantly, the tethering effect may be sufficiently severe as to keep the urethra in a constantly ‘open’ position even at rest, so leakage is continuous.

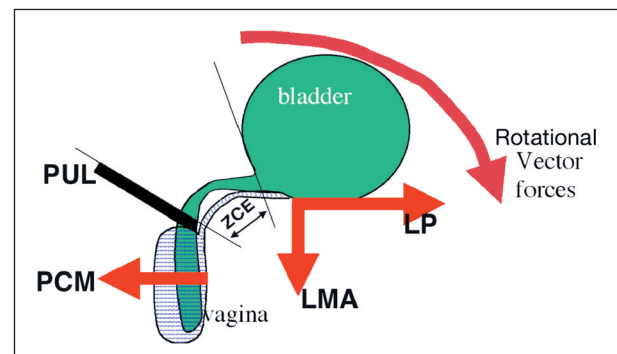


Figure 1. – Normal urethral closure in the female during coughing or straining. PCM = m.pubococcygeus; LP= levator plate; LMA= conjoint longitudinal muscle of the anus; PUL=pubourethral ligament. ZCE (zone of critical elasticity) allows separate action of forward and backward vectors.

## Management and surgical methodology according to the hypothesis

In the Hypothesis<sup>1</sup> we stated, “It is our belief that the focus of treatment for post-fistula incontinence should, above all, be on prevention: ensuring that there is adequate elasticity in the bladder neck area of the vagina during the primary fistula repair. In this endeavor, only a single principle should be observed: if, after dissection, there is a natural gap between the two walls of vagina, the tissues should not be forcibly closed. Rather, a skin graft should be ap-

plied to cover the gap. Ideally, the graft should come with its own blood supply. A skin-on graft, e.g. Singapore graft (Figure 3), needs to be applied to the bladder neck area of the vagina (ZCE), as this is the only way to restore the elasticity required in this area for independent function of the opposite vector forces.”

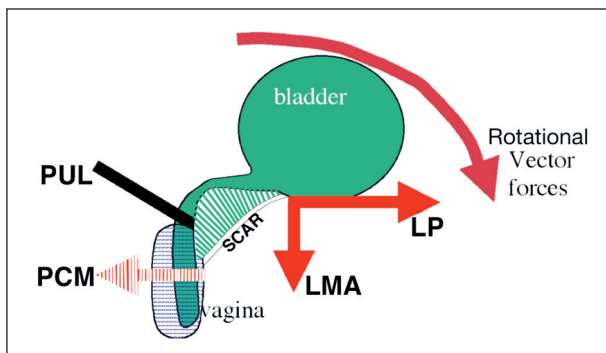


Figure 2. – Mechanism of scar induced incontinence. During effort, LP/LMA vectors overcome the weaker PCM vector (weakness indicated by broken lines) to open out the urethra as per micturition.

### Interim Report

Positive results from initial testing of the hypothesis were reported as a postscript<sup>1</sup>.

The aim of this report is to present further data. The surgical principles as set out in the hypothesis were followed by the first author (AB), who performed all the surgery. Because application of the graft also loosens the PUL, the middle part of the urethra was surgically reinforced at the same time as application of the graft.

The first author (AB) now has a series of 41 patients where the Singapore flap was used at the time of primary fistula repair. The worse type of fistula with regards to being completely continent after repair is the Goh type 4, meaning nearly all the urethra has been destroyed in the long labour. With the basic principles of maintaining the urethral length and sling with no flap, the more severe type 4 (more scarring, larger, repeat and or circumferential defects), only 19% were completely dry. With the basic principles plus the Singapore flap 46% were completely dry.

For Goh Type 3 fistula, without the flap 46% were dry, with the flap 87% are completely dry.

The flap has been used in 24 cases with severe ongoing incontinence after fistula closure. Some cases had been operated on 9 times before and deemed incurable. After dissection and releasing of the tethered anterior vagina on average there was a 2cm gap created in the anterior vaginal wall that needed to be covered. With urethralisation, sling and the flap, 71% of cases were completely dry and 29% improved, often satisfied with their improvement or dry using a urethral plug. The average standard ICS one hour pad test on these patients was 224ml in one hour before the operation and 29ml afterwards with a range of 0-176ml.

The same method of urethralisation and sling without the flap yielded a 26% dry rate on the most severe cases of ongoing incontinence with multiple previously failed procedures.



Figure 3. – Augmentation of ZCE with a skin-on Singapore Graft restores independent movement of the vector forces. The Singapore Graft is taken lateral to the labium majus. Ureteric (white) and urethral (yellow) catheters are seen in situ.

### DISCUSSION

It was found that insertion of a skin graft either prophylactically in primary procedures or therapeutically in successful VVF repairs which continue to leak, gave far higher cure rates than previous practice. These results seem to support the hypothesis that adequate elasticity is required in the bladder neck area of the vagina to facilitate the 3 directional forces which were demonstrated to activate the proximal and distal urethral closure mechanisms, figs 1&2<sup>2</sup>. The key surgical principle followed for placement of the graft was that if, after dissection of the scar tissue, the two edges of the vagina did not naturally approximate, without tension, a graft was required.

This study provides the ultimate test for the Integral Theory<sup>2</sup>, as it tests key predictions of the Theory as to what is required for normal urethral closure: 3 directional vector forces; competent ligaments against which the 3 vector forces contract; sufficient elasticity in the mid-part of the anterior vaginal wall ‘ZCE’ to allow the *separate function* of the 3 directional forces.

### CONCLUSIONS

The skin flaps restore the closure mechanisms and continence as hypothesized. We believe the initial results from the graft technique are sufficiently convincing to announce this as a significant advance in fistula surgery. Nevertheless, more data is being assembled to complete a statistically valid comparative analysis of the new methods with the old.

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## Commentary

The risks of reproduction are borne exclusively by females, who face the hazards of childbirth that arise from the “human obstetrical dilemma:” a narrow “hourglass” pelvis whose size and shape are constrained by the requirements of upright bipedal locomotion together with big babies who develop big brains as a result of our species’ progressive encephalization<sup>1</sup>. These conflicting evolutionary forces mean that humans are predisposed to obstructed labor. When that obstruction is not relieved by timely intervention (assisted delivery, often by cesarean section), the consequences can be catastrophic. Large areas of soft tissue which line the bony pelvis may be injured or destroyed by pressure necrosis from the prolonged impaction of the fetal head, and the fistulas that result are often breathtaking in size and complexity. As a result, rarely are the tissues around an obstetric fistula completely healthy. Although the neighboring tissues are still living, often they have been severely injured, losing both vitality and elasticity. Sometimes the fistula is so deeply embedded in dense scar tissue that extensive dissection is needed even to locate the opening prior to any consideration of repair.

The “continence gap” that persists in patients whose fistulas have been closed successfully but who remain incontinent (transurethrally) after surgery has been a persistent puzzle<sup>2</sup>. For a long time this post-fistula incontinence was thought to be stress incontinence from severe urethral damage (so-called “Type III” stress incontinence), but urodynamic studies have demonstrated multiple intermingled pathophysiological processes in these patients<sup>3</sup>. Whatever it is, it is clearly not “simple” stress incontinence, but exactly how to describe it, how it originates, and (most importantly) how it should be treated, have all been elusive.

In this issue, Browning, Williams and Petros advance an idea – supported by intriguing preliminary clinical data – to suggest that one of the main culprits in the “continence gap” is tethering of the vagina occasioned by the scarring produced by the pressure effects of obstructed labor. Those familiar with the barely-mobile anterior vagina that may be found in many fistula patients will understand the underlying logic of their argument. The same phenomenon of vaginal tethering may explain the profound stress incontinence that develops in some women with post-hysterectomy vaginal vault prolapse, who, although continent before surgery, may develop debilitating stress incontinence after undergoing sacral-colpopexy. The pathphysiology that produces urine leakage in these cases presumably is also “tethering” of the anterior vaginal wall through excessive suspensory tension which alters the dynamics of the urethral closing mechanism in a similar way as that proposed here. In this case the incontinence is not “unmasked” by reduction of the prolapse; rather, it is created by altering the normal physiologic mechanisms of urethral closure. Further clinical research to verify this hypothesis is greatly to be desired.

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# Anal incontinence and severe acquired brain injury: a retrospective study of 347 rehabilitation inpatients

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**Abstract:** Patients with ABI often present, from the outset, problems with intestinal function such as anal incontinence and difficulty in defecating, in a clinical picture termed Neurogenic Bowel Dysfunction. The aims of the study are to evaluate the incidence of neurogenic anal incontinence at the beginning and end of the intensive rehabilitation period after ABI due to trauma, haemorrhage, anoxia or neoplasm; to evaluate any correlation between its progression and the duration of coma, site of the encephalic lesion, occurrence of paroxysmal sympathetic hyperactivity, presence of diffuse axonal injury (DAI), duration of tube feeding, duration of hospitalisation and discharge setting, incidence since the acute event of healthcare-related infections, in particular *Clostridium Difficile* infections, and concomitant urinary incontinence when the patient is discharged. At discharge from Neurorehabilitation Unit, only the presence of frontal lesions seems to correlate with persistent faecal incontinence.

**Keywords:** Acquired Brain Injury; Anal Incontinence; Frontal lobe; Neurogenic Bowel Disease.

## INTRODUCTION

Acquired Brain Injury (ABI) may be secondary to a vascular, anoxic or neoplastic injury and is characterised by the onset of coma of variable duration (Glasgow Coma Scale  $\leq 8$ ) and the resulting motor, sensory and cognitive impairment<sup>1</sup>.

The progression of ABI can be characterised as the passage from coma to Unresponsive Wakefulness Syndrome (UWS), which has replaced the former term 'vegetative state', with its potentially negative connotations.

The patient with UWS presents with eyes open and autonomous functions (cardiovascular control and thermoregulation) intact, even without environmental contact. Emergence from UWS characterises Minimally Conscious State (MCS), defined in 2002 by the Aspen Work-group as a condition in which minimal, but definite, behavioural evidence of self or environmental awareness is demonstrated<sup>2</sup>.

Patients with ABI often present, from the outset, problems with intestinal function such as anal incontinence and difficulty in defecating, in a clinical picture termed Neurogenic Bowel Dysfunction (NBD)<sup>3</sup>.

Neurogenic anal incontinence is defined as the involuntary loss of faeces (solid or liquid) and gas from the rectum, secondary to neurological pathology<sup>4</sup>. The literature contains few studies describing anal incontinence in ABI; varying incidence is described, from 20% to 70% in the acute phase<sup>5-7</sup>, persisting in 12% of cases until the patient is discharged from rehabilitation<sup>5,8</sup>, and varying between 2% and 20% at six and twelve months from the acute event<sup>5-7</sup>.

It is notable that in 20% of cases, in the chronic phase, persistent constipation occurs in these patients. It is also important to emphasise that, in some cases, faecal incontinence is in reality secondary to constipation even in the acute phase, in particular due to the difficulty of managing constipation pharmaceutically and of device-based treatment in patients with impaired consciousness (and the risk of over-treatment), or the occurrence of pseudo-incontinence due to obstruction by a faecaloma.

In these cases, the consistency of stool, as well as the involuntary loss, can help to establish a working differential diagnosis<sup>9</sup>.

The aims of the study are to evaluate the incidence of neurogenic anal incontinence at the beginning and end of

the intensive rehabilitation period after ABI due to trauma, haemorrhage, anoxia or neoplasm; to evaluate any correlation between its progression and the duration of coma, site of the encephalic lesion, occurrence of paroxysmal sympathetic hyperactivity, presence of diffuse axonal injury (DAI), duration of tube feeding, duration of hospitalisation and discharge setting, incidence since the acute event of healthcare-related infections, in particular *Clostridium Difficile* infections, and concomitant urinary incontinence when the patient is discharged.

