

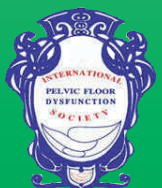
# PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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*Le Meridien Hotel in Vienna, Austria was the venue for the latest AAVIS Annual Scientific Meeting and International Pelviperineology Conference, held on September 19th-21st 2010. The meeting was a tremendous success with a high quality scientific program and wonderful opportunity for fellowship and social interaction. The full scientific content of the meeting can now be viewed via webcast which is available through the AAVIS website at [www.aavis.org](http://www.aavis.org).*

*At the meeting it was decided to change the name of the society to reflect the changes that have occurred in recent years. AAVIS is now a true multidisciplinary and international society. The new name will be the International Society for Pelviperineology. There will soon be a new website to reflect this change. Plans are now underway for the next **International Pelviperineology Conference** which will be held in Sydney during the second half of 2011. Further information will be available as soon as the program and venue are finalized.*

*The Annual General Meeting of the International Society for Pelviperineology (formerly AAVIS) was held in Vienna and new Office Bearers were elected for 2011 as follows*

*President: Professor Giuseppe Dodi, Colorectal Surgeon, Padova, Italy*

*Vice President: Dr Bruce Farnsworth, Gynaecologist, Sydney, Australia*

*Treasurer: Dr Jeff Tarr, Gynaecologist, Buderim, Australia*

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BRUCE FARNSWORTH

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# Tethered vagina syndrome: cure of severe involuntary urinary loss by skin graft to the bladder neck area of vagina

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**Abstract:** *Background* The tethered vagina syndrome is an iatrogenic condition caused by scar-induced tightness in the bladder neck area of the vagina. The classical symptom is commencement of uncontrolled urine leakage as soon as the patient's foot touches the floor on getting out of bed in the morning. With this condition, the bladder works like a watering can, due to loss of elasticity in the bladder neck area. This situation is somewhat similar to "motor detrusor instability", and so is considered as being incurable. 1990 Petros described a new strategy for treatment. The first step is to free all scar tissue from urethra and bladder neck, the second to increase the tissue in the bladder neck area of vagina, thereby restoring elasticity. *Aim:* To test the efficacy and safety of three procedures which aim to restore elasticity in the bladder neck area of vagina. *Methods:* Between Jan. 2001 and Dec. 2009 we performed a plastic operation in the bladder neck area of vagina, "I-plasty" in 13 patients, a free skin graft in 21 patients, and a bulbo-cavernosus muscle-fat-skin-flap-operation from the labium majus in 85 patients. *Results:* At 6 month review, the cure rate (Urine loss <10 gm during 24 hours) for I-plasty was 3/13 (23%), for the skin graft, 11/21 (52%) and for the bulbo-cavernosus-flap, 68/85 (80%). The mean operating time was 62 minutes (range 41 – 98 min). Exclusively, a tethered vagina repair was performed in 5 patients, and in 114 cases, an entero/rectocele repair was performed at the same time. Blood loss was minimal. The mean hospital stay was 5 days (range 2 – 9 days). All patients were mobile at least 4 hours after the operation. Three patients could not pass urine after extraction of the catheter one day after the operation, and in another, an indwelling catheter was necessary for 1 day. *Conclusion:* The bulbo-cavernosus-fat-skin-flap is the most effective way to cure severe incontinence caused by scarring due to previous vaginal or bladder neck surgery.

**Key words :** Tethered vagina; Motor detrusor instability; Integral Theory; Martius graft; I-plasty

## INTRODUCTION

The 'tethered vagina syndrome' is a iatrogenic, but as yet, not well recognized, condition. It is caused by scar-induced tightness in the middle zone of the vagina. It was described by Petros & Ulmsten in 1990, and again in 1993.<sup>1-3</sup> It is not defined as a separate entity by the International Continence Society.<sup>4</sup> This problem is somewhat similar to 'motor detrusor instability', and may arise in patients with multiple previous operations in the bladder neck area of vagina. The classical symptom is commencement of uncontrolled urine leakage as soon as the patient's foot touches the floor, indeed, often commencing as the patient rolls over to get out of bed in the morning. The patient does not complain of bed-wetting during the night. The symptoms are caused by loss of elasticity in the bladder neck area of the vagina:

the so-called 'zone of critical elasticity' (ZCE), (figure 1). Vaginal examination characteristically describes a very tight anterior vaginal wall, with thick scarring or excessive elevation evident in the area of bladder neck, (figure 2). On ultrasound, no significant movement, funnelling or opening out of bladder neck is evident during straining. Because scar tissue contracts with time, it may present many years after vaginal repair or bladder neck elevation. The anatomical basis of this operation resides in the Integral Theory,<sup>5,6</sup> which states that adequate elasticity is required in the bladder neck area of the vagina so as to allow the opposite muscle forces to operate independently of each other, fig 1. The aim of this study is to prospectively test the validity of three different operations,<sup>1-3</sup> all of which aim to restore elasticity in the bladder neck area of the vagina.

## MATERIALS AND METHODS

Prospective observational studies were performed to prove the efficacy and safety of three separate surgical procedures. The study was based on 119 patients with the above mentioned problems due to at least two bladder neck operations in the past. All patients had undergone hysterectomy. Between Jan. 2001 and Dec. 2009 we

performed in 13 patients an I-plasty, in 21 patients a free skin graft and in 85 patients a bulbo-cavernosus-muscle-fat-skin-flap from the labium majus. All patients were examined pre- and postoperatively, and operated by the first author. A follow up was performed 5-7 days, 6-8 weeks and 6 month after the operation.

Mean was 65 years (range 42 to 80), mean weight 81 kg (range 61 -105), the mean number of previous bladder neck operations was 3.4 (range 2-11), parity: mean 2.6 (range 1 -5). Mean urine loss during the 24 hour pad test was 453 ml (range 175 – 1330).

All patients presented symptoms of sudden uncontrolled urine loss on getting out of bed, or getting off a chair. Urine began running uncontrollably immediately the patient's foot touched the floor. All were tested pre-operatively with urodynamics and pre- and post-operatively with vaginal ultrasound and 24 hour pad test.

### Preliminaries

Whatever the technique used to restore elasticity, it is essential to dissect the vagina from the bladder neck and urethra, and then to free all scar tissue from urethra' bladder neck ('urethrolysis') and pubic bones.

*The I-plasty-operation* was performed in 13 patients with a co-existing cystocele. I-plasty aims to increase the volume of tissue in the bladder neck area of the vagina, thereby restoring elasticity (figure 3). To reach this aim a vertical full thickness incision was made from midurethra to at least 3-4 cm beyond bladder neck. The vaginal skin was dissected off the scar tissue and was extensively mobilized, forwards to the edges of the vaginal hammock, backwards as far possible right down to the hysterectomy scar, and as laterally as possible.

The freed tissue was brought into the ZCE and sutured transversely with interrupted sutures.

*The skin graft operation*, (figure 4), was performed in 21 Patients. After a full thickness transverse incision in the area of bladder neck the vagina, urethra and bladder neck were freed from the scar tissue. This resulted in opening

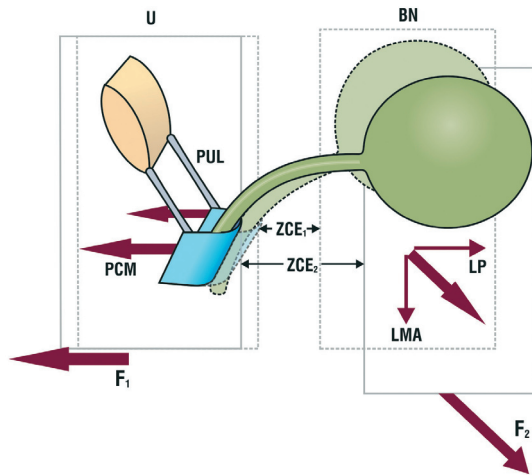


Fig. 1 – The Zone of Critical Elasticity (ZCE)  $ZCE_1 = ZCE$  at rest;  $ZCE_2 = ZCE$  during effort or micturition. Adequate vaginal elasticity at ZCE allows the oppositely acting urethral (U) and bladder neck (BN) closure mechanisms to operate.  $F_1$  represents the forward acting vector which stretches the vaginal hammock forwards to close the distal urethra (“urethral closure mechanism”).  $F_2$  stretches the proximal urethra backwards and downwards against the pubourethral ligament “PUL”, to close it (“bladder neck closure mechanism”). A scar at ZCE “tethers” the oppositely acting muscle vector forces, so that on application of a strong prolonged force, such as occurs on getting up out of bed in the morning,  $F_2$  overcomes  $F_1$ , and the posterior wall of the urethra is pulled open, exactly as occurs during micturition. Coughing exerts a short sharp force. If there is just sufficient elasticity remaining at ZCE,  $F_1$  and  $F_2$  may be able to operate separately, so no urine lost on coughing. However, if the vagina just behind the scar is gently stretched backwards by Allis forceps, all the residual elasticity is removed from ZCE, and urine is now lost on coughing. PCM = m. pubococcygeus; LP=m. levator plate; LMA=m. longitudinal muscle of the anus.  $F_2$  represents the resultant force of the LP/LMA vectors.

up of a large gap. Care was taken to effect haemostasis. A full thickness skin graft approximately 6x4 cm was taken from the lower abdominal wall. After removal of underlying fat the graft was applied to the bladder base using several ‘quilting sutures’. The graft was then trimmed as necessary, and sutured to the adjacent vaginal skin with interrupted 00 Vicryl.