## MATERIALS AND METHODS

Retrospective evaluation was made of 497 patients, admitted consecutively to the Neurorehabilitation Unit in Cuneo following ABI, between January 2000 and December 2013, of whom 347 were male and 150 female, with an average age of  $46.5 \pm 22.3$  years. Patients who presented associated spinal cord injury (11 patients) were excluded, as were those with previous faecal incontinence (4 patients). Also excluded were 135 patients having a value  $\leq 3$  on the Level of Cognitive Functioning (LCF) Scale<sup>10</sup>. The LCF, including the modified LCF-R version, is a "process scale", that is, it evaluates patient behaviour and thus the patient's cognitive level from the moment he or she goes into coma until recovery; it tracks the patient throughout the process, from intensive care to intensive and then extensive rehabilitation, through to social rehabilitation. It can function as the instrument for patient evaluation across different units, e.g. it can also be used in the intensive care unit.

LCF is a scale of observation in context, and not a neuropsychological test score. It allows the whole rehabilitation team (nurse, logopedist, occupational therapist, physiotherapist, clinician, psychologist, neuropsychologist, etc.) to use the same metric, since it is not specific to any individual professional. It therefore enables a "dialogue" between all members of the team.

This retrospective cohort study was conducted at an academic, urban, tertiary care hospital. Data were collected from electronic medical records and supplemented with chart review.

The Neurorehabilitation Unit in the Department of Rehabilitative Medicine accepts clinically stabilised patients

with a diagnosis of traumatic brain injury or non-traumatic brain injury. The only criterion precluding access to the Unit is mechanical ventilation. Patients with a tracheotomy tube or percutaneous endoscopy gastrostomy (PEG) tube are accepted and there are no time limits with respect to the acute event, although the earliest possible access is guaranteed.

A detailed medical history was collected for all patients. A physical medicine examination and neurological examination were carried out every week and routine blood tests and, where necessary, radiological and neuroradiological investigations were carried out every month.

The rehabilitation programme for these patients includes the provision of optimal nutrition, control of infections, management of bladder, bowel and autonomic disorders, provision of specialist seating and control of posture and tone problems. Patients underwent one hour of physical therapy treatment and one hour of speech therapy every day, to prevent tertiary injury. Rehabilitative treatment involved passive joint mobilisation and helping/placing patients into an upright sitting position on a tilt table.

All the patients were evaluated upon entry as to their bladder and bowel voiding, combining clinical observations with items specific to related activities contained within the Functional Independence Measure (FIM).

*Clostridium Difficile* and multi-resistant bacteria were routinely tested for using rectal swabs, even in asymptomatic patients; in cases of fever, increased leucocytosis with neutrophilia, and elevated C-reactive Protein (CRP) and procalcitonin, repeated blood cultures were performed.

The occurrence of neurogenic anal incontinence upon discharge from neurorehabilitation was verified, seeking any correlatable factors such as the pathogenesis of the ABI, duration of coma, site of the encephalic lesion, occurrence of paroxysmal sympathetic hyperactivity, presence of DAI, duration of tube feeding, duration of hospitalisation and discharge setting, incidence since the acute event of healthcare-related infections, in particular *Clostridium Difficile* infections, and concomitant urinary incontinence upon patient discharge.

STATISTICAL ANALYSIS

Kruskall-Wallis analysis of variance with Bonferroni correction for post-hoc comparisons and Mann-Whitney tests were used to compare ordinal and non-normally distributed continuous variables. Categorical data were analysed by  $\chi^2$  test and Fisher's exact test, correlations were checked with Spearman's rho. A correlation matrix was used to determine variables affecting neurogenic anal incontinence, and multiple regression analysis was used to determine the effect of neurogenic anal incontinence on discharge rehabilitation outcome. For a better understanding, data of continuous variables were expressed as means  $\pm$  SD. The level of significance for all tests was set as  $p < 0.05$ .

RESULTS

Of the 347 patients included in the study (208 male and 139 female), the ABI was post-traumatic in 111 (31.9%), post-haemorrhagic in 180 (51.9%), and post-anoxic in 56 (16.2%). The average length of stay in acute care units was 28.5 days; the average length of coma was 7.4 days for post-traumatic patients, 9.1 for post-haemorrhagic patients and 15.4 for post-anoxic patients. 51% presented signs of DAI, with localised frontal lobe lesions, unilateral or bilateral, in 32% of cases.

Upon their admission to rehabilitation, faecal incontinence was detectable in 244 patients (70%); all patients were being fed by percutaneous gastroenterostomy or nasogastric tube and treatment continued for 55 days on aver-

age. All patients were fitted with a permanent urinary catheter upon admission; lesions of the pelvic girdle were present in 29 patients; in 69 cases (19.8%), paroxysmal sympathetic seizures were indicated in the acute phase.

Table 1 summarises the main demographic and clinical characteristics of the sample upon admission to neurorehabilitation.

Upon admission, the only variables seeming to display statistically significant correlation with the presence of faecal incontinence are the number of previous healthcare-related infection episodes and previous *Clostridium Difficile* infections (Table 1).

During their hospitalisation, 17 patients died and 21 were transferred back to acute care units due to worsening of their clinical condition. Upon discharge, faecal incontinence was present in 56 of the 309 remaining patients, down from 70% to 18.1%.

Those patients still suffering incontinence were either discharged to their own homes (11 patients), transferred to other rehabilitation facilities (19) or transferred to care homes (26) ( $p = n.s.$ ).

With regard to the variables taken into account, the LCF scale values upon admission do not seem to affect the persistence of faecal incontinence upon discharge; the same is true of the duration of coma, average duration of tube feeding, presence of diffuse axonal injury, lesions of the pelvic girdle, paroxysmal sympathetic hyperactivity and healthcare-related infections.

At discharge from Neurorehabilitation Unit, only the presence of frontal lesions seems to correlate with persistent faecal incontinence (Table 2).

DISCUSSION

NBD is common in patients suffering medullary lesion, myelomeningocele, multiple sclerosis, Parkinson's disease, and stroke. In particular, suprapontine neurological pathologies can cause changes to supraspinal control mechanisms, leading to the onset of constipation and/or faecal incontinence.

The occurrence of NBD following neurological illness is linked to reduced quality of life<sup>3</sup>, reduced social interaction and significant economic impact, both on the person affected and on healthcare services<sup>11-14</sup>.

TABLE 1. Demographic and clinic characteristics at rehabilitation admission (n=347)

		Continent	Incontinent	
sex	female (n=139)	42	97	p=n.s.*
	male (n=208)	61	147	
Mean age $\pm$ SD	female (n=139)	45.3 $\pm$ 15.4	42.1 $\pm$ 19.2	p=n.s.*
	male (n=208)	47.2 $\pm$ 10.2	44.8 $\pm$ 9.8	
Lenght of coma (days $\pm$ SD)	traumatic (n=111)	7.8 $\pm$ 5.4	7.1 $\pm$ 6.3	p=n.s.*
	hemorrhagic (n=180)	10.8 $\pm$ 3.4	8.3 $\pm$ 4.7	
	anoxic (n=56)	17.8 $\pm$ 3.9	13.7 $\pm$ 4.4	
Acute lenght of stay (days $\pm$ SD)		30.4 $\pm$ 28.6	32.6 $\pm$ 20.3	p=n.s.**
Frontal lobe injury	present	35	87	p=n.s.*
	absent	68	157	
Diffuse axonal injury	present	67	135	p=n.s.*
	absent	36	109	
Pelvic Injury	present	12	17	p=n.s.*
	absent	91	227	
Paroxysmal sympathetic hyperactivity	present	29	60	p=n.s.*
	absent	74	184	
Tube feeding (days $\pm$ SD, acute phase)		16.4 $\pm$ 2.6	14.2 $\pm$ 7.3	p=n.s.**
Clostridium Difficile infection (n. of episodes, acute phase)		8	32	p=0.008*
Hospital-acquired infections ( $\geq$ 3 episodes, acute phase)		29	88	p=0.029*

\* Fisher's exact test - \*\* Unpaired t-test



TABLE 2. Clinic characteristics at rehabilitation discharge (n=309)

		Continent	Incontinent	
Mean age $\pm$ SD	female (n=119)	103	16	p=n.s.*
	male (n=190)	150	40	
Length of coma (days $\pm$ SD)	traumatic (n=99)	7.2 $\pm$ 3.9	7.7 $\pm$ 5.2	p=n.s.*
	hemorrhagic (n=177)	10.7 $\pm$ 3.4	9.6 $\pm$ 2.9	
	anoxic (n=33)	14.5 $\pm$ 5.6	16.7 $\pm$ 2.6	
Inpatient Rehabilitation length of stay (days $\pm$ SD)		95.4 $\pm$ 38.6	102.5 $\pm$ 23.9	p=n.s.**
Frontal lobe injury	present	110	49	p<0.0001*
	absent	143	7	
Diffuse axonal injury	present	138	24	p=0.139*n.s.
	absent	115	32	
Pelvic Injury	present	118	20	p=0.139*n.s.
	absent	135	36	
Paroxysmal sympathetic hyperactivity	present	129	32	p=0.460*n.s.
	absent	124	24	
Clostridium Difficile infection (n. of episodes, acute + inpatient rehabilitation phase)		57	20	p=0.059*n.s.
Hospital-acquired infections (n. of episodes, acute + inpatient rehabilitation phase)		324	68	p=0.057**n.s.
Tube feeding (days $\pm$ SD, acute + inpatient rehabilitation phase)		57.2 $\pm$ 19.6	62.3 $\pm$ 15.6	p=n.s.**
Discharge disposition	home	87	15	p=0.168*n.s.
	other rehabilitation	92	20	
	institutional care	74	21	

\* Fisher's exact test - \*\* Unpaired t-test - \*\*\* Kolmogorov-Smirnov test

However, the incidence of NBD resulting from an ABI is still to be determined and healthcare professionals have paid no particular attention to its occurrence in patients suffering from serious changes in their state of consciousness, with the result that research activity has been limited, in particular with regard to therapeutic strategies.

Our case study seems to highlight a single significant element in the persistence of faecal incontinence upon discharge from rehabilitation, namely the presence of frontal lesions.

Together with the peripheral control of intestinal function, various cerebral areas compromised by traumatic and vascular encephalic pathology can cause the partial or complete loss of sensory and motor function in the anorectal tract and pelvic floor<sup>15</sup>.

This leads to changes in colonic motility and affects the absorption of electrolytes and water, clearly contributing to change in the normal mechanisms for propulsion of the faecal bolus and for defecation<sup>16,17</sup>.

Completing the picture of NBD resulting from ABI are the associated motor and cognitive disabilities. Although these are not always present, they nonetheless represent a major problem for those patients in which they do occur.

Various parts of the central nervous system contribute to the control of gastrointestinal function, such as the limbic system, hypothalamus, periaqueductal grey matter and amygdala.

Information reaches the encephalic centres through the spinomesencephalic and spinotelencephalic tracts, together with parasympathetic and sympathetic projections through the solitary tract nucleus.

Within the reticular substance of the cephalic trunk there are also close connections between gastrointestinal function and certain haemodynamic reflexes (for example, the decrease in cardiac contractility induced by gastric distension), just as the cerebellum seems able to influence gastric and intestinal motility.

At the cortical level, the perception of rectal distension is predominantly in the right prefrontal cortex<sup>18</sup>; the limbic cortex in turn modulates gastrointestinal function through

the pathways descending to the dorsal nuclei of the vagus nerve: its stimulus determines gastric distension and the reduction of gastrointestinal motility.

A number of recent studies have finally shown how cortical influences in emotional terms can affect the behaviour of the gastrointestinal tract in inflammatory disease<sup>19</sup>. However, despite all these observations, we still cannot be certain of the effects on colorectal physiopathology following a stroke.

The association between faecal incontinence and frontal lesions therefore has particular foundation in cases of traumatic ABI, where the frontal cortex is usually involved<sup>20</sup>, just as the limbic system is involved in all forms of ABI, whether primarily from the lesion or secondarily in the post-acute phase.

However, our observations do not seem to confirm the data linking persistent anal and urinary incontinence with cognitive functional deficit<sup>21</sup> and modest functional recovery<sup>22</sup>: the LCF value upon discharge does not differ significantly between the two groups (continent and incontinent).

The brain mapping confirms, however, that the prefrontal cortex normally controls continence via connections with other areas, as well as executive functions, damage to which causes changes in cognitive and behavioural functions<sup>23</sup>. The data relating to the discharge setting also seem to confirm the lack of correlation between persistent faecal incontinence and cognitive-behavioural deficit; there is in fact no statistically significant difference between the discharge settings of the two populations (continent and incontinent). This all points toward an interpretation of persistent faecal incontinence as secondary to frontal lobe impairment rather than to the cognitive-behavioural effects caused by such impairment.

Finally, it remains to point out some clinical situations that are possible causes of iatrogenic diarrhoea and therefore correlatable to healthcare activity; it is often impossible to evaluate precisely the connection between diarrhoea and faecal incontinence in patients with impaired consciousness.

Clostridium Difficile is the microorganism most easily identified as a cause of nosocomial diarrhoea<sup>24</sup>. In our case study, the number of Clostridium Difficile infection episodes in the acute phase alone correlates positively with the presence of faecal incontinence upon admission into rehabilitation, while the total number of Clostridium Difficile infection episodes (acute phase and hospital rehabilitation phase) does not correlate with persistent faecal incontinence upon discharge.

Similarly, diarrhoea and the presence of loose faeces can commonly be secondary to tube feeding via nasogastric tube or PEG, or to antibiotic treatment for the frequent nosocomial infections<sup>25</sup>. These elements combined make difficult the diagnostic interpretation of faecal incontinence in the acute phase, but again, our case study shows no apparent correlation with the duration of tube feeding, upon either admission to, or discharge from the rehabilitation unit.

Another element of our study that does not match previously presented data<sup>5</sup> is the lack of any correlation between persistent faecal incontinence upon discharge from inpatient rehabilitation and pelvic girdle fractures.

In conclusion, from our observations, a correlation emerges between unilateral or bilateral prefrontal lobe damage and persistent faecal incontinence upon discharge from rehabilitation, although there was no corresponding correlation with incidences of cognitive-behavioural impairment.

The most obvious limitations of this study arise from the retrospective evaluation of the data, which are often incomplete as to any incidence of faecal incontinence prior to the acute event. Similarly, our observations may be affected by the non-correlation with the feeding arrangements.

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## Comment

This study effectively points out that bowel dysfunctions causing fecal constipation and/or incontinence are not only secondary to a spinal cord injury (SCI), but also constitute a major clinical and Quality of Life issue, even after a brain injury in its acute phase. Unlike SCI, where the percentage of patients with no sphincter control remains unvaried, even in later stages, that is during neurorehabilitation and after discharge, in patients with ABI this percentage significantly decreases, as shown in this study, where it drops from 70% at admission to 18% at discharge. Anyway, it is still a considerably high percentage and a more effective therapeutic rehabilitation approach is desirable, if compared, it has to be said, to what is currently proposed for the management of these disorders in our rehabilitation or long-term care units.

The correlation between persistent fecal incontinence and frontal lesion is also very thought-provoking. It is as if patients are losing what they acquired in their first two or three years of life, when they learned to control their pelvic floor and sphincter muscles, so that, with equal efficiency, they can hold the content of bowel and bladder when social conditions requires it, and expel it when they decide to. In fact, it is a complex learning (we learn to walk and talk first!) that is compromised by neurological deficits, ranging from more peripheral lesions (pudendal nerve neuropathies, dyssynergies and pelvic floor myopathies) to frontal lobe impairment, as this study underlines.

The definition of "no sphincter control" according to the FIM Scale, on the basis of which this study was conducted, does not allow a very sophisticated symptom classification: it does not distinguish between defecation which is indeed physiological, but which occurs at an inappropriate time, and fecal incontinence or soiling, and not even between paradoxical diarrhea and colorectal fecal impaction. Therefore, more prospective studies with a significant follow-up are necessary to return data on this issue, which is absolutely critical both from a clinical point of view and in terms of costs for patient care.

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# Surgical management of rectal prolapse: a cross-sectional perspective

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**Abstract:** *Background:* Rectal prolapse presents with a constellation of symptoms which can impact on patient lifestyle. Significant equipoise exists amongst the surgical community with regards to the diagnosis of internal rectal prolapse and its management. *Objective:* To demonstrate that the management of patients with rectal prolapse is far from standardized and that there is uncertainty in the decision making in rectal prolapse treatment. *Methods:* A prospective survey to assess practices was mailed to colorectal surgeons in Australia and New Zealand. The survey was divided into sections on surgeon demographics, patient evaluation, clinical scenarios with varied patient morbidity and preferred surgical approach, and finally a section on complications and follow-up. *Results:* The results of this study illustrate that as in other countries, the management of patients with rectal prolapse is far from standardized. Most controversy appears to be associated with the significance of the different grades of internal rectal prolapse versus external rectal prolapse and then its subsequent management. It was also noted that treatment preferences varied when comparing senior with junior colorectal surgeons. *Conclusion:* This survey affirmed that the management of patients with rectal prolapse is far from standardized and that there is uncertainty in the decision making in rectal prolapse treatment. By shedding more light on the debate amongst surgeons, this survey demonstrates the need for further more prospective studies to be conducted to aide in the development of guidelines.

**Keywords:** Surgery; Rectal prolapse; Survey epidemiology.

## INTRODUCTION

Prolapse of the rectum involves full thickness intussusception of the upper rectum and/or colon<sup>1-3</sup>. When the prolapse descends as far as the anal canal it is considered an internal rectal prolapse (IRP). When it protrudes beyond, it is an external prolapse (ERP)<sup>4</sup>.

Rectal prolapse presents with a constellation of symptoms which can significantly impact on patient lifestyle<sup>5-6</sup>. It principally affects women and its incidence increases with age. In more than 50% of cases, ERP is associated with fecal incontinence<sup>5-7</sup>. Patients presenting with IRP often complain of obstructed defecation and/or fecal incontinence symptoms. Mucosal prolapse can also occur and should not be confused with rectal prolapse, which is full thickness.

Significant equipoise exists amongst the surgical community with regards to the diagnosis of IRP and its management. Investigation of these patients is often not consistent as is the choice of surgical intervention, whether open, laparoscopic, transabdominal or perineal<sup>8</sup>. Of late there is increasing literature being published reflecting institutional results from prospectively collected data, but generally there is no community consensus on accepted guidelines.

This prospective survey was performed as a cross-sectional study of the evaluation and management of rectal prolapse in Australia and New Zealand.

## METHODS

A prospective survey was sent to all members of the Colorectal Surgical Society of Australia and New Zealand. This group was selected due to the area of specialization. A survey was mailed out to 202 members of the society asking questions to evaluate the decision making and management surrounding the management of rectal prolapse. Two further reminder surveys were sent out to increase recruitment. Of the 202 members, we received 126 responses (62% response rate).

The survey (appendix A) was constructed with separate sections. Initially a surgeon demographics section provided background on training, place of practice and participant

understanding of rectal prolapse. The Oxford scale for rectal prolapse was used. (Table 1) This was followed by a section on patient evaluation of rectal prolapse. Different clinical scenarios looking at internal and external rectal prolapse, gender and patient morbidity were then presented and preferred surgical approach asked. This was done to elicit whether there were generational differences in practice based on preferred procedure. Colorectal surgeons in practice for greater than ten years (senior) were compared to those of less than 10 years (junior) when looking at treatment preferences, and finally, a section on complications and follow-up.

## RESULTS

*Participant Demographics:* 91.6% of respondents actively perform pelvic floor surgery. Only 21% of respondents had an established multidisciplinary meeting (MDT) in their institution specifically for the management of pelvic

TABLE 1. Classification of rectal prolapse (12).

		Oxford Rectal Prolapse Grade	Radiological characteristics of rectal prolapse
Internal Rectal Prolapse	Recto-rectal	I (low grade)	Descends no lower than the proximal limit of the rectocele
	Intussusception	II (low grade)	Descends into the level of the rectocele, but not onto the sphincter/anal canal
		III (high grade)	Descends onto the sphincter/anal canal
	Recto-anal Intussusception	IV (high grade)	Descends into the sphincter/anal canal
External Rectal Prolapse		V (overt rectal prolapse)	Protrudes from the anus

TABLE 2. Participant Demographics.

Years in Clinical Practice	53 (42%) < 10 years	73 (58%) > 10 years
Years in Pelvic Floor Practice	47 (43%) < 10 years	62 (57%) > 10 years
Specific Pelvic Floor Training	74 (62%) Yes	46 (38%) No
MDT in Practice	23 (21%) Yes	88 (79%) No
Ratio of IRP vs ERP treated in practice	34% IRP	66% ERP

floor disease. Of the respondents without a MDT in their institution, 49% overall liaised with a gynecologist and 46% with a physiotherapist to aide in the management of their patients.

*Aetiology:* In order to ascertain the community consensus on their understanding of the condition of IRP, three questions were asked. These are represented in Table 3.

*Patient Evaluation:* Participants were asked about the evaluation of their patients and any tests that were performed. Over 74% of respondents performed defecography, sphincter manometry or endoanal ultrasound in their standard workup prior to a pelvic floor operation. Many respondents also performed a colonoscopy and/or examination under anesthetic. 41% of colorectal surgeons always preceded surgery with biofeedback therapy. 38% occasionally performed biofeedback while 21% seldom/never performed biofeedback therapy.

*Treatment:* In the treatment of IRP, respondents noted that 60% of their patients had symptoms of obstructed defecation, 22% fecal incontinence while 30% had mixed symptoms. Findings for the preferred treatments are shown in Table 4. Laparoscopic ventral mesh rectopexy is the preferred intervention for healthy female patients. It was noted when looking at treatment preferences and comparing to years of practice, that senior surgeons were five times more likely to perform a laparoscopic resection rectopexy in the treatment of external prolapse than junior surgeons. When treating internal rectal prolapse in healthy females 18-50 years of age, laparoscopic ventral mesh rectopexy was performed twice as often by junior surgeons, while Delorme's procedure was more likely to be performed by senior surgeons (14vs86% RR81%). When looking at the 50-80 year old age group, senior surgeons were three times more likely to perform a laparoscopic resection rectopexy while laparoscopic ventral rectopexy was preferred by junior surgeons

TABLE 4. Preferred Procedure (%).