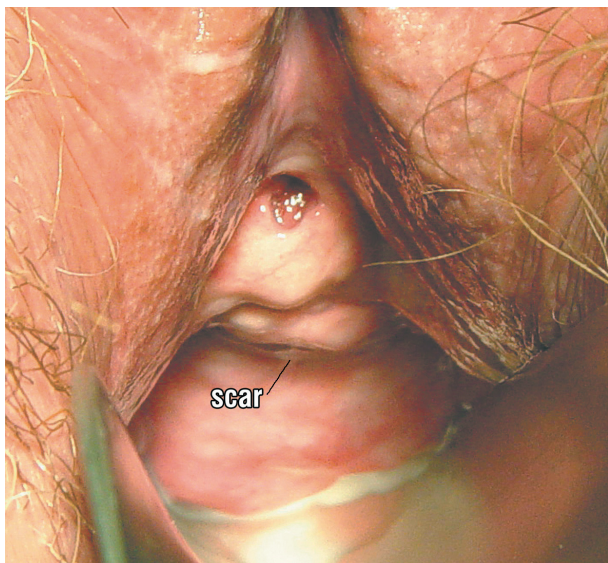


Fig. 2 – Thick scar tissue in the bladder neck area of vagina typical of the “tethered vagina syndrome”.

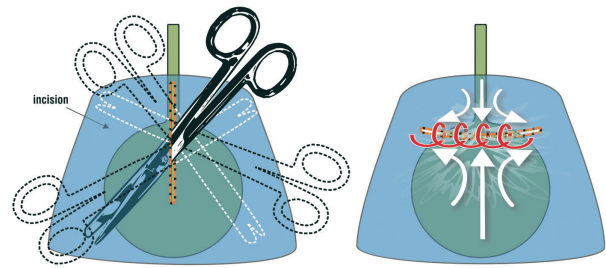


Fig. 3 – I-plasty operation A vertical incision is made in the bladder neck area of vagina. The vagina and urethra are extensively mobilized off the adjoining tissues and pelvic side wall. The incision is sutured horizontally, thus introducing fresh tissue to the site.

“Skin-on” Martius flap graft (figure 5). In 85 patients the large gap after scar dissection was covered with a bulbocavernosus-muscle-fat-skin-flap from the labium majus. A 5x3 cm ellipse of vulval skin was created over the labium majus and transferred with underlying fat and muscle through a tunnel into the dissected area. The tunnel must be sufficiently large to avoid constriction of the vascular pedicle. The graft was attached to the adjacent vaginal skin.

## RESULTS

The cure rates (Urine loss <10 gm during 24 hours) were, for I-plasty 3/13 (23%), for the skin graft 11/21 (52%) for the bulbocavernosus-flap and 68/85 (80%). The mean operating time was 62 minutes (range 41 – 98 min).

Exclusively a tethered vagina repair was performed in 5 patients, and in 114 cases, an entero/rectocele repair was necessary at the same time. No serious bleeding was observed.

The mean hospital stay was 5 days (range 2 – 9 days). All patients were mobilized at least 4 hours after the operation. Three patients could not pass urine after removal of the catheter one day after the operation and further permanent catheter was necessary for another 1 day.

## DISCUSSION

The International Continence Society (ICS) considers that ‘Motor Detrusor Instability’ is not surgically curable, and beyond treatment with anticholinergics (ineffective for this condition), little can be done to help patients with such a condition. There is no ICS definition for the ‘tethered vagina

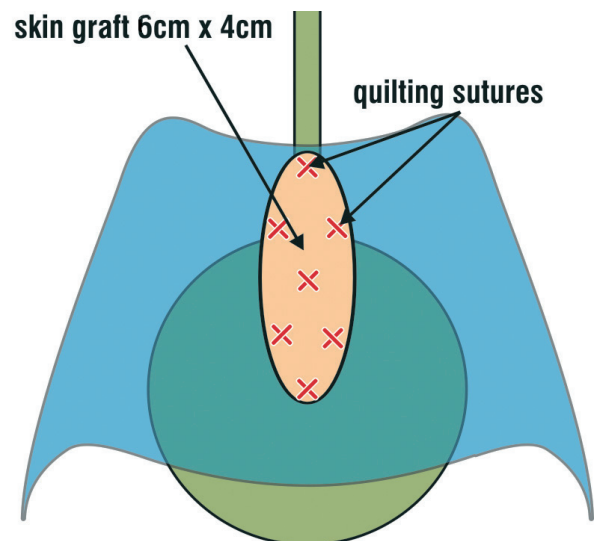


Fig. 4 – Skin graft to bladder neck area of vagina is attached by quilting sutures.





Fig. 5 – Martius skin graft . The graft is brought through a hole in the lateral vaginal wall. The skin is sutured to the edges of the vagina. The wound from the site of the graft is to the left. This is sutured with subcuticular 00 Dexon sutures

syndrome'. The 'tethered vagina syndrome'<sup>1</sup> is conceptually similar to "motor detrusor instability", in that the urine loss is massive and uncontrolled. As the mechanism for opening out the posterior urethral wall is mechanical, urgency is frequently not found with this condition. The cause is iatrogenically induced fibrosis in the bladder neck area of the vagina. It is far more common in regions where surgeons are taught to remove significant amounts of vaginal skin during vaginal repairs.

The explanation for cure of this condition by restoration of elasticity in this area may be explained by reference to a previously described hypothesis<sup>5,6</sup> (figure 1): there are separate urethral and bladder neck closure mechanisms. In the former, forward vectors stretch the underlying vagina on each side to close the urethra from behind. In the latter, backward/downward vectors stretch the proximal vagina and bladder base backwards and downwards to close off the bladder neck. Adequate elasticity is required for these separate movements. If fibrosis occurs at this critical point then the opportunity for independent movement is lost and the stronger posterior force overcomes the weaker anterior force. As a result the urethra is forced open (figure 1).

Often there is very little stress incontinence. The reason is that cough creates short sharp fast switch contractions, and there may be just sufficient elasticity at ZCE to prevent urine leakage on coughing. Getting out of bed in the morning stretches ZCE far more as the pelvic floor contracts to support all the intra-abdominal organs. The classical symptom is commencement of uncontrolled urine leakage as soon as the patient's foot touches the floor. Often there is no urgency, as the cause is mechanical: a scar at ZCE 'tethers' the more powerful backward forces 'F2' (figure 1) to the weaker forward forces 'F1', so the bladder is pulled open as in micturition.

To cure this condition the aim must be to restore elasticity in the bladder neck area of the vagina, the 'zone of critical

elasticity' (ZCE), so that 'F1' and 'F2' can act independently of each other. As a first step, it is essential to dissect the vagina from the bladder neck and urethra, and to free all scar tissue from urethra, bladder neck and pubic bones ('urethrolysis').

There must be no scar tissue anchoring the bladder neck to the pelvic side wall.

The second step is to bring fresh tissue to the bladder neck area of the vagina to restore elasticity, and prevent new scar creation in this area. Our results demonstrate that the I-plasty operation cures less than one fourth of the patients. Therefore we decided not to continue with this method in cases where there is obvious tissue deficit. It is still the simplest technique but only indicated if there is no tissue deficit. The I-plasty works very well in patients where the cause is excessive bladder neck elevation, for example, after a Burch colposuspension. If there is a severe shortage of tissue or a large gap after dissection, this defect has to be covered with a skin graft or a flap.

The results with free skin graft are much better than with I-plasty, but a cure rate of about 50% is still not convincing. A free graft is problematical because there is no blood supply.

Therefore up to one third may not 'take', or the graft may shrink excessively.

The bulbocavernosus-flap operation is technically more challenging, but brings its own blood supply. This is in our opinion the explanation for the high cure rate. Using this technique it is very important not to compromise the blood supply of the graft. Therefore the pedicle must be thick enough to prevent too much compression to the vessels in the pedicle, and the space created in the lateral vaginal wall for passage of the graft must be adequate.

## CONCLUSION

The results appear to sustain the hypothesis that adequate tissue elasticity is required for the separate function of the bladder and urethral the closure mechanisms.<sup>5,6</sup> Application of a muscle-fat-flap to the zone of critical elasticity after scar dissection restores the tissue elasticity in the bladder neck area of vagina and continence in about 80% of patients.