		Laparoscopic Resection Rectopexy	Laparoscopic suture rectopexy	Laparoscopic ventral (mesh) rectopexy	Laparoscopic posterior (mesh) rectopexy	Delormes Procedure	Altemier's Procedure	STARR Procedure	Other
External Rectal Prolapse	Healthy women 18-50 y.o.	15	12	52	8	8	1	-	10
	Healthy women 50-80 y.o.	12	10	54	7	12	2	-	13
	Healthy men 18-50	12	19	30	11	20	4	-	8
	Health men 50-80	8	19	35	11	18	3	-	10
	Frail and elderly	1	3	13	0	68	16	-	0
Internal Rectal Prolapse	Healthy women 18-50 y.o.	2	4	52	3	14	0	-	26
	Healthy women 50-80 y.o.	4	-	64	-	-	-	4	27
	Healthy men	7	-	36	-	-	-	12	45
	Frail and elderly	1	-	20	-	-	-	9	70

TABLE 3. Surgeon understanding of rectal prolapse.

		Yes	No
Do you believe in the theory that internal rectal prolapse contributes to obstructed defecation?	Grade 1/2	42 (37%)	73 (63%)
	Grade 3/4	93 (80%)	23 (20%)
Do you believe in the theory that internal rectal prolapse contributes to fecal Incontinence?	Grade 1/2	16 (14%)	100 (86%)
	Grade 3/4	82 (70%)	35 (30%)
Do you believe that internal rectal prolapse is a normal functional variant in the majority of patients with:	Grade 1/2	102 (88%)	14 (12%)
	Grade 3/4	32 (28%)	83 (72%)

(60% vs. 40% RR:72%). For fixation, polypropylene mesh was used 48% of the time, while biological mesh was used 52% of the time.

*Complications:* 32% of respondents noted severe bleeding as a complication from their management of rectal prolapse. Others also commented on hematoma, discitis and pelvic pain. 12% experienced bowel perforation, 11% anastomotic leakage, 8% mesh infection, and 9% erosion.

In the follow-up of their patients 14% of surgeons included a questionnaire as standard, while 6% included radiological imaging in the follow-up of their patients. When asked about current evidence, 60% of respondents believed that high-level research was achievable by means of prospective comparative studies.

DISCUSSION

The results of this study illustrate that as in other countries, the management of patients with rectal prolapse is far from standardized. Most controversy appears to be associated with the significance of the different grades of IRP verses ERP and then its subsequent management<sup>7</sup>.

In the assessment of patients presenting with rectal prolapse, over 74% of respondents performed defecography, sphincter manometry or endoanal ultrasound in their standard workup prior to a pelvic floor operation. Only 9 % utilized dynamic MRI. Due to the multi-organ involvement of pelvic floor pathology, dynamic MRI proves to be a useful

non-invasive tool in the evaluation of selected patients pelvic floor function by combination of novel defecography<sup>9</sup>.

A lot of prospective data has been published of late advocating laparoscopic ventral mesh rectopexy as the treatment of choice for external and symptomatic internal rectal prolapse in both female and male populations<sup>8,10-13</sup>. Furthermore, the utility of mesh and type of mesh (synthetic versus biological) has also received much attention<sup>8,10,14</sup>. From the locoregional perspective it can be seen that there is variation in the treatment modalities offered to patients in the treatment of this condition. The majority of respondents preferred laparoscopic ventral mesh rectopexy in the management of healthy female patients between the ages of 18 and 80 with either internal or external rectal prolapse. A perineal approach (Delormes procedure) was preferred by 68% of surgeons in the management of external rectal prolapse for frail and elderly patients. For the same subgroup of patients with internal rectal prolapse, the majority of surgeons preferred either non-operative management or a Delormes approach.

From the survey it is evident that there are varied management options that are offered to these patients.

Currently there are numerous prospective studies published advocating particular techniques. Three prospective trials of note that are being conducted include the PROSPER trial comparing abdominal (rectopexy with or without resection) vs perineal surgery (Delormes vs Altemeier's) and reported no significant differences in any of the randomized comparisons, although substantial improvements from baseline in quality of life were noted following all procedures<sup>15</sup>. The DeloRes trial aims to compare Delormes procedure versus resection rectopexy and aims to clarify which procedure results in a smaller recurrence rate but also give information on how morbidity and functional results compare<sup>16</sup>. The LaProS study is another trial, which is comparing laparoscopic ventral rectopexy with laparoscopic resection rectopexy primarily looking at improvement of the quality of life in the selected cohort of patients<sup>17</sup>.

This survey affirmed that the management of patients with rectal prolapse is far from standardized and that there is uncertainty in the decision making in rectal prolapse treatment. There are noted generational differences with surgeons who have recently (<10years) completed their training preferring laparoscopic ventral mesh rectopexy when suitable and avoiding resection rectopexy. By shedding more light on the debate among surgeons, this survey demonstrates the need for further and more comparative prospective studies to be conducted to demonstrate the benefits of one procedure over the other, prior to the development of guidelines.

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## Commentaries

The paper by Zahid et al is an epidemiological study of the understanding, investigation and management of intra-rectal intussusception and overt external rectal prolapse. 126 responses were received, the results of which highlight the significant discordance in the approach to managing this condition. Why is there such discordance?

Table 3, evaluates the understanding of two aspects of rectal prolapse by the respondents to the questions that start, “Do you believe in the theory that.....?” . To which theory are the authors alluding? They do not provide any references to any theory. What they are asking is “do you accept that the co-existence of IRP and ODS are related?”, and “do you accept that the co-existence of IRP and faecal incontinence (FI) are related? The significant differences in the response suggest that within colorectal circles there is little understanding of causation or the awareness of any theory that might accurately determine the answer to some of these questions. The next question to ask is, “are you aware of the Integral Theory by Petros and Ulmsten!”

The Integral Theory relates symptoms of pelvic dysfunction to pelvic supporting ligamentous weakness. It relates the the co-existence of numerous pelvic symptoms such as ODS, faecal incontinence, urinary urgency and urge incontinence, pelvic pain, nocturia and others. The symptoms are related to weakness in the uterosacral, cardinal, pubourethral and deep transverse perineal pelvic ligaments. Does the co-existence of ODS and FI suggest a role for this theory, that relates these symptoms predominantly to weakness in the uterosacral ligaments? Is it *the* Theory the authors might be looking for?

Together as four subspecialties, uro(gynaeco-)logists, gynaecologists and colorectal surgeons admit they have made little impact over the last half century into dealing with the above mentioned symptoms. Numerous procedures exist for the management of prolapse. Many are successful at dealing with the prolapse, but only the prolapse.. None are aimed at symptoms. None are aimed at ligamentous support. Could the Integral Theory be the missing link?

First colorectal surgeons should read and familiarise themselves with the Integral Theory. Then they should read the papers by Abendstein<sup>2</sup> and Haverfield<sup>3</sup>. Only then can we start to transform discordance into concordance.

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I congratulate the authors on an important contribution. They identify generational approaches to management of rectal prolapse and the various rationales thereof.

It is a little bold for a gynecological surgeon to make a comment on colorectal surgical techniques for correction of rectal prolapse. In the search for legitimacy, I revert to the basic anatomy of the female pelvic floor, the directional vector forces which activate anorectal closure and evacuation<sup>1-3</sup> and to general surgical reconstructive principles.

Drawing parallels prior between rectal prolapse surgery and the midurethral sling for cure of urinary stress incontinence (USI), prior to the present dominance of the midurethral sling, there had been > 160 operations described. So the presence of so many different rectal prolapse techniques indicates to me, at least, that none of them are sufficiently superior to dominate.

My view is the reason for so many techniques is that none of the operations which are performed address the underlying pathogenesis, which is that, due to childbirth and age changes, the USLs become loose. This looseness allows the uterus to prolapse downwards *along with the rectum*. The evidence that this may be so comes from cadaveric dissections at the University of Padova, Italy where loose ligamentous reflections were found between uterosacral ligaments (USL) and the lateral walls of the rectum; also by observing the results from patients treated for uterine prolapse with the TFS (Tissue fixation System); these operations work by shortening and reinforcing the USL and cardinal (CL) ligaments. We have found that along with the uterine prolapse, hemorrhoids and rectal prolapse usually disappear following TFS CL/USL ligament reconstruction.

It is clear from Fig. 1 that a mesh inserted onto the anterior rectal wall does not address elongated USLs. Rather, it risks stretching the anterior rectal wall upwards towards the promontory. The vector force created is at 45 degrees to that of the USLs. It could be predicted from this, that a rectum which has been overdistended upwards by a rectopexy mesh would prevent the descent observed during anorectal closure and defecation<sup>1-3</sup>. This may result in fecal incontinence, obstructive defecation, or both<sup>4</sup>.

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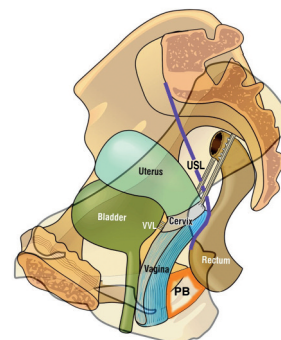


Figure 1. – Pelvis, organs and rectopexy mesh, standing position. Rectopexy tape in purple attaching anterior rectal wall to the sacral promontory. In the normal patient, lateral ligament reflections from the uterosacral ligaments (USL) suspend the rectum to the skeleton. The distal 2-3cm of urethra, vagina and rectum are tightly adherent to each other and to the perineal body (PB).

# Impact of apical prolapse surgical correction on the quality of life of women

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**Abstract: Introduction and Objectives:** The surgical treatment of vaginal prolapses improves the quality of life of women, namely the social and sexual aspects. The present study was designed to evaluate the impact on the quality of life of women undergoing surgical correction of genital prolapse, using the “Prolapse and quality of life (P-QOL) of Brazilian women with pelvic organ prolapse (POP)”. **Patients and Method:** 31 women were interviewed and 4 were lost in the follow-up. Twenty seven women with anterior vaginal wall prolapse associated with apical prolapse, stage  $\geq 3$  of the POP-Q Classification, were enrolled. The “Prolapse and quality of life” (P-QOL) questionnaire provided the subjective evaluation. All patients were submitted to surgery for prolapse correction. **Results:** At least three months after surgery, the questionnaire was applied to compare the score obtained before and after surgery. The anatomical cure criteria can be defined as POP-Q stage  $< 1$  or absence of prolapse beyond the hymen (point C position zero), with no symptomatic prolapse or surgery due to recurrence. Improvement in the quality of life was taken into account with the decrease of the symptoms score. A data exploratory analysis was performed using the summary measures (average, standard deviation, minimum, median, maximum, frequency and percentage). Times were compared by using ANOVA for repeated measurements, adjusting for the postoperative time, the variable responses being transformed into points. The significance level adopted was 5%. **Conclusion:** The women’s quality of life had a statistical improvement with the surgical treatment of apical prolapse and the techniques were safe and efficacious.

**Keywords:** Anterior prolapse; Apical prolapse; Quality of life.

## INTRODUCTION

Longevity is one of the major changes that took place in the 21<sup>st</sup> century. Humans have never lived so long in our society. The number of supercentenarians increases year after year and these alterations in the demographic profile also change the morbimortality pattern resulting in new needs from the health point of view.

The aim is to have a healthy ageing, that is, *to age with quality of life*. The quality of life concept is related to family, decent housing, sexual life, to have friends and we can also add labor activities, frequent social contacts among others. General and specific questionnaires were developed as tools for an objective evaluation of the quality of life levels that are presently currently found<sup>1</sup>.

The increase in women’s longevity has resulted in an increase in pelvic organ disorders (POD). More than 50% of postmenopausal women have DOP, with a marked effect on their family relationships, their sexuality and self-esteem<sup>2</sup>. As the elderly population increases, we will have to know how to manage and treat this population, emphasizing this new approach: *quality of life*.

POP has a marked effect on patients’ quality of life, with impacts on social, psychological, and occupational aspects; on physical and domestic activities; on general and sexual well-being, sexuality is an important factor in quality of life<sup>3,4</sup>.

Several techniques can be used to correct POPs. The *Cochrane Data Base of Systematic Reviews* did not show significant differences among the methods in relation to the recurrence statistics<sup>5</sup>.

**Objectives:** To evaluate the impact of apical prolapse surgical correction, associated or not to prolapse of the vaginal anterior wall on patients’ quality of life using the P-QOL questionnaire for *Brazilian women with pelvic organ prolapse (POP)*<sup>6</sup>.

## MATERIALS AND METHODS

Twenty-seven women with an indication for surgery to correct symptomatic apical prolapse at the Female Urology

Outpatient Department of the Unicamp (University of Campinas) Hospital de Clínicas were included in the study. The patients were selected between June 2015 and October 2016.

Only the patients that agreed with and signed the Free and Clarified Consent Term (Annex 1) were enrolled. The study was approved by the Ethics and Research Committee of the School of Medical Sciences of Unicamp (CEP-FCM-Unicamp), the National Ethics and Research Committee (CONEP). The selected patients underwent surgical treatment for apical prolapse. The objective was to restore the function of the damaged ligament by using a synthetic neoligament, we use kits “UP HOLD”, “SPLENTS” e “CAL-ISTAR”.

The preoperative evaluation included anamnesis, complete urogenital exam, evaluating the pelvic organs prolapse using *Pelvic Organ Prolapse Quantification* (POP-Q), or the classical “eyeball” measurement<sup>7,8</sup>; stress test to evaluate the presence of concomitant stress urinary incontinence (SUI) and application of the questionnaire: Prolapse and quality of life (P-QOL).

The anatomical objective cure was evaluated by quantifying the pelvic organs prolapse using the anatomical points of POP-Q at least three months after surgery. There is no standardized definition to characterize success after a surgery to correct POP, and depending on the definition used it can vary between 19.2% and 97.2%<sup>9</sup>. The criteria for anatomical cure can be defined as POP-Q  $< 1$ <sup>10</sup> or absence of recurrence. The improvement in quality of life should also be taken into consideration with a decrease in the symptoms score.

**Statistical Methodology – Annex III:** A data exploratory analysis was performed using the summary measures (average, standard deviation, minimum, median, maximum, frequency and percentage). Times were compared by using ANOVA for repeated measurements, adjusting for the postoperative time, the variable responses being transformed into points. The significance level adopted was 5% ( $p < .005$ ).

The statistical analysis was performed by the Statistics Department of the School of Medical Sciences of Unicamp.

*Computer Program:* SAS System for Windows (Statistical Analysis System), version 9.4. SAS Institute Inc., Cary, NC, USA.

## RESULTS

The study enrolled thirty-one women with apical prolapse, associated or not with anterior or posterior prolapse, stage III or higher, according to POP-Q<sup>11</sup>. Four of them did not answer the second questionnaire, and 27 patients (87.10%) remained in the study as they came back for the follow-up and answered the questionnaire. As they were followed up to at least three months after surgery, they are the population of our study.

All domains showed an improved score (see Figure 1 below). It is important to stress that 100% of the women had an improvement in quality of life after the apical prolapse correction when considering the sum of all domains -  $p = .0002$ .

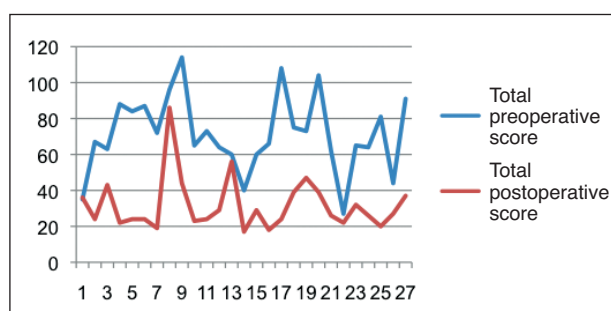


Figure 1. – Evolution of the pre- and post-op scores, sum of all domains.

According to the statistical analysis, there was no significant alteration in the temporal variation found in the interviews (from 3 to 12 months).

The improvement was non-significant ( $p = 0.07$ ) only in the sleep and energy items and significant in all other items ( $p \leq 0.05$ ).

Items related to sexuality had a significant improvement: item 4 ( $p < 0.02$ ) and item 7 ( $p < 0.05$ ). Four patients, 14.8%, did not meet the anatomical cure criteria and this percentage is in agreement with literature data<sup>7,9,12</sup>.

## DISCUSSION

The POP treatment should be mainly based on its impact on quality of life, the symptoms severity, and not only on the grade (Baden Walker) or do POP (POP-Q)<sup>6</sup>.

The vagina is held in place by ligaments on the upper part and by muscles on the lower part, in the same way as steel cables support bridges. If the structures do not provide the necessary stability due to laxity of the uterosacral ligament (USL) and/or cardinal ligament (CL), the posterior muscles strength is inactivated, stimulating the stretching receptors and leading to a wide array of symptoms and loss of *Quality of life*<sup>13</sup>.

The “posterior fornix syndrome” caused by apical prolapse is characterized by urgency and nocturia, abnormal bladder emptying sensation, chronic pelvic pain (uterosacral ligament), anal incontinence or constipation (rectovaginal fascia), and has a strong impact on women’s *Quality of life*<sup>13-15</sup>.

It is estimated that 25% of women with POP avoid sexual intercourse because of pelvic symptoms<sup>16</sup>, interfering with the interpersonal relationships and self-image that are often associated to depression that will further decrease sexual

motivation<sup>17</sup>. The hypoactive sexual desire disorder (HSDD) in female sexual activity is not related only to hormonal variables and in clinical evaluation it is important to have new approaches in analyzing sexuality, emphasizing the importance of taking these non-hormonal factors into account as well as other factors when indicating the treatment<sup>18</sup>. POP can be one of the factors that lead to HSDD as it triggers a poor self-image related to “sexual image”, altering the level of arousal, causing pain, altering orgasm as well as thickness of the vagina wall that is increased in women with POP<sup>17,19-21</sup>. POP is also related to mood disorders and depression<sup>22</sup>.

The apical prolapse treatment aims to provide support at level I once more. As all ligaments are inserted in the vagina and/or uterus, they usually have a poor tissue quality when damaged and the repair with native tissue can result in recurrence. Thus, the integral theory recommends the use of artificial neoligaments using polypropylene synthetic ribbons<sup>20</sup>.

Interestingly, Barber<sup>9</sup> states that treating anatomy is not the most important factor for patients’ perception of success. Quite the opposite as the absence or presence of symptoms is what lead to this perception. It seems that relief of symptoms, improvement in activities conditions, improved self-image and general health and improvement in *Quality of life* are the criteria of cure<sup>12,23</sup>.

Absence of the “vaginal ball” sensed by patients seems to be more significant than the anatomical success. If point C is  $< -1$ , it can be clinically considered as an anatomical success<sup>10,23</sup>, but paradoxically 17% of patients with anatomical cure report the presence of “vaginal ball”<sup>9</sup> and 58% of patients reporting cure remained with a 1 cm prolapse beyond the hymen<sup>12</sup>.

Apical prolapse has a direct impact on all domains of the P-QOL questionnaire and its correction aims at improving symptoms and as a consequence to improve *Quality of life*. After analyzing the P-QOL questionnaires applied both pre- and post-operatively in our study it was found that 100% of patients with surgical correction of apical prolapse had improved quality of life ( $p < 0.0002$ ), in agreement with published trials<sup>24,25</sup>.

## CONCLUSION

The present study demonstrated that subjective and objective improvements or cure were achieved at the follow-up after three months. These results were stable during a period equal to or longer than one year.

After analyzing the pre-op and post-op questionnaires it was possible to determine that surgical correction of apical prolapse resulted in an improved quality of life in 100% of the patients ( $p < 0.0002$ ).

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# Should uterus be removed at pelvic organ prolapse surgery: A reappraisal of the current propensity

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**Abstract:** Pelvic organs are anatomically supported by ligamentous-fascial attachments of endopelvic fascia and muscular support provided by levator ani muscle complex. Dysfunction or disruption of these components, alterations in tissue tensile forces, which are associated with collagen content and turnover within the tissue, as well as lack of hormonal support emerging as the menopausal transition advances, contribute to the pelvic organ prolapse. Hysterectomy has been the treatment of choice for years, despite the recent trend shifting toward uterus preserving measures. In this article, we intended to review the pros and cons of both hysterectomy and uterus preserving approaches through a critical perspective.

**Keywords:** Pelvic organ prolapse; Hysterectomy; Uterus preservation.

## INTRODUCTION

Pelvic organ prolapse is downward descent of pelvic organs including vagina, uterus, bladder, bowels or post-hysterectomy vault, resulting in the protrusion of these structures or some combinations. Although the prevalence of pelvic organ prolapse is as much as 40% in women aged above 45<sup>1</sup>, only 10-20% of those seek evaluation for their condition<sup>2</sup>. The incidence is still rising as a result of aging population and increasing obesity rates<sup>1</sup>. Pelvic organ prolapse typically does not engender morbidity or mortality but can disrupt a woman's quality of life, and is associated with physical, psychological and sexual problems.

Epidemiological studies of the frequency of the condition are rare. The overall prevalence of POP varies significantly depending upon the definition utilized, ranging from 3% to 50%<sup>3</sup>. The reported prevalence is 3-6% if POP is defined and graded on symptoms, whereas it remains at around 50% when the definition is based on examination. The difference in the prevalence rates arises from the fact that mild prolapse is a common finding on examination and frequently asymptomatic<sup>4-6</sup>. The lifetime incidence of surgical intervention for POP is estimated to be 10-20%, with 13% of patients undergoing repeat surgery for POP within 5 years<sup>7,8</sup>.

The incidence and prevalence for prolapse surgery increase with age. The peak incidence of such surgery is in women aged 60-69 years (42.1 per 10 000 women). However, almost 58% of procedures are undertaken in people younger than 60 years<sup>9</sup>. The most commonly performed surgical procedure for uterine prolapse is hysterectomy<sup>10-12</sup> and 15% to 18% of all hysterectomies are performed for POP, making POP the third most common reason for hysterectomy overall and the leading indication in postmenopausal population<sup>13,14</sup>. Current studies report more than 430,000 inpatient hysterectomies performed in the United States annually with uterovaginal prolapse cited as the indication for approximately 74,000 cases<sup>15</sup>. However, whether or not the uterus should be removed is debatable since the argument that the uterine descent is result rather than the cause of the problem is still largely accepted. More recently, a trend of preserving uterus remarked by both patients and physicians has arisen for a variety of reasons. This article will critically review the reasons, risks and benefits for hysterectomy and the evidence for its efficacy in modern practice.

## ANATOMICAL CONSIDERATIONS

Pelvic organs are anatomically supported by a variety of structures, including ligamentous-fascial attachments of endopelvic fascia and muscular support provided by levator ani muscle complex. Dysfunction or disruption of these components can lead to loss of support and, eventually, pelvic organ prolapse<sup>14</sup>. Levator ani muscle is the essential component of active support with three major components identified: pubococcygeal, iliococcygeal and puborectal<sup>16</sup>. Puborectal bundle, the thick and medial sphincteric region spreading from the pubis to external anal sphincter, plays an essential role in pelvic organ support and urogenital hiatus closure<sup>17</sup>. Levator ani muscle, as well as internal obturator muscle, is covered by a layer of connective tissue, named endopelvic fascia, which is a loose connective tissue network consisting of a variable layer of collagen-elastic, smooth-muscle cells, and neurovascular pedicles<sup>18</sup>. Endopelvic fascia thickens into a true pubourethral ligament in the middle third of the urethra at the pubic symphysis. At the lateral sides of pelvic floor, two collagenous connective condensations are identified as the tendinous and ligamentous condensations of endopelvic fascia, the arcus tendineus levator ani and arcus tendineus fasciae pelvis<sup>19</sup>. Arcus tendineus fasciae pelvis suspends vagina and bladder from their lateral aspects, bonding them to the pelvic wall. Uni- or bilateral detachment from the tendinous arc induces pelvic imbalance that may lead to lateral cystocele.