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# Arc to Arc minisling 1999: a critical analysis of concept and technology

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**Abstract:** The aim is to critically review the Arc to Arc minisling (Palma's technique), a less invasive midurethral sling using bovine pericardium as the sling material. **Methods:** The Arc to Arc minisling, using bovine pericardium was the first published report of a minisling, in 1999. The technique was identical to the "tension-free tape" operation, midline incision and dissection of the urethra. The ATFP (white line) was identified by blunt dissection, and the minisling was sutured to the tendinous arc on both sides with 2 polypropylene 00 sutures. **Results:** The initial results were encouraging, with 9/10 patients cured at the 6 weeks post-operative visit. However, infection and extrusion of the minisling resulted in sling extrusion and removal, with 5 patients remaining cured at 12 months. **Critical analysis and conclusion:** The Arc to Arc minisling was a good concept, but failed because of the poor technology available at that time. Further research using new materials and better technology has led to new and safer alternatives for the management of stress Urinary Incontinence.

**Key words:** Urinary stress incontinence; Arc to Arc minisling, Bovine pericardium

## INTRODUCTION

The understanding of stress urinary incontinence (SUI) pathophysiology has consistently improved over the past decade, and has resulted in the development of many surgical techniques. Based on the Integral Theory, Petros and Ulmsten proposed the tension-free vaginal tape (TVT). According to this theory a midurethral tape can stabilize the urethra during straining without modifying the urethral mobility.<sup>1,2</sup> Despite the good cure rate reported for TVT, major complications as injuries to bowel and major blood vessels have been described.<sup>3</sup>

As an alternative to the TVT procedure, the transobturator tape (TOT) technique was developed by Delorme in 2001, to reduce the perioperative complications related to the penetration in the retropubic space.<sup>4</sup> Several short-term studies reported high cure rates and low complication rates for TOT, and discussed the mechanism responsible for the success of this treatment based only on preoperative urodynamic findings and postoperative clinical examination, uroflowmetry and the cough test. The continence rate with the transobturator approach has been similar to those obtained with the transvaginal retropubic approach.<sup>5</sup> Most of the described complications are related to the blind nature of these procedures.<sup>6</sup>

The aim of this paper is to report the initial results and complications of the Arc to Arc minisling (ATAM); then to critically analyse the ATAM technique, the materials used,<sup>7</sup> and finally, to compare and contrast the ATAM as regards subsequent minislings.

## MATERIALS AND METHODS

### Patients

An open prospective non-randomized clinical trial involving SUI patient was conducted after receiving the approval of the Hospital Ethics Committee. Ten patients (mean age –58 years) underwent the Arc to Arc minisling (ATAM) procedure for SUI. The procedures were performed between March 1997 and October 1998.

### Study design

All patients were given a routine work-up for incontinence, including history, physical examination, stress test and urodynamic investigation. Urodynamic evaluation was performed with 2 urethral catheters (one 10F for filling and another 4F for bladder pressure measurement). A rectal 4F

catheter-balloon was placed above the anal sphincter to obtain abdominal pressure. The test included water cystometry, Valsalva leak point pressure (VLPP) assessment, which was performed with a intravesical volume of 200ml and Valsalva maneuvers, and pressure-flow study.

The stress test was positive in all patients. Patients who presented involuntary detrusor contractions during bladder filling or Maximum flow (Qmax) less than 15ml/s and/or post void residual urine of more than 20% of the volume voided were excluded from the study but those with irritative symptoms without urodynamically proven involuntary contractions were included. Although urodynamically proven detrusor instability does not have a significant effect on surgical outcome, this decision was based on the concept regarding the postoperative improvement of sensory urgency, as described previously.

Follow-up was performed at 1, 6 and 12 months. At these recalls, the patients were questioned about presence of spontaneous voiding, involuntary urinary leakage, lower urinary tract symptoms, vaginal and suprapubic pain, and underwent stress test. The patients were considered subjectively dry in the absence of incontinence, improved, when the incontinence episodes were less than once in two weeks and when incontinence episodes were superior to once a week the patients were recorded as subjective failures.

### Surgical technique

The procedure is performed with the patient in the lithotomy position. A 18F Foley catheter is introduced for safety. A inverted U vaginal incision is made at the level

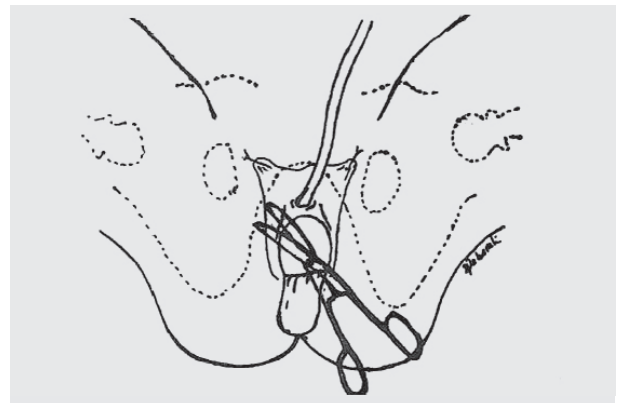


Fig. 1 – An inverted U shape incision is made and a metzenbaum scissors is used to dissect the vaginal wall (original illustrations).

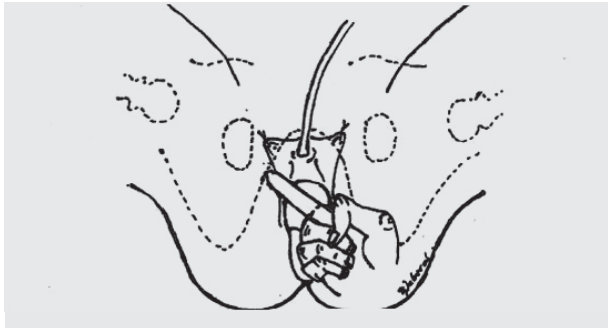


Fig. 2 – Digital identification of the Arcus tendineus fascia pelvis (ATFP).

of the bladder neck. The vaginal wall is dissected from the underlying periurethral fascia, bilaterally to the inferior ramus of the pubic bone. The urethra is identified and a small perforation of the endopelvic fascia was made at the border of the ascending ramus of the pubic bone bilaterally (fig 1).

Next, the surgeon's index finger is introduced in the Retzius space towards the obturator internus muscle in order to identify the white line (fig 2).

Once the white line is identified, 2 polypropylene 00 stitches are placed in the tendinous arc at both sides (fig 3).

Then a minisling of bovine pericardium 6 cm long and 2 cm width is used to create a ATAM, providing back board support to the urethra (fig. 4).

The vaginal incision is closed in the usual manner and and a Foley catheter is left in place overnight.

## RESULTS

There were no vascular or visceral lesions, nor urinary retention.

Nine out of 10 patients were cured of the incontinence at the first post operative month. After 2 months 2 patients presented infection of the minisling that were removed, late complications included 3 more patients that presented extrusion of the sling at 6 month. The remaining five patients did well and were continent after 12 months. All but one patient that has the minisling removed were incontinent account for 50% of good results after one year follow-up.

## DISCUSSION

The understanding of physiopatological concepts of stress urinary incontinence has consistently improved over the last years and their applications have lead to the development of many surgical techniques.

In the past decade minimally invasive synthetic slings, such as TVT, have become the preferred technique, replacing

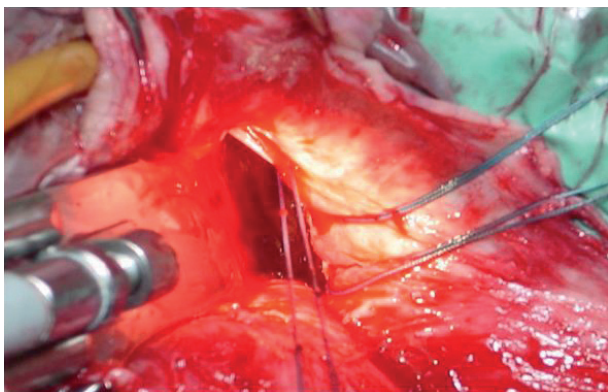


Fig. 3 – Sutures placed in the white line (ATFP).

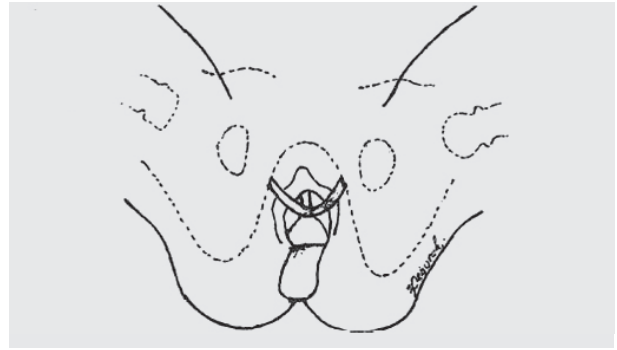


Fig. 4 – Suburethral minisling anchored to the obturator internus muscles at the level of tendinous arc bilaterally.

the Burch colposuspension for the treatment of stress urinary incontinence.<sup>8</sup>

Various factors have contributed to the popularization of slings, among them, the fact that needle suspensions have not stood the test of time, together with the various paradigm changes and the evolution of biomaterials.<sup>1</sup>

Synthetic slings present several advantages over autologous slings.