The uterosacral and cardinal ligaments hold the uterus and upper third of the vagina in the pelvic space above the levator plate<sup>19</sup>. Uterosacral ligaments originate from the presacral fascia at the level of S2-S3-S4 without direct bone insertion and are attached to the postero-lateral aspect of the cervix at the level of the internal os and to the lateral vaginal fornices. The posterior third fans out to attach to the presacral fascia opposite the sacroiliac joint. Given the major supportive effects of uterosacral ligament, there is a substantial concern that the removal of uterus disrupts the uterosacral ligament, which may further weaken the support. However, uterosacral ligament attaches into the distal cervix and proximal vagina and thus the supportive effects of the ligament would continue following hysterectomy. Moreover, support of the vaginal vault after hysterectomy relies on the uterosacral ligaments<sup>20</sup>.

On the other hand, cardinal ligaments, areolated connective tissue with neuro-vasculature, inserts to the antero-su-

perior cervical neck and pubocervical fascia. A morphological study of the pelvic floor revealed that only the round and uterosacral ligament exist<sup>21</sup>. Other so called ligaments contain adipose tissue, vessels and nerves and together may be confounded as a ligamentous structure when in fact they have no function as ligament, i.e. the cardinal 'ligament'. Even though these septa may be attached to the fascia of levator ani they argue that they are not supportive.

Given the complexity of the regional anatomy and uncertainty of the roles and the mechanical properties of the pelvic floor structures, a set of theories<sup>22-26</sup> sought the pathophysiological mechanisms underlying pelvic organ prolapse. Petros's integral theory explains pelvic organ prolapse by laxity of connective tissue and ligamentous-fascial structures and describes a sagittal ligamentous-fascial support, 'hammock', which extends from the posterior aspect of the pubis to the sacral concavity. This sagittal hammock comprises, from front to back, the urethra, bladder, uterus, and upper rectum between the two uterosacral ligaments<sup>23,25</sup>. Conversely, according to DeLancey, the keystone to the urogenital prolapse pathophysiology was 'paravaginal support' and he described a pelvic support 'hammock' on a transverse plane<sup>24</sup>. This musculofascial hammock is constituted by vaginal wall and endopelvic fascia connected to the arcus tendineus fasciae pelvis and the urethra lies on this hammock and is compressed under abdominopelvic pressure<sup>19</sup>.

#### CONCOMITANT DISEASES

The lifetime risk of a woman's undergoing hysterectomy in the USA has been reported as 45%<sup>27</sup>. As the hysterectomy procedure has been questioned in its role as part of POP surgery more frequently, there has been a renewed interest in uterine conservation among patients. Moreover, recent published data indicated uterine-sparing procedures to be an acceptable option for most patients with uterovaginal prolapse<sup>28</sup>. However, careful patient selection is a crucial step prior to considering uterine conservation in women with pelvic organ prolapse. There exist several reported contraindications for uterine preservation, including fibroids, adenomyosis, abnormal endometrial sampling, abnormal uterine bleeding, endometrial abnormalities, current or recent cervical dysplasia, postmenopausal bleeding, familial cancer syndrome BRCA 1 and 2 due to the increased risk of ovarian cancer and theoretical risk of fallopian tube and serous endometrial cancer, hereditary non-polyposis colonic cancer, which imposes 40-50 % lifetime risk of endometrial cancer, tamoxifen therapy, inability to comply with routine gynecological surveillance<sup>28,29</sup>. Given the high frequency of fibroids, adenomyosis, abnormal uterine bleeding in the similar age group that uterovaginal prolapse also occur, it would be reasonable to think that the women undergoing uterus-preserving surgery would continue to carry the potential risks of having these pathological conditions and the associated sequel. Hence, cons and pros of preserving uterus should be analyzed in detail prior to the surgical correction.

Vaginal bleeding in perimenopausal women may rarely be due to malignancy and distinguishing hormonal-based irregular bleeding from that of cancer is challenging without a thorough evaluation of all women with these complaints in order to avoid overlooking malignant conditions. Four to eleven percent of postmenopausal women experience vaginal bleeding, which constitute 5% of all doctor visits<sup>30,31</sup>. The main reason for focusing on postmenopausal bleeding is the high proportion of malignancy, mainly of the cervix and corpus uteri, which ranges from 8 to

17.5%<sup>32,33</sup>. On the other hand, endometrial carcinoma accounts for approximately 10% of causes of postmenopausal bleeding<sup>31</sup>. Although dilatation & curettage (D&C) and hysteroscopy have been the gold standard for the endometrial diseases and in evaluating women with postmenopausal bleeding, both have significant false negative rates (10% and 3%, respectively)<sup>31</sup>. Moreover, the controversies in the efficacy of biopsies, evaluation and the frequency of follow-up visits and the financial and psychological burden, render postmenopausal bleeding still a challenging task for clinicians. Recent studies revealed the need for hysterectomy in women with postmenopausal bleeding, even with a negative work-up, because of the high risk of unanticipated endometrial cancer or hyperplasia<sup>34</sup>.

On the other hand, women at perimenopausal years may not desire the continuation of menses, which possibly occur irregularly or excessively due to the anovulatory cycles, even in the lack of any of the above-mentioned conditions. Uterine preserving procedures would give the chance of maintaining fertility and burden the risk of undesired pregnancies.

#### EVIDENCE OF HARM

For decades, the effects of hysterectomy on pelvic organ function have been controversial. Several studies reported that hysterectomy, irrespective of route or mode of surgery, increased the risk for subsequent uterovaginal prolapse<sup>14,35,36</sup> or stress urinary incontinence surgery<sup>37-39</sup>. The most commonly adopted rationale for this association was the trauma of surgery itself when the uterus is severed from pelvic-floor supportive tissues during hysterectomy<sup>40</sup>. On the other hand, hysterectomy was reported to interfere with the urethral sphincter mechanism by distorting local nerve supply to the urethra from pudendal nerves and inferior hypogastric plexus<sup>41,42</sup>. Moreover, the procedure might cause changes in urethral pressure dynamics by damage to pelvic-organ anatomy, including urethral and bladder neck support<sup>24,43</sup>.

The uterosacral and cardinal ligaments maintain the temporospatial anatomy of uterus within the pelvic space<sup>19</sup>. Uterosacral ligaments originate from the presacral fascia at the level of S2-S3-S4 without direct bone insertion and are attached to the postero-lateral aspect of the cervix at the level of the internal os and to the lateral vaginal fornices, thus proximal support of the vaginal vault after hysterectomy is maintained by uterosacral ligaments<sup>20</sup>. Considering that the cervix plays a crucial role in preventing uterovaginal prolapse, it could be reasonable to compare long-term postoperative incontinence and prolapse outcomes between women undergoing total and subtotal hysterectomies, and the results of supracervical hysterectomies could be extrapolated to uterine-sparing surgery. In 2007, Gimbel H<sup>44</sup> published a meta-analysis of 34 randomized controlled trials comparing the effects of subtotal and total abdominal hysterectomies and reported that less women suffered from urinary incontinence and prolapse and cervical stump problems after total than after subtotal hysterectomy. Similarly, Andersen et al.<sup>45</sup> reported that a smaller proportion of women suffered urinary incontinence after total abdominal hysterectomy than after subtotal abdominal hysterectomy 5 years postoperatively. However, subtotal hysterectomy was faster to perform, had less peroperative bleeding, and seemed to have less intra- and postoperative complications. The difference regarding pelvic organ prolapse between total and subtotal hysterectomies was associated to performing a suspension of the vaginal top at total hysterectomy, which might serve as a

minor bladder neck suspension procedure, thus decreasing/removing the problem of incontinence by decreasing the bladder neck mobility<sup>44</sup>. Persson et al<sup>46</sup> reported no difference in pelvic organ prolapse measurements and pelvic floor dysfunction symptoms between patients who underwent total or subtotal hysterectomies in a long-term follow-up study. A recent randomized clinical trial with 14-year questionnaire follow-up revealed that subtotal abdominal hysterectomy was not superior to total abdominal hysterectomy on any outcomes and more women had subjective urinary incontinence 14 years after subtotal than after total abdominal hysterectomy<sup>47</sup>.

Another concern that the physicians hesitate to perform a hysterectomy was the sexual life and functioning after hysterectomy due to the belief that hysterectomy may have detrimental effects on orgasm by eliminating the uterine contribution and by possible neuronal damage in the surgery. However, Gimbel<sup>44</sup> reported that sexual functioning did not differ between women undergoing subtotal and total abdominal hysterectomy. On the other hand, recent studies report favorable outcomes with regard to sexual and urinary outcomes following nerve-sparing radical hysterectomies<sup>48-52</sup>. These studies conferred better clinical outcomes with fewer long-term bladder, colorectal and sexual complications. Moreover, post-operative quality of life after nerve-sparing procedures was better as compared to traditional radical hysterectomies.

#### TOTAL/SUBTOTAL COST

According to the 2014 report of Centers for Disease Control and Prevention (CDC) risk of developing cervix, corpus uteri and ovary malignancy is 0.66%, 2.69% and 1.37%, respectively and risks of dying from these cancers are 0.23%, 0.55% and 0.99%, respectively<sup>53</sup>. Number needed to prevent (NNP) could be assessed in order to help clinicians assess the overall impact of hysterectomy on mortality rates due to associated disease over a one-year period. Given the total percentage of the development of cervix and corpus uteri malignancies would be 3.35%, the number of women needed to be hysterectomized to prevent one woman at any age from developing cervix-corporis uteri carcinoma during the one-year follow-up was calculated as 30. Moreover, based on these rates, 25 hysterectomy plus oophorectomy would prevent the development of 1 cervix-corporis-ovary cancer.

Since cancer is a heterogeneous disease, there exist several variables that affect the total cost of the management of a cancer patient, including the stage of the disease, therapeutic options employed and the years of survival. The direct medical care costs associated with cervical cancer were estimated to equal \$1.7 billion in 1996 dollars<sup>54</sup>. Chemotherapy typically costs \$10,000-\$200,000, depending on the chemotherapeutic agents used, how they are administered and the number of treatments required. Twelve-month cost of treating cervical cancer among Medicaid beneficiaries in the USA has been reported to be \$46,681 and \$83,494 for stage II-IVA and stage IVB cancers, respectively<sup>55</sup>. Another study reported that a common combination of Cisplatin, which is thought to be the most active single agent in periodic diseases, with radiotherapy, typically costs about \$41,000 total, while adding Gemcitabine increased the total cost to more than \$61,000<sup>56</sup>. Since the 5-year survival rate for patients diagnosed with localized cervical cancer is 92%, patients will need regular follow-up through Pap test, performed every 3 months for the first 2 years, every 6 months for the next 3 years and yearly thereafter, and PET/CT in early local recurrence and metastasis detection, which would increase the total cost.

On the other hand, mean total hospital cost for vaginal hysterectomy was \$7903 whereas was \$10,069 for LAVH, \$11,558 for TLH<sup>57</sup>. The total cost of performing vaginal hysterectomy in order to prevent one corpus-cervix carcinoma would be \$237,090 whereas \$197,575 to prevent one corpus-cervix-ovary carcinoma.