Harvesting the graft, a time consuming step of the conventional technique is eliminated along with its related morbidity and a well standardized procedure is obtained. Besides it may be performed under local anesthesia as an outpatient procedure. Not to mention less post-operative pain and shorter seek leave.<sup>2</sup>

On the other hand synthetic slings brought about new complications related to the tape and even fatal complications.<sup>3</sup>

As an alternative to the TVT procedure, the transobturator tape (TOT) technique was developed by Delorme in 2001. This procedure reduces per operative complications related to the penetration in the retropubic space.<sup>4</sup> Several short-term studies reported high cure rates and low complication rates for TOT.

But, as with any form of surgery, adverse events can occur, and the surgeon should be aware of the common complications that can accompany sling surgery, and how to best manage them.<sup>3</sup>

The most common complication reported with sling surgery is bladder perforation during needle passage. Bladder perforation usually occurs on the side opposite the surgeon's dominant hand, and with greater frequency in patients undergoing repeat procedures.

Many studies report an incidence of bladder perforation of between 1–15%, and an average perforation rate of 5%. Management of bladder perforation includes recognition of the injury during cystoscopy, withdrawal and repositioning of the needle and a Foley catheter for 24 to 48 hours.

Transobturator sling, on the other hand present a lower rate of bladder and urethral injury during the needle passage, which generally occurs in less than 1% of patients, usually during the learning curve of the procedure.

Bleeding is another important complication and can occur mainly during needle passage. Bleeding upon entry into the retropubic space can be difficult to manage, as exposure of the perivesical venous plexus is difficult.

Care must be taken during lateral replacement of needles to avoid injuring the external iliac vein for vascular injuries are usually caused by excessive lateral passage of the needle.

Despite the good results described worldwide, with cure rates of more than 80% of the cases, some major complications like bowel, vascular injuries and deaths were described.<sup>3</sup>

Most of the described major complications are related



to the blind nature of these procedures. <sup>6</sup> In fact, reducing needles diameter alone was not enough to overcome these problems that occurred even with experimented surgeons.

In an attempt to reduce major complications, mainly deaths, anatomical reconstruction of the urethral support placing a low- tension suburethral tape anchored to the obturator internus muscles bilaterally at the level of the tendineous arc, the Tissue Fixation System (TFS) were described. <sup>6</sup> By doing so, bowl lesions and major vessels injury are avoided.

A decade ago, we used this good principle, but poor technology in biomaterials at that time, lead to less than optimal results due to an unacceptable extrusion rate.

Insisting in the principle of restoring the urethropelvic ligament, we used the porcine small intestine submucosa (SIS) in 25 patients in 2001. <sup>9</sup>

Long term results with arc to arc minisling using swine intestine submucosa, produced 60% of good results after six years follow-up. <sup>10</sup>

Although the concept was good and the biomaterial improved, the absence of an appropriate anchoring system and delivery instruments were a major drawback to its widespread use.

The first commercially available kit, was the Tissue Fixation System (TFS) described by Petros. This kit contained two polypropylene anchors and a multifilament mesh. Preliminary report disclosed similar cure rates and fewer complications when compared to TOT. <sup>6</sup> This preliminary studies reported no pain, mesh exposure, vascular or visceral complications. No doubt a remarkable achievement.

Long term follow-up with TFS disclosed good cure rates after 3 years (11) and good technology available today allowed for using the TFS System to perform uterus sparing procedures as well (12) .

Many other devices are available now, some of them depending on mesh integration for the fixation, like TVT-Secur and therefore presenting until 60% of failure in the first post-operative year. <sup>13</sup>

Primary fixation of mini slings is a key issue for success, and our experimental data disclosed that Ophira and TFS presents the best primary fixation when copared to others minisling. <sup>14</sup>

But needless to say that even minimally invasive procedures require a learn period and failure is an important complication as well.

At this point in time, all we can say is that after many years or research and development we now have good concepts and good technology.

## CONCLUSION

Minisling are here to stay and evidences are being building to determine its indications in the surgeon's armamentarium.

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# Two year outcome data on efficacy and quality of life following mesh augmented vaginal reconstruction

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**Abstract:** Objective: To evaluate quality of life 2 years following mesh augmented vaginal reconstructive surgery. Methods: Patients who underwent a mesh augmented vaginal reconstructive surgery during an 18 month period were invited to participate. Subjects filled out validated quality of life questionnaires (PFDI, PFIQ and PISQ), underwent POP-Q examination and were asked if they would have the surgery over again and if they would recommend it to a friend. Results: Eighty-one patients underwent a mesh augmented repair; 38 (46.9%) consented to return for follow-up. The average length of follow-up was 25 +/- 6 months. The QOL measures showed improvement comparing pre-operative to post-operative scores (PFDI: 239.2 vs. 26.5; PFIQ: 152.2 vs. 4.8). Eighty-four percent said they would have the surgery again and 95% would recommend it to a friend. Conclusion: We found an overall improvement in patients' quality of life, subjective and objective outcome 2 year post-operative, following mesh augmented vaginal reconstruction.

**Key Words:** Mesh, Prolapse, Quality of Life, Vaginal reconstruction

## INTRODUCTION

A woman has an 11% lifetime risk for pelvic organ prolapse and a third of patients who undergo corrective surgery have repeat procedures.<sup>1</sup> Methods of repair vary greatly and there is limited evidence to help guide surgeons to determine which techniques have better outcomes. The high rates of failure with traditional colporrhaphy<sup>2</sup> have led to the use of graft materials to augment pelvic floor reconstruction. This has led to the debate as to what graft material is best? To help answer this question one has to look at both objective outcomes as identified by the surgeon as well as patient perception regarding success of the surgery and improvement in their quality of life. Our study presented here evaluates the objective, subjective and quality of life outcomes for a single surgeon's use of synthetic mesh over an eighteen month period for the correction of pelvic organ prolapse.

## MATERIALS AND METHODS

After institutional review board approval, a cohort of subjects who underwent polypropylene mesh augmented vaginal reconstruction between June 2005 and December 2006 were asked to participate in the study. Vaginal reconstructive surgeries included any prolapse repair of the anterior, posterior or apical compartment using mesh. Based on the practice patterns of the primary surgeon, this included the use of polypropylene mesh in one of two ways. The graft was positioned in the appropriate compartment(s) in the vagina and secured utilizing suture or tension free mesh arms brought through the obturator foramen or ischioanal fossa to achieve surgical correction of the prolapse. Our "traditional" anterior repairs included the use of a 10 X 15 cm polypropylene mesh (Polyform, Boston Scientific Corp., Boston MA or Pelvitex, Bard Corp., Atlanta, GA) cut in a trapezoidal fashion, anchored to the arcus tendineus fascia pelvis from the level of the ischial spines to the bladder neck. The alternative technique for anterior repair utilizes a prefabricated piece of polypropylene mesh with arms as described above using what is commonly referred to as a "lift kit" (Avaulta Anterior, Bard Corp., Atlanta, GA). Our "traditional" posterior repairs included the use of a 10 X 15 cm polypropylene mesh (Polyform, Boston Scientific Corp., Boston MA or Pelvitex, Bard Corp., Atlanta, GA) cut in a "top hat" like fashion with the 15 cm side of the mesh anchored to

the sacrospinous ligaments bilaterally and the distal portion of the mesh anchored to the levator fascia laterally and the rectovaginal septum distally. The alternative technique for posterior repair utilizes a posterior "lift kit" placed in the ischioanal fossa as previously described (Avaulta Posterior, Bard Corp., Atlanta, GA).

Each patient underwent a pelvic exam with prolapse staging utilizing the Pelvic Organ Prolapse Quantification scale (POP-Q)<sup>3</sup> pre-operatively, at 3 months and an average of 25 +/- 6 months post-operatively. At the initial pre-operative and 2 year post-operative visits, patients filled out validated questionnaires. Pre-operative and post-operative questionnaires included the long and short form versions, respectively of the Pelvic Floor Distress Inventory (PFDI) and the Pelvic Floor Impact Questionnaire (PFIQ).<sup>4</sup> Both of these questionnaires contain 3 domains assessing prolapse, colorectal and urinary dysfunction. At the 2 year follow-up visit patients additionally filled out the Prolapse and Incontinence Sexual Function Questionnaire short form (PISQ-12).<sup>5</sup> Subjective evaluation was based on three questions asked to the patients at an average of 25 +/- 6 months post-op: 1) Would you do the surgery all over again? 2) Would you recommend the surgery to a friend? 3) In terms of your prolapse how do you feel; 1: markedly worse, 2: worse, 3: same, 4: improved, 5: markedly improved? Patients who did not return for participation in the study, were contacted by telephone and were specifically asked questions 1 and 2. These two questions were chosen because of their ability to have a concise yes or no answer.

A retrospective chart review was performed to collect the following data for analysis: patient demographics, POP-Q results, PFDI and PFIQ scores, post-operative physical examination findings, additional surgical interventions and length of follow-up. Independent T test, Fisher Exact test and Pearson Chi Square test were used to determine if there was any demographic data associated with surgical failure. Mean, median and standard deviations were calculated for objective and subjective data.

## RESULTS

Eighty-one patients, during the study period had a mesh augmented vaginal repair. Demographic data for all patients are listed in Table 1. Thirty-eight patients (46.9%) consented to return for this study and were included in the analysis. Of these 38 patients, the mean age at the time of surgery was

TABLE 1 – Demographics for all 81 Patients

Age (yrs) (Mean (St Dev) / Range)	58 (10)	38-84
BMI kg/m <sup>2</sup> (Mean (St Dev) / Range)	29.1 (5.5)	19.7-50.1
Parity (Mean (St Dev) / Range)	3.3 (1.8)	0-10
Tobacco users (N / %)	18	22
Premenopausal (N / %)	17	21
Postmenopausal (N / %)	64	79
HRT (N / %)	8	10
Vaginal estrogen only	3	4
Oral estrogen only	2	2.5
Estrogen patch	1	1.2
Vaginal and oral estrogen	2	2.5
Race (N / %)		
Not recorded in chart	30	37
White	40	49
African American	3	4
Hispanic	8	10
Diabetes Mellitus	9	11
Previous Hysterectomy	24	30
Previous prolapse or incontinence procedure	13	16
Urodynamics (UDTs)		
No UDTs pre-op	14	17
UDTs pre-op	67	83
Detrusor Overactivity Pre-op	15	18.5
Pre-op Stress Incontinence by UDT	37	46

BMI – Body mass index; HRT – Hormone replacement therapy

59 +/- 9.9 years. Most patients were Caucasian (84%), postmenopausal (84%), and did not have a hysterectomy prior to the vaginal reconstructive procedure (68%). The average length of follow-up was 25 +/- 6 months. Five patients had an anterior polypropylene mesh augmented repair only: 4 were performed using the Avaulta Anterior lift kit and 1 was performed using a Polyform mesh suture based repair. Seven patients underwent a posterior polypropylene mesh augmented repair only: 4 were performed using the Avaulta Posterior lift kit and three using a Polyform mesh suture based repair. Twenty-six patients had a combined anterior and posterior polypropylene mesh augmented repair: seventeen patients had a combined graft augmented suture based repair: 13 were performed with Polyform and 4 were with Pelvitex. Of the remaining 9 patients, Avaulta Anterior and Posterior lift kit was placed in 8 patients and 1 patient had an anterior repair with Polyform and a site-specific posterior repair.

The mean and median pre-operative, three month post-operative and two year post-operative POP-Q points of the thirty-eight patients seen for follow up are found in Table 2.

TABLE 2 – POP-Q points for pre-operative, 3 month post-operative and 2 year follow-up visit (for patients who had long term follow-up (N=38).

POP Q Points	Pre-op Mean(std dev)/Median		3 mos Post-op Mean(std dev)/ Median		2 year Follow-up Mean (std dev)/ Median	
Aa	0.89(1.89)	1	-2.72(0.61)	-3	-1.92(1.24)	-2
Ba	1.39(2.36)	1.5	-2.66(0.75)	-3	-1.47(1.18)	-2
Ap	-1.53(1.47)	-2	-2.95(0.23)	-3	-2.89(0.31)	-3
Bp	-1.45(1.52)	-2	-2.95(0.22)	-3	-2.82(0.46)	-3
C	-3.04(4.17)	-4.75	-7.08(3.20)	-7.5	-6.30(1.39)	-6
D	-6.33(1.74)	-6.5	-9.40(1.14)	-9	-7.00(1.00)	-7
TVL	9.79(0.84)	9.75	9.21(1.02)	9	8.22(1.18)	8
GH	4.42(1.19)	4.25	2.78(0.63)	3	3.20(0.72)	3
PB	3.73(1.18)	3.5	4.46(0.74)	4.75	4.14(0.79)	4

Of the 3 patients with stage 3 prolapse, 2 had undergone a posterior repair only and presented with a stage 3 anterior prolapse at their latest follow-up visit. For the purposes of our analysis these 2 patients were counted as having recurrent prolapse although the initial defect repair was in a different compartment. Two of these three patients with stage 3 prolapse said they would have the same surgery again and the other patient said she was unsure.

All of the eleven patients who had stage 2 recurrent prolapse were found to have the defect in the anterior compartment. One patient had stage 2 prolapse in both anterior and posterior compartments. Another patient initially underwent a posterior repair and was found to have stage 2 anterior prolapse at her two year follow-up visit. She was also added as another patient with recurrent prolapse. In response to our subjective quality of life measures nine of these subjects said they would have the surgery again, one said she would not have the surgery again and one said she was unsure. All fourteen of the patients considered to have recurrent prolapse (defined as greater than or equal to stage 2 at their 2 year follow-up visit) said they would recommend the surgery to a friend. In all subjects with stage 2 prolapse at follow-up the greatest point of descent on the POP-Q was an Aa of -1. There was a trend suggesting that those who had recurrent prolapse or were our surgical failures were more likely to have had previous urogynecologic procedures. (p=0.052) There were no other associations with surgical “failure” (Table 3). The information in table 3 is not stable due to the small sample size.

Of the forty-three patients who did not participate in the study, twenty-one were able to be reached by phone. Twenty stated they would have the surgery again and would recommend it to a friend. Table 4 demonstrates the mean and median scores from the quality of life surveys of the patients who followed-up 2 years post-op. Twenty-seven out of thirty-eight patients filled out the long form version of the PFDI and PFIQ pre-operatively and thirty-five of thirty-eight patients filled out the short version of these questionnaires post-operatively. The median pre-operative PFDI and PFIQ was 256.7 and 143.9 (long form) respectively and post-operatively 29.1 and 4.8 (short form) respectively. This demonstrates an overall improvement in quality of life symptoms. The PISQ-12 was filled out by twenty-four patients post-operatively with results seen in Table 4. Twelve were not sexually active at the time of follow-up and two did not complete the survey. We did not have pre-operative PISQ-12 scores.

There were two subjects who underwent additional surgery for recurrent prolapse during the two year follow-up period. There was one mesh erosion found in the thirty eight patients (2.6%) who followed up at two years. Eighty four percent of these patients said they would have the surgery again and 95% would recommend the surgery to a friend. The median score for satisfaction was 5: markedly improved.



TABLE 3 – Associations with Surgical Failure

	Stage of Prolapse at 2 Year Visit *		P-Value
	0 or 1 (N=24)	≥2 (N=14)	
<b>Race</b>			
Caucasian (N/%)	21 (87.5)	11 (78.6)	
African American (N/%)	0 (0.0)	2 (14.3)	
Hispanic (N/%)	3 (12.5)	1 (7.1)	0.153
<b>Age (yrs) (Mean)</b>	57.33	62.57	0.114
<b>BMI (kg/m<sup>2</sup>) (Mean)</b>	27.94	29.71	0.325
<b>BMI</b>			
Obese (BMI ≥30) (N/%)	7 (29.2)	7 ((50.0)	
Not Obese (BMI<30)	17 (70.8)	7 (50.0)	0.199
<b>Tobacco Users</b>			
Yes (N/%)	5 (20.8)	1 (7.1)	
No (N/%)	19 (79.2)	13 (92.9)	0.383
<b>Postmenopausal</b>			
Yes (N/%)	20 (83.3)	12 (85.7)	
No (N/%)	4 (16.7)	2 (14.3)	1.000
<b>Hormone Replacement Use</b>			
Yes (N/%)	2 (8.3)	3 (21.4)	
No (N/%)	22 (91.7)	11 (78.6)	0.337
<b>Diabetes Mellitus</b>			
Yes (N/%)	1 (4.2)	3 (21.4)	
No (N/%)	23 (95.8)	11 (78.6)	0.132
<b>Previous Hysterectomy</b>			
Yes (N/%)	8 (33.3)	4 (28.6)	
No (N/%)	16 (66.7)	10 (71.4)	1.000
<b>Previous prolapse or incontinence procedure</b>			
Yes (N/%)	3 (12.5)	6 (42.9)	
No (N/%)	21 (87.5)	8 (57.1)	0.052
<b>EBL (Mean)</b>	315.22 ml	371.43 ml	0.476
<b>EBL &gt;500 ml</b>			
Yes (N/%)	4 (17.4)	3 (21.4)	
No (N/%)	19 (82.6)	11 (78.6)	1.000

\* Stage 2 or greater considered recurrent prolapse or surgical failure  
 BMI – Body Mass Index  
 EBL – Estimated Blood Loss at time of reconstruction

DISCUSSION

In surgery for pelvic organ prolapse, there is increasing evidence in support of the use of mesh when correcting pelvic floor defects.<sup>66-11</sup> This management is supported by a recent Cochrane Review reporting a higher risk of recurrent prolapse after anterior colporrhaphy than after mesh repairs.<sup>72</sup> The availability of “lift kits” has resulted in more surgeons performing mesh augmented repairs for pelvic organ prolapse. This study demonstrates an overall improvement in the quality of life and outcome variables two years post-operative following mesh augmented vaginal reconstruction in a busy urogynecology practice. Many complications can occur from the use of mesh in the vagina. These complications include sexual dysfunction, de novo stress urinary incontinence or fecal incontinence, voiding dysfunction, pain, failure, and reoperation risk.<sup>12-17</sup> Any of these complications can affect a person’s quality of life. A recent warning by the Food and Drug Administration describes many of these risks (<http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html>). Subjective and objective data in this study demonstrate an overall improvement in quality of life following these procedures and the majority of