Moreover, in women undergoing uterine-preserving surgery the necessity of continuation of cervical and ovarian cancer screening, risk for menstrual disorders and associated therapies, and the side-effects of these therapies should be taken into account when considering cost-effectivity of pelvic organ prolapse surgeries.

#### PROPHYLACTIC HYSTERECTOMY AND OOPHORECTOMY

Tissue collagen content has a key role in the setting of uterovaginal prolapse. Collagen also appears to play a role in maintenance of normal urinary continence by imparting structural stability to the proximal urethra through the paraurethral connective tissue connections to the pelvic floor<sup>58</sup>. In women with pelvic organ prolapse, total collagen content is decreased in the vaginal wall compared with premenopausal controls<sup>59</sup> while the proportion of immature collagen is increased<sup>60</sup>. Also, it has been suggested that collagen metabolism shifts to a degradative state after menopause and in the setting of vaginal prolapse, with increased activity of endogenous matrix proteases<sup>59,61</sup>. These studies suggest the crucial role of estrogen in the maintenance of extracellular matrix and connective tissues for pelvic organ support. Estrogen supplementation increases collagen content of the skin, vasculature, and pelvic tissues in postmenopausal women<sup>62,63</sup>. Animal studies demonstrated increases in collagen mRNA expression after systemic estradiol treatment<sup>64</sup>. Recent studies reported that estrogen treatment increased total and cross-linked collagen content and markedly stimulated collagen mRNA expression and relief of epithelial atrophy in menopausal animal models<sup>65</sup>. These results may have important clinical implications in menopausal women with uterovaginal atrophy, urogenital ageing and associated prolapse symptoms.

As well as urogenital senescence, most menopausal women experience a variety of problems, including bone fractures due to decreased bone mineral density, increased risk for cardiovascular diseases, regression in cognitive functions and depression and vasomotor symptoms often lasting longer than one decade. Since the majority of these problems are considered to derive from estrogen deprivation, hormone therapy (HT) might be recommended to postmenopausal women to overcome these clinical issues<sup>66</sup>. HT, which initially comprised of estrogen monotherapy, is known to improve quality of life, vasomotor symptoms, vulvovaginal symptoms and sexual function whereas decrease the risks of vertebral and hip fractures by increasing bone mineral density, colon cancer, ischemic heart disease and cardiometabolic risk by improving insulin sensitivity<sup>67-69</sup>. However, unopposed systemic estrogen therapy (ET) in postmenopausal women with an intact uterus is associated with increased endometrial cancer risk related to the estrogen dose and duration of use. In order to negate this increased risk, adequate concomitant progestogen is recommended for women with an intact uterus when using systemic ET, however, the addition of a progestogen to the HT regimen has been associated with an increased risk of breast cancer<sup>70</sup>. Several randomized controlled studies revealed an increased risk of breast cancer in women receiving estrogen-progestogen combination than in women using estrogen monotherapy<sup>71-73</sup>. WHI trial indicated that the risk of breast cancer was affected by addition

of a progestin and that women receiving conjugated equine estrogens (CEE) only for a mean of 7.1 years had a 0.77 relative risk of invasive breast cancer as compared to the placebo group<sup>73</sup>. A recent analysis of estrogen only arm of the WHI reported that after 11.8 years of observation, women who had used estrogen treatment for a median of 5.9 years had a lower incidence of breast cancer (RR 0.77, CI 0.62-0.95) compared to placebo<sup>74</sup>. On the other hand, women receiving estrogen – progestin therapy for a median of 5.6 years had a 1.28 (CI 1.11-1.48) relative risk of breast cancer compared to placebo<sup>75</sup>. Similarly, in the EPIC study, women receiving estrogen only therapy had 1.42 relative risk of breast cancer as compared to 1.77 of women on estrogen – progesterone therapy<sup>71</sup>. Now that the addition of a progestogen to estrogen in postmenopausal hormone therapy increases the risk of breast cancer, it is now recommended that hysterectomized women seeking relief of menopausal symptoms with estrogen monotherapy be reassured concerning the long term effects of ET on breast cancer incidence<sup>66</sup>. Moreover, estrogen as a single systemic agent is indicated as appropriate in women after hysterectomy but additional progestogen is required in the presence of a uterus<sup>76</sup>. In the light of the data from these studies, it appears to be plausible to remove the uterus as part of pelvic organ prolapse surgery to avoid the necessity of addition of a progestogen and, hereby, to prevent the increase in the risk of breast cancer. The limitations of an estrogen monotherapy arising from the increased risk of endometrial cancer could be eliminated and postmenopausal women would not be deprived of the multiple beneficial effects of estrogen. More importantly, urogenital tissues could be supported by promoting collagen synthesis, which result in decrease in urogenital ageing, vaginal dryness, dysuria, urethral discomfort, stress urinary incontinence and dyspareunia.

#### PATIENT PERCEPTION

Pelvic organ prolapse negatively affect a woman's perception of body image, physical and sexual attractiveness, and femininity<sup>77,78</sup>, which significantly improve after the surgical correction of prolapse<sup>79</sup>. However, the role of uterus as well as hysterectomy, as part of the surgical treatment of pelvic organ prolapse, in a woman's sexual function and perceived femininity is an issue of debate.

A common concern among women who are candidate for hysterectomy is the possible impacts of the surgery on their sexual function. Hysterectomy is considered to improve the quality of life in the way that alleviation of pain, decrease of anxiety due to elimination of unwanted pregnancies and risk of cancer, positive psychological factors and disease relief<sup>80</sup>. Older studies reported decreased sexual function after hysterectomy-oophorectomy, based on physiological rather than psychological factors<sup>81</sup>. The rationale to assume that removal of the uterus might have detrimental impacts on female sexual functioning was the impairment of the anatomical relations and neuronal innervation in the pelvis and eliminating the uterine contribution to orgasm. However, symptom relief of the primary disease may lead to increased sexual enjoyment and increased orgasm frequency and may outweigh any loss of sensation due to removal of the cervix<sup>82</sup>. Nevertheless, the pathology for which the hysterectomy was performed may differentially affect sexual response<sup>83</sup>.

On the other hand, solid evidence is lacking for sexual dysfunction caused by the disruption of local nerve and blood supply, or by changing anatomical relationships<sup>84</sup>. Increased understanding of patients' attitudes and expectations appears to change the perception of body image, sex-

uality and femininity. Removal of the ovaries at hysterectomy was reported to associate with no change or even an improvement in sexual function, particularly in women on hormone replacement therapy, regardless of surgical method or removal of the cervix. This was attributed to the amelioration of the symptoms that have previously had a negative effect on sexual function<sup>84</sup>. A study by Good et al.<sup>85</sup>, investigating the attitudes toward the uterus in women with pelvic organ prolapse, revealed that majority of women did not believe the uterus was important for body image or sexuality and did not believe that hysterectomy would negatively affect their sex lives. In this study, 47.4% of women strongly disagreed that uterus was important for sex while 63.9% and 66.7% strongly disagreed the comments 'hysterectomy will make me less feminine' and 'hysterectomy will make me less whole', respectively. Jeng et al.<sup>86</sup> examined the changes after vaginal hysterectomy or sacrospinous hysteropexy for uterine prolapse correction and reported a decrease in the frequency of orgasm in the both groups. However, they found no significant differences between groups in terms of orgasm frequency, sexual function and sexual interest. Sexual functioning scores also were not different between before and after the surgery in either groups. Komisaruk et al.<sup>83</sup> reviewed the results of studies investigating the relationship between hysterectomy and sexual function, between 1977 and 2007, and accentuated that most of the studies indicated a 'decrease' in dyspareunia while a majority reported 'no change' after hysterectomy in sexual activity, orgasm frequency, orgasm intensity, vaginal lubrication and libido. They also stressed that effects of hysterectomy on sexual response may not always be deleterious but may depend on whether the surgery desensitizes a woman's preferred genital site of stimulation.

#### INCIDENTAL CANCER

The recent trend towards uterine preservation in the management of pelvic organ prolapse has necessitated an important issue, the risk of failure to detect an occult malignancy, to be addressed<sup>87</sup>. Besides, in contrast to women with fibroids or menorrhagia, patients seeking treatment for POP rarely exhibit signs or symptoms that raise suspicion for uterine cancer and typically do not have indications to prompt evaluations of the endometrium<sup>88</sup>. The number of studies reporting the incidence of malignancy in specimens obtained from hysterectomies performed with the diagnosis of uterovaginal prolapse are low<sup>87,89-92</sup>. These studies reported low rates of unanticipated uterine malignancies. Renganathan et al.<sup>93</sup> reported an unanticipated endometrial malignancy rate of 0.8% among 517 women undergoing pelvic organ prolapse surgery. Ramm et al.<sup>88</sup> determined 5 endometrial cancer cases (0.6%), 4 of which had had a normal preoperative screening, among 708 women and concluded that endometrial assessment prior to prolapse surgery in asymptomatic women was unreliable at detecting malignancy. Similarly, Wan et al.<sup>94</sup> reported that the frequencies of malignancy and premalignant lesions were 0.47% and 0.78%, respectively, in their cohort of 640 women with uterovaginal prolapse. On the other hand, there has been an effort as to whether asymptomatic women could be detected prior to POP correction surgery. Ramm et al.<sup>88</sup> assessed preoperative screening trends and final pathologic diagnoses of women undergoing uterovaginal prolapse surgery and concluded that endometrial assessment via endometrial biopsy or transvaginal sonography prior to POP/UI surgery in asymptomatic women was unreliable at detecting malignancy. Although an intraoperative dilatation and curettage (with or without hys-

teroscopy) was recommended in women undergoing uterine preservation, the fact that the diagnosis would only be made after the surgery had been completed rendered this approach implausible<sup>93</sup>. Frick et al.<sup>89</sup> reported that premenopausal women with uterovaginal prolapse and normal bleeding patterns or with negative evaluation for abnormal uterine bleeding still had a minimal risk of abnormal gynecologic pathology. In postmenopausal women without bleeding, the risk of unanticipated uterine pathology was 2.6% but may be reduced by preoperative endometrial evaluation. However, in women with a history of postmenopausal bleeding, even with a negative endometrial evaluation, they did not recommend uterine preservation at the time of prolapse surgery. Consequently, the possibility of uterine pathology should be considered when deciding the therapeutic strategy to recommend in women with pelvic organ prolapse and it should be kept in mind that conserving a prolapsed uterus without further investigations runs the risk of missing women with endometrial malignancy<sup>93</sup>.

#### IMPACT OF PRIMARY DISEASE ON INCONTINENCE OR PROLAPSUS

Although the current hysterectomy trend has shifted from abdominal to laparoscopic and robotic approaches through the last decade, the commonest indications for which hysterectomy was performed have not changed, the vast majority being for benign conditions, including fibroids, abnormal uterine bleeding (AUB), pelvic organ prolapse, endometriosis, benign ovary tumors, pain, fibroma, and polyps. Since all these conditions have quite different nature, pathogenesis and clinical consequences, risk of subsequent pelvic organ prolapse in women undergoing hysterectomy for different indications may naturally vary. However, the number of studies investigating the risk of POP surgery after hysterectomy, as the indication for the surgery was considered a risk factor, has remained limited. Two studies by Dallenbach et al.<sup>95,96</sup> demonstrated no difference among the hysterectomy indications in the risk for subsequent POP. They reported that the incidence of pelvic organ prolapse that required surgical correction after hysterectomy was 1.3 per 1,000 women-years. The risk of prolapse repair was 4.7 times higher in women whose initial hysterectomy was indicated by prolapse than indicated by myoma and 8.0 times higher if preoperative prolapse grade 2 or more was present<sup>95</sup>. In their following study, vaginal vault prolapse repair after hysterectomy was reported to be an infrequent event and was due to preexisting weakness of pelvic tissues<sup>96</sup>. Similarly, Blandon et al.<sup>97</sup> reported that, compared with women without prolapse, women who had a hysterectomy for prolapse were at increased risk for subsequent pelvic floor repair. Lykke et al.<sup>98</sup> followed up 154,882 women from hysterectomy to POP surgery and reported that the indications POP, AUB, pain, endometriosis were associated with higher risks of subsequent POP surgery after hysterectomy than the indication fibroids/polyps. Also POP as an indication for hysterectomy was associated with the highest cumulative incidence of subsequent POP surgery. Another large cohort study, comparing vaginal hysterectomy for POP and vaginal hysterectomy for other indications showed that vaginal hysterectomy for POP has a higher hazard ratio (HR) than vaginal hysterectomy for other indications<sup>99</sup>. The increased risk of subsequent pelvic organ prolapse in women undergoing hysterectomy with POP indication could be attributed to underlying risk factors and damage to pelvic floor that they already have. Thus, they become more likely to

undergo subsequent POP repair surgery<sup>98</sup>. Based on the results of these studies, it might be reasonable to perform a hysterectomy in a woman presenting with POP, to prevent a subsequent prolapse and POP correction surgery.

#### EFFECTS OF OPERATIVE COMPLICATIONS

Although the short- and long-term risks of hysterectomy are well described in the literature, morbidities of neither preserving uterus and nor the addition of hysterectomy to a prolapse repair have not been described. There are several complications described in the literature related to surgical correction of uterovaginal prolapse, including buttock pain, blood loss, vaginal or incisional hematoma, ureteral obstruction, urinary tract infection, dyspareunia, vaginal adhesion and rectal injuries<sup>100,101</sup>. Gutman & Maher<sup>29</sup> reviewed the studies reporting the results of surgical correction procedures and reported that vaginal hysterectomy was associated with higher success rates, but also with higher complication rates.

Buttock pain is a prevalent complication POP surgery that lasts no longer than 6 weeks. Several studies reporting the results of correction surgery, with or without hysterectomy, indicated buttock pain as a complication of the procedures, with a rate up to 18% of the patients<sup>86,100,102-104</sup>. However, the comparison of this complication's rate between uterine preserving procedures and hysterectomy remains sparse in the literature. Hefni et al.<sup>103</sup> compared the outcomes of sacrospinous hysteropexy with vaginal hysterectomy and reported the rates of buttock pain to be 3% vs. 4%, respectively. Another prospective study comparing sacrospinous hysteropexy with vaginal hysterectomy reported transient buttock pain with comparable rates between the groups<sup>86</sup>.

Some studies comparing vaginal hysterectomy with sacrospinous hysteropexy reported an increase in overactive bladder and urge incontinence symptoms in vaginal hysterectomy groups<sup>101,103,105</sup>. Another complication of pelvic organ prolapse surgeries is mesh erosion, which was reported with varying rates and the evidence in the literature regarding the mesh exposure is conflicting. Although Collinet et al.<sup>106</sup> reported a 5-fold increase in the rates of mesh exposure in vaginal hysterectomy group, other studies reported comparable mesh erosion rates between groups with and without hysterectomy<sup>107,108</sup>. Gutman & Maher<sup>29</sup> indicated that the risk of mesh erosion was approximately 4 times greater if a hysterectomy was performed at the time of sacral colpopexy compared to no-hysterectomy or subtotal hysterectomy. They extrapolated that introducing synthetic mesh transvaginally or laparoscopically after vaginal hysterectomy, or through a posterior vaginal excision appears to significantly increase the risk of mesh erosion after sacral colpopexy, probably due to exposure of the synthetic mesh to vaginal microbiota.

In the current literature, uterine-preserving procedures have been reported to associate with shorter operating time and lesser intraoperative blood loss as compared to vaginal hysterectomy<sup>103,105,107,109</sup>. A RCT comparing sacrospinous hysteropexy with vaginal hysterectomy and uterosacral ligament suspension reported that hysteropexy was associated with shorter hospitalisation, quicker recovery with more rapid return to work and longer vaginal length<sup>110</sup>. Another study comparing uterine-preserving surgery with vaginal hysterectomy reported that uterus-preservation at time of POP-surgery was associated with significantly shorter operation time<sup>109</sup>. Similarly, Chu et al.<sup>107</sup> compared women undergoing hysterectomy with uterine preservation and hysteropexy group had a shorter operating time and

less blood loss. Results of the studies investigating the operative complications reveal more favorable outcomes in women undergoing uterine preserving procedures.

#### LONG TERM OUTCOME AND RECURRENCE WITH OR WITHOUT HYSTERECTOMY

Success rates of uterine preserving procedures and hysterectomy were compared in several studies. A RCT by Dietz et al<sup>10</sup> reported the success rates of sacrospinous hysteropexy and vaginal hysterectomy as 79% vs 97%, respectively, without statistical significance. Van Brummen et al<sup>101</sup> demonstrated the success rates of these two procedures to be 89% and 93% respectively. Hefni & El-Toukhy<sup>104</sup> compared these two surgeries and the success rate of vaginal hysterectomy was 97% as compared to sacrospinous hysteropexy was 92%. Chu et al<sup>107</sup> compared hysterectomy plus mesh with uterine preservation plus mesh and demonstrated that hysterectomy was superior with a success rate of 100% as compared to sacrospinous hysteropexy with a 96% success. Similarly Neumann & Levy<sup>108</sup> reported a success rate of 95% in hysterectomy group compared to 91% in hysteropexy group. A meta-analysis by Gutman & Maher<sup>29</sup> revealed no difference in the mean objective success rate of 87% in the sacrospinous hysteropexy vs 93% in the hysterectomy group.

Long-term outcomes of surgical correction of POP and the subsequent risk of pelvic organ prolapse after hysterectomy have been controversial<sup>101,103,105</sup>. Dietz et al<sup>110</sup> reported that women who underwent a vaginal hysterectomy for uterine descent stage 2 or more had considerably fewer recurrences (3%) of the apical compartment compared to women after a sacrospinous hysteropexy (27%). Moreover, of women with stage IV prolapse who underwent hysteropexy, all recurred within a year. Symptomatic recurrent prolapses were 4-times higher in the uterine-preservation group than in vaginal hysterectomy group (23.8% vs. 6.7%;  $p = 0.023$ ). Dallenbach et al. stressed that vaginal hysterectomy was not a risk factor when preoperative prolapse was taken into account<sup>95,96</sup>. An 8-year follow-up study after vaginal hysterectomy revealed a 10% rate of vaginal vault prolapse, which correlated with severity of preoperative rectocele, not with severity of uterine descent<sup>111</sup>. In a 10-year follow-up study of 456 women who underwent a primary operation for pelvic organ prolapse, predominantly vaginal hysterectomy with colporrhaphy, the rate of reoperation for POP was reported to be 2.9%<sup>112</sup>. Contrarily, Forsgren et al.<sup>99</sup> compared women having vaginal hysterectomy due to or with concurrent prolapse repair and those having vaginal or total abdominal hysterectomy for other gynecological indications in their large population-based cohort study. They reported that the greatest risks of POP (HR 4.9, 95% CI 3.4-6.9) or SUI surgery (HR 6.3, 95% CI 4.4-9.1) were observed subsequent to vaginal hysterectomy for pelvic organ prolapse and consequently suggested that hysterectomy in general, in particular vaginal hysterectomy, was associated with an increased risk for subsequent POP and SUI surgery. Gutman & Maher<sup>29</sup> stressed that women with severe advanced prolapse desiring uterine conservation were at a high risk of recurrence and should consider alternative approaches to hysteropexy.

In previous population-based studies, hysterectomy, in particular vaginal hysterectomy, has been blamed to excess the risk of subsequent pelvic floor disorders<sup>36,37,113,114</sup>. Even though this notion has wide acceptance, prospective studies are few, small in size, and hampered by limited inference to the general population<sup>35,115</sup>. Vaginal hysterectomy is predominantly performed in women with uterovaginal

prolapse<sup>116</sup>. Large cohort studies report that vaginal hysterectomies comprises 30% of all hysterectomies, whereas 95.5% of vaginal hysterectomies are performed for pelvic organ prolapse indications<sup>117</sup>. In other words, women undergoing vaginal hysterectomy already possess the risk factors for pelvic organ prolapse and have damage to pelvic floor, which would continue to exist after the surgery, rendering them more prone to develop subsequent prolapse. Hence, it is difficult to distinguish the effects of underlying pathophysiologic pathway of the primary disease from those attributable to the harm of surgical procedure itself, which appears to be the source of bias. Nevertheless, the authors reporting the association between vaginal hysterectomy and subsequent prolapse admit that they could not fully adjust for selection bias caused by surgeons selecting patients with particular characteristics for vaginal hysterectomy which, in turn, could contribute to an overestimation of prolapse and urinary incontinence subsequent to vaginal hysterectomy<sup>99</sup>. Additionally, many studies lack data on confounders such as body mass index, smoking and obstetrical history.

#### FUTURE RESEARCH TARGETS

Prolapse surgery must consider the cost-benefit analysis, success, complication rate and morbidity of the procedure, both immediately and over the long-term. Long-term data on uterine preserving procedures are limited and the subsequent need for hysterectomy in the surgical correction of POP is not known (Grade C). Uterine preserving techniques appear to be a promising option in women with POP, particularly in those with future desire of fertility. However, long-term follow up studies with appropriate control groups are still lacking.

Randomized control trials with close long-term follow-up and quality-of-life assessment are still lacking and would be necessary to determine the benefit of such preventive techniques. Sacrospinous hysteropexy is as effective as vaginal hysterectomy and has reduced the operation time, blood loss and hospital stay as compared to vaginal hysterectomy. However, the advantage of the procedure is hampered by the higher recurrent prolapse rates than that of vaginal hysterectomy (single RCT). Moreover, the more severe the prolapsus is, the more common the subsequent prolapsus is. Thus, women with stage IV uterovaginal prolapse or cervical elongation should have a concurrent hysterectomy as part of their surgery. Vaginal hysterectomy plus uterosacral ligament suspension is superior to sacral hysteropexy in terms of reoperation rates (Level 1). Moreover, hysterectomy lowers the risks of uterine or cervical malignancy and postmenopausal bleeding, and thus, the surveillance or therapeutic costs for these situations. Careful patient selection is a crucial step prior to considering uterine conservation in women with pelvic organ prolapse and women with abovementioned diseases should not be candidates for uterine preserving procedures.

Mesh use in anterior compartment has similar outcomes between sacrospinous hysteropexy and hysterectomy, however, performing a vaginal hysterectomy at the time of sacral colpopexy increases the risk of mesh exposure four- to five times compared to uterine preservation (Grade B).

Based on the data available, decision of the kind of the uterovaginal prolapse surgery should be tailored to the patient with careful consideration and uterine preserving procedures should be reserved for patients with early stage prolapse, who desire future fertility. Vaginal hysterectomy with uterosacral ligament suspension, and thus, removing

the 'weight' and tightening the 'hammock', still appears to be rational to uterosacral hysteropexy or laparoscopic hysterectomy alone. Reattaching uterosacral and cardinal ligaments at the time of hysterectomy may help strengthen these fibers and thus minimize the risk of post-hysterectomy prolapse.

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