TABLE 4 – Results of Questionnaires Pre-operatively and at 2 year Follow-up visit for the Patients who had long term follow-up

PFDI		Pre-op N=27 (Long Forms)		2 yr follow N=35 (Short Forms)	
	POPDI-6 Mean (std dev)/Median	103.8(57.2)	10E07.7	14.0(21.0)	8.3
	CRADI-8 Mean (std dev)/Median	72.0(67.8)	60.1	14.8(18.2)	7.85
	UDI-6 Mean (std dev)/Median	89.5(65.2)	72.2	18.9(21.0)	8.3
	Total Mean (std dev)/ Median	265.3(159.7)	256.7	48.5(50.8)	29.1
PFIQ	UIQ-7 Mean (std dev)/Median	108.4(91.5)	98.35	7.9(12.8)	0
	CRAIQ-7 Mean (std dev)/Median	57.3(81.3)	21	9.2(23.3)	0
	POPIQ-7 Mean (std dev)/Median	57.0(81.8)	20.4	3.9(9.8)	0
	Total Mean (std dev)/ Median	222.6(214.7)	143.9	21.3(37.6)	4.8
PISQ 12 N=24*		Not Done	Not Done	88.1(19.6)	92.9

\*12 patients were not sexually active at time of 2 year f/up and 3 did not complete any surveys

patients would do their procedure again with the knowledge of their experience since the surgery. These results infer that these risks are likely minimal. Previous studies have defined failure as a POP-Q staging of 2 or greater. Stage 2 prolapse is defined as any point between -1 and +1, relative to the hymenal ring. In our study, all patients with Stage 2 prolapse at follow-up had no point of descent greater than -1. Most of these patients were unaware of any recurrence and were pleased with the results of their surgery based on the subjective questions put forth to them. This might lead us to redefine failure from a subjective point as opposed to a purely objective one. Of the three patients with stage 3 recurrent prolapse, two of them had a failure in the compartment not operated on at the time of their initial surgery. It is often a struggle in the field of urogynecology to decide whether to prophylactically repair an otherwise asymptomatic defect. Although these numbers are small, this might lead us to consider repairing even minor defects in compartments opposite to those which appear to be causing the patients complaints. More evidence is needed in this area. Some of the limitations of this study include the retrospective nature of our data as well as the limited percentage of patients who followed up at two years. Although our rate of return was comparable and acceptable compared to other studies we would have liked to have seen a greater long term follow up rate. Other limitations include the varying brands of mesh as well as different techniques employed to perform these repairs. Our practice now uses the short form versions of the PFDI and PFIQ and thus made it difficult to show an exact comparison of data secondary to the use of the long form versions used previously. Unfortunately, at the time of this study, the PISQ-12 surveys were not filled out by our patients pre-operatively. It is now our practice to include this survey in our pre-operative packet distributed to all patients at their initial office visit. We can not make any assumptions with regards to patients’ change in sexual function following graft

augmented repairs. However, we can say that other similar studies have demonstrated similar results for the overall PISQ-12 score as our study.<sup>18,19</sup> The strength of our study is its long term follow-up after the use of polypropylene mesh for a single surgeon in vaginal reconstruction. Subjective questions and objective validated questionnaires along with other outcome variables demonstrate overall satisfaction and efficacy.

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# Common genitourinary fistulae at a referral hospital in Saudi Arabia

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**Abstract:** Objective: To evaluate genitourinary fistulae cases, including factors, management, and outcome. Material and Methods: A retrospective chart review of 10 genitourinary fistulae cases at a referral hospital. Results: Ten patients: 4 vesicouterine fistulae (VUF), 4 vesicocervical fistulae (VCF), and 2 vesicovaginal fistulae (VVF). All VUF were complications of cesarean section (CS). Three VCF were secondary to cesarean subtotal hysterectomy, and one was subsequent to CS. One VVF was a complication of hysterectomy, and the other was secondary to a road traffic accident. Three VUF cases underwent surgical repair and one had fulguration. One VCF underwent surgical repair, and 3 had conservative management. One VVF underwent surgical repair, and one underwent fulguration. All patients were asymptomatic during follow up. Conclusion: The majority of cases were CS related, one was post gynecologic surgery, and one was related to an external injury. None were complications of prolonged or instrumental delivery. All cases were cured.

**Key Words:** Fistula, Genitourinary, Saudi Arabia, Urinary incontinence.

## INTRODUCTION

Genitourinary fistulae can be classified anatomically, etiologically,<sup>1</sup> or by surgical size.<sup>2</sup> It is generally accepted that surgical fistulae occur after unrecognized incision in urinary structures, pressure necrosis, devascularization, or a combination of these mechanisms.<sup>3</sup> Obstetric fistulae occur because of damage during the course of prolonged labor, instrumentation during delivery, or as consequences of cesarean section (CS).<sup>3</sup> Historically, most vesicovaginal fistulae (VVF) were the result of birth trauma; accordingly, they remain the major urinary fistulae and the most common cause of urinary incontinence in many underdeveloped nations.<sup>4</sup> In developed nations, genitourinary fistulae usually occur as rare complications of gynecologic or other pelvic surgery, or of radiotherapy.<sup>5</sup> In North America, for example, the most common cause of VVF is injury to the bladder during hysterectomy,<sup>6</sup> and the risk is reported as being more than 1% after radical surgery and radiotherapy for gynecologic malignancies.<sup>7</sup> Although vesicouterine fistula (VUF) is an uncommon condition comprising only 1% to 4% of all urogenital fistulae, its prevalence has been rising in recent decades<sup>8</sup> because of the increased incidence of CS. VUF may develop immediately after a CS, or may not be observed until the late puerperium.<sup>9</sup> Management of genitourinary fistula is primarily surgical.<sup>6</sup> Nevertheless, conservative treatment or cystoscopic fulguration have met with some success.<sup>9,10</sup> The goal of our study was to determine the number of genitourinary fistula cases in our facility over 10 years, evaluate their causes, and assess their management and outcome.

## MATERIALS AND METHODS

This was a retrospective review of all cases of genitourinary fistula between January 1995 and May 2006 at the Security Forces Hospital (SFH), Riyadh, Kingdom of Saudi Arabia (KSA). SFH is a referral hospital with approximately 500 beds. Through the medical coding system, all cases of genital fistula, urinary fistula, VVF, vesicocervical fistula (VCF), and VUF were identified and reviewed, whether they were admitted under the care of the Obstetrics and Gynecology or Urology Departments. Cases of rectovaginal fistula and other unrelated fistulae were excluded. Research committee

approval was obtained prior to data collection. Both vaginal and abdominal repair were done in layers after excising the fistula tract. Abdominal repair was accompanied by interposition of an omental graft.

## RESULTS

Ten cases of genitourinary fistula were identified during the study period: 4 cases of VUF, 4 cases of VCF, and 2 cases of VVF. Four cases were diagnosed by cystogram, 3 by cystoscopy, and one by hysterosalpingiogram. This information was missing from 2 files.

All VUF cases were complications of CS (Table 1). The reasons for doing CS included: elective CS with 5 previous CS (n=2, one with placenta previa), 3 previous CS (n=1), and one patient with 2 previous CS followed by vaginal delivery, and then a failed trial of vaginal delivery, which ended by emergency CS. Three of 4 post CS cases underwent surgical repair through an abdominal approach, and were kept on urethral catheterization for 9 to 11 days postoperatively. All 3 cases were asymptomatic at their last follow up from 7 months to 3 years after repair. The fourth case was initially treated with urethral catheterization for 2 months, but the patient continued leaking after catheter removal. Accordingly, cystoscopic fulguration of the tract was done, followed by urethral catheterization for 2 weeks, after which the patient became dry and remained so 10 years after repair.

Three of the 4 VCF cases were post emergency cesarean subtotal hysterectomy due to placenta accreta causing uncontrolled bleeding, and one was post emergency CS. In the 3 post emergency subtotal hysterectomy cases, CS was done as an elective repeated CS. One case had a recognized bladder injury that was subsequently repaired surgically. Two of the cases were treated by transurethral and suprapubic catheterization for 3 to 4 weeks, after which they were dry. The third patient declined any intervention, including catheterization. On her follow up visits up to 7 months after surgery, she continued to be dry. The post CS patient was treated by surgery through an abdominal approach followed by urethral catheterization for 10 days, after which the patient became dry, remaining so at a 7-month follow up visit. One of the 2 VVF cases was post hysterectomy due to uterine fibroid. The patient underwent



TABLE 1 – Genitourinary Fistula Cases

Management	Incident	Type	Parity	Age	Case No.
Abdominal repair	CS	VUF	P6+1	37	1
Abdominal repair	CS	VUF	P3+1	36	2
Abdominal repair	CS	VUF	P6+2	41	3
Cystoscopic fulguration; “Failed catheterization”	CS	VUF	P4+0	37	4
Bladder catheterization	CS	VCF	P4+0	28	5
Conservative management;”Patient refused any intervention”	Cesarean subtotal hysterectomy	VCF	P4+6	38	6
Bladder catheterization	Cesarean subtotal hysterectomy	VCF	P3+1	25	7
Abdominal repair	Cesarean subtotal hysterectomy	VCF	P5+0	33	8
Abdominal repair	Hysterectomy	VVF	P1+0	52	9
Trans-vaginal fulguration	RTA	VVF	P0	28	10

VUF: vesico-uterine fistula - CS : cesarean section - VCF: vesico-cervical fistula - VVF: vesico-vaginal fistula - RTA: road traffic accident

surgical repair through an abdominal approach, followed by suprapubic catheterization for 10 days, and then urethral catheterization for 13 days. Subsequently, the patient was completely dry through 6 months of follow up. The other case was post road traffic accident (RTA), and had multiple pelvic fractures and a vaginal hematoma ended by a VVF. This was treated by trans-vaginal fulguration, after which the patient became dry, and remained so at a 4-year follow up. Surgical repair of fistulae was done abdominally in all cases (5/5) because of location of the fistula and surgeons’ expertise and preferences. Cases were operated on by 3 surgeons: 2 urologists, and one urogynecologist.

## DISCUSSION

The incidence of VUF is increasing worldwide because of the increase in CS.<sup>9</sup> All 4 of our VUF cases were secondary to CS, similar to a study from Spain, where over a period of 25 years, 5 out of 6 (83%) VUF cases were secondary to CS.<sup>11</sup> In another series of 15 cases of VUF occurring over 7 years from Benin, 14 were related to CS.<sup>12</sup>

Surgery is the mainstay and definitive treatment of VUF, although spontaneous healing occurred in 5% of cases.<sup>9</sup> In our series, conservative management was tried unsuccessfully in one case of VUF, after which the patient underwent successful cystoscopic fulguration without additional treatment. A similar successful case of cystoscopic fulguration was reported; however, hormonal amenorrhea was induced prior to fulguration.<sup>10</sup> Four of our cases (40%) were the rare VCF, occurring as complications of elective CS, 3 of which required concomitant subtotal hysterectomy. Only one required surgical treatment after conservative management failed. Interestingly, one patient became asymptomatic with no intervention. Only 2 of our cases (20%) were VVF, which were secondary to an RTA and hysterectomy. This paucity of cases is similar to reports from developed countries,<sup>5</sup> and unlike the situation in many developing countries like Nigeria, where 889 cases of VVF over 7 years were found to be complications of labor and delivery.<sup>13</sup> Another report from Pakistan showed that over 7 years, 27 out of 32 cases of VVF were secondary to obstetrical trauma, out of which the success rate for surgical repair through the abdominal route was 100%, and through the transvaginal route was 80%. Repair was attempted through transvaginal fulguration in one case in that series, in which it failed.<sup>14</sup> Although one of our VVF cases was treated surgically, one was successfully treated by transvaginal fulguration. A study of 15 VVF cases with sizes less than 3.5 mm in the United States revealed 73% of the patients had complete resolution after fulguration of the fistulae, either

cystoscopically or vaginally.<sup>15</sup> Unfortunately, the size of fistulae in our study was not mentioned in any of the charts or radiology reports. Another study reported 4 cases of VVF treated successfully using conservative management, which involved simple bladder drainage for periods ranging from 19 to 54 days.<sup>16</sup> A review by Haferkamp et al showed that surgical repair of VVF using transvaginal, transvesical, and transperitoneal approaches have similar results. They emphasize that adequate surgical exposure and mobilization of the bladder and vagina, successful excision of the fistula tract, tension-free closure, and placement of an interposition flap, when applicable, are essential components of successful repair.<sup>17</sup>

The majority of our cases (80%) were related to CS or its complications (cesarean subtotal hysterectomy). This finding is unlike reports from developed or developing countries, in which fistulae were mainly related to gynecological surgeries or obstructed labor, respectively.<sup>4,5</sup> Also in contrast to the world literature,<sup>18,19</sup> VUF was noted to be more common in our population than VVF. This could be explained by the number of CS performed per year in our facility, which was approximately 900 cases out of 7000 deliveries per year, compared with hysterectomies, which were only 20 cases per year. The significant low frequency of hysterectomies in our hospital and our society can possibly be explained by the commitment to preserving fertility as much as possible, and the myth that hysterectomy can negatively affect the quality of sexual life.

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# Diagnosis and management of adult female stress urinary incontinence. Summary of the guidelines for clinical practice from the French College of Gynaecologists and Obstetricians (CNGOF)

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**Abstract:** During the thirty third French College of Gynaecologists and Obstetricians (CNGOF) meeting, guidelines for good clinical practice (RPC) defined by the French High Authority for Health (HAS) were exposed about diagnosis and management of adult female urinary incontinence without any neurological pathology and, particularly with stress urinary incontinence. Guidelines had been established by a multidisciplinary committee's work, directed by B Jacquetin, X Fritel, and A Fauconnier.<sup>1</sup> Methods, texts by the expert authors, synthesis of recommendations have already been published in French in a special number of the CNGOF journal. The intention of the French College of Gynaecologists and Obstetricians (CNGOF) was to improve previous recommendations, which had already been drawn up by several scientific societies, and by this way, to be complementary to these previous undertakings. This article is a summary of the French recommendations, and its aim is to give readers a clinical approach, and help them in their current and usual practices.

**Key words:** Urinary incontinence, Stress urinary incontinence, TVT, TOT, Guidelines, Raccomandations

## DEFINITIONS OF URINARY INCONTINENCE

Stress Urinary Incontinence (SUI) describes the complaint of involuntary urinary leakages during exertions, coughing or sneezing. It is divided into two groups: intrinsic sphincteric deficiency, or increased urethral mobility.<sup>2</sup>

Urge urinary incontinence (UII or overactive bladder) is involuntary loss of urine, preceded or accompanied by a strong desire to void.

Mixed urinary incontinence (MUI) is the association in variable proportions of SUI and UII.

## ASSESSMENT OF FEMALE URINARY INCONTINENCE

### *Clinical assessment of female urinary incontinence*<sup>3</sup>

During examinations, you have to precise several points (symptoms) to try defining urinary incontinence type (even if there is not always a correspondence between urinary symptoms and real diagnosis), and checking severity of it:

- Circumstances, frequency, and severity of leakages,
- Urinary symptoms questionnaires: USP (urinary symptom profile), UDI-6 (Urogenital distress inventory-6), ICIQ (international consultation on incontinence questionnaire), MHU (mesure du handicap urinaire)...
- A 3-days bladder diary,
- Quality of Life (QOL) questionnaires, such as general ones (SF 36...), or specific ones (IIQ, Contilife, Ditrovie, ...)
- pad-test

In case of UII (urge incontinence, nocturia, frequency), a bladder diary is recommended. It is not specified in this guidelines but that is probably not necessary to precise that an urinary tract infection must be eliminated as first line.

In case of SUI, several facts are pointed:

- Cough test proves SUI. It Shows loss of urines and confirm SUI. It is recommended before all type of SUI surgery. If the test is negative, you can repeat it particularly in an up-standing position.
- Urethral mobility can be assessed by examination, observation, sub urethral manoeuvres, and Q-Tip test. The best method to check urethral mobility has not yet been established.
- Post-void residual urines (less than 50 ml) and functional bladder capacity measurements (up to 400 ml) are performed during urodynamic investigations.

### *Urodynamic investigations (UDI)*

UDI includes a uroflowmetry with post-void residual urine measurement, a cystometry with detrusor pressure flow study, and an urethral profile including Maximal Closure Urethral Pressure (MCUP) and Valsalva Leak Point Pressure (VLPP) measurements.<sup>4</sup>

UDI's indications are:

- all urinary incontinenes before surgical treatment,
- all recurrent urinary incontinence,
- all POP previous surgical treatment's failures, in association with urinary incontinence.

UDI prescription is not needed before pelvic floor rehabilitation for urinary incontinence management.

In case of pure SUI (without urge symptoms), UDI is not necessary before surgery if clinical assessment is complete (standardised questionnaire, cough test, bladder diary, establishment of post-void residual volume) and with concordant results.

A low pre-operative flow rate (measured during uroflowmetry) is associated with a higher risk of postoperative voiding dysfunction (after sub urethral tape placement).

Urinary sphincter deficiency (defined with a decreased MCUP or VLPP during UDI) is not a decisive prognostic factor for the result of a sub-urethral tape procedure.

### *Others investigations?*

Others investigations are not recommended, with these guidelines, to improve your diagnosis or prior to perform a SUI surgery. Therefore, is there any place for ultrasound, and particularly bladder exam with ultrasound, to verify its normality (lithiasis, polyps...), in case of UII. We probably have to remain that ultrasound can be usefull for a few cases, and preoperatively. Furthermore, MRI and cystography are not needed for urinary incontinence assessment.

## HOW TO TREAT A FEMALE SUI?

### *Conservative treatment of female SUI*

- Treatment of female SUI with lower urinary tract rehabilitation.

Pelvic floor muscle training (PFMT) is recommended first to treat SUI or MUI (PFMT seems to give better results than vaginal electrostimulation). Bladder training is



recommended first in cases of UUI, or MUI with predominant urge symptoms.

- Oestrogen.

Currently, studies don't allow us to establish an optimum method of administration, dosage and type of oestrogen for prevention or treatment of urinary incontinence. Vaginal oestrogen treatment improves urge incontinence and frequency. Oral oestrogen treatment is not recommended for treatment or prevention of SUI.<sup>5</sup>

Vaginal oestrogen treatment can be used in postmenopausal women to improve urge incontinence or frequency.

- Duloxetine.

Objective data (24-hours pad-tests) don't demonstrate any superiority for duloxetine in comparison with placebo. By this way, in France, duloxetine is not recommended at first line.

- Hygiene and dietary measures.

For overweight patients, loss of weight improves urinary incontinence, and dietary measures as well as physical exercises can be proposed.

#### *Surgical treatment at first line for female SUI*

##### Procedures

Among many surgical procedures described to treat SUI, sub-urethral tape (retropubic or transobturator route) is the technique recommended at first line due to the easier and shorter postoperative course than Burch colposuspension. It is performed under local, locoregional or general anaesthesia. It can be placed on a one-day surgery or a traditional hospitalisation (depending on patient's and surgeon's preferences). And postoperative course is less expensive with sub-urethral tapes compared with colposuspensions by laparotomy or laparoscopy.<sup>6</sup>

Concerning sub urethral tapes :

- ascending retropubic route gives better results in terms of continence than transobturator route in case of urinary sphincter deficiency,
- transobturator routes from inside to outside or from outside to inside give similar results,
- concerning sub-urethral tape procedures, both retropubic and transobturator routes give advantages, and it does not allow us to recommend a preferred route,
- Place of mini-slings (in order to treat SUI) is not established because of the absence of any comparative studies,
- Urinary sphincter deficiency is not a contra-indication for sub-urethral tape surgery.

What about risks?

The French college (CNGOF) offers (on line) an information letter for patients undergoing a SUI surgery.<sup>7</sup>

Main intra-operative complications of sub urethral tapes are:

- Urinary tract injuries,
- vaginal sulcus tract injuries, (greater risk of vaginal perforation with transobturator route, particularly in case of passage from outside to inside compared with inside to outside route)
- bowel injuries,
- bladder injuries. (frequency of bladder injury is higher with retropubic than transobturator route)

Main postoperative complications of suburethral tapes are:

- urinary retention,
- urinary tract infection,
- urge incontinence,
- pain,
- vaginal, bladder or urethral erosion (erosion rates are greater with transobturator route than retropubic route).

Postoperatively, it is recommended to assess the quality of voiding function in order to screen eventual bladder retention. (urinary post-void residual measurements)

#### *Surgical treatment at second line for female SUI*

These French recommendations don't give readers any explanations about recurrent SUI treatment, or complex SUI. In fact, in our practice, it can be a second sub urethral tape placement, an adjustable continence therapy next to the bladder neck (ACT, manufactured and distributed by AMS®), trans or peri-urethral injections, artificial urinary sphincter, which are, for most of these procedures, intrinsic sphincter deficiency treatments.

#### *Surgical treatment for UUI*

These guidelines don't treat UUI surgical treatments and their indications (botulinic toxin, sacral nerve neuromodulation).

## PARTICULAR CIRCUMSTANCES

#### *Urinary incontinence during or after pregnancy*

Events of vaginal childbirth have no impact on the appearance or persistence of urinary incontinence during the postnatal period or later.<sup>8</sup>

At long term, birth by caesarian section doesn't seem to reduce the risk of SUI, and so it is not a good way to prevent postnatal urinary incontinence.

Pregnant women who already underwent a sub-urethral tape placement, frequency of postnatal urinary incontinence is not significantly reduced with a birth performed by caesarean section.

Postnatal perineal rehabilitation including PFMT with a therapist (midwife or physiotherapist) decreases prevalence of urinary incontinence at short term (one year after birth) compared with councils on selfmade pelvic floor exercises. However, at long term, efficacy of this postpartum rehabilitation is not established.

Pelvic floor rehabilitation during pregnancy improves urinary incontinence during pregnancy, and until 3 months in postpartum time. But, it doesn't appear to treat it with a long drop, at long term.

During pregnancy or immediate postnatal time, the first treatment to perform, in order to treat a SUI, is pelvic floor rehabilitation (PFMT), and so there is no place for other medical or surgical treatment at first line.

#### *Urinary incontinence in elderly women*

Before deciding any treatment in elderly women, it is recommended to screen for urinary tract infection (using a strip test), to make a bladder diary, to measure post-void urinary residual volume, and to search after triggering factors (such as confusion syndrome, polymedication, excessive diuresis, reduced mobility or terminal constipation).<sup>9</sup>

It is recommended to search after main vulnerability signs too: age over 85, polymedication, deteriorated cognitive functions, depression, undernutrition, neurosensorial problems, postural instability, lack of physical exercise, loss of independence, and social isolation. Elderly women who are heavily dependent from the cognitive and/or physical point of view should be managed by nursing methods: programmed voids, physical mobilisation and activity, use of suitable palliatives, regulation of bowel function.

Anticholinergics are effective for urge incontinence or MUI in women aged over 65. Anticholinergics may cause cognitive deterioration in elderly patients who did not suffer from it before. Prescription of an anticholinergic in an elderly woman must be monitored about appearance of deterioration in brain functions, constipation, urinary voiding dysfunction, or restricted food intake.

*Urinary incontinence and genital prolapse*

Genital prolapse may be associated with SUI, urge incontinence, and obstructive urinary symptoms. Urge incontinence or obstruction symptoms disappear in half of cases as soon as prolapse is cured.

Prolapse may occur SUI from 20% to 70% of cases according studies recorded. In case of genital prolapse without SUI, POP's correction with pessary reveals lesser rates of subsequent SUI, than with a speculum. Pessary test had also been used to predict postoperative continence result of prolapse surgery. But, the predictive value of the pessary test used in this cases is unclear, and it is not recommended to use it systematically.<sup>10</sup>

In order to find out an associated SUI before POP repair treatment, cough test is recommended and allow surgeons to identify patients who could need an associated urinary tract procedure during the same time of surgery. In this case, suburethral tape placement, during the same time of POP repair by the vaginal route, reduces the risk of postoperative SUI. In other cases, (no symptomatic or no occult SUI), there is no indication for a surgical procedure to prevent incontinence.

In case of genital prolapse surgery in a woman who also presents symptomatic or occult stress urinary incontinence, associate surgical procedure for continence is a decision depending of SUI severity, risk factors, technique chosen and potential undesirable effects.

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# Development of a third generation surgical technique for mesh repair for pelvic organ prolapse using a lightweight monofilament polypropylene mesh. A preliminary report of efficacy and safety

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**Abstract:** A comprehensive 3 level repair technique for prolapse is presented with preliminary results of efficacy and safety after short term follow up of 42 patients.

**Key words:** POP; Genital prolapse; Lightweight macroporous polypropylene mesh; Comprehensive 3 level repair.

## INTRODUCTION

As a result of audit and evaluation of existing techniques of pelvic reconstruction over 10 years (1997-2007), a third generation technique of prolapse repair with mesh has evolved into a standardized technique. Other mesh techniques have been associated with a high success rate and good functional results but erosion rates associated with defective healing have been reported at 5-10% and higher in the first three months after surgery using a number of commercially available mesh kits<sup>2,3,4</sup> and slings.<sup>5,6</sup> Reports of the significant advantages of light weight wide pore monofilament meshes in hernia and other surgery led to the adoption of this material.

## MATERIALS AND METHODS

A total of 42 patients were followed prospectively as part of an ongoing quality assurance program. Ethics committee approval was obtained to report the outcomes of all patients undergoing reconstructive surgery on the condition that patient anonymity was preserved.

All patients underwent surgery using a specialized prosthesis (CR Mesh) developed at the Centre for Pelvic Reconstructive Surgery and manufactured by Agency for Medical Innovation (AMI GmbH, Feldkirch, Austria). The author performed all surgery using a standardized technique documented in the Appendix 1.

## TECHNIQUE

The CR Mesh technique involves comprehensive reconstruction of all three levels of pelvic support.

Level 1 support is provided by an independent suspension of the cervix or vaginal vault, using a monofilament non absorbable Prolene suture which is attached to the proximal end of the sacrospinous ligament using a specialized instrument, either the AMI Suture Instrument or the AMI I-Stitch device.

Level 2 support involves reattachment of the fascia to the adjacent levator and obturator complex by the passage of transobturator and translevator slings. Separate distal slings are also able to recreate the Level 3 support of the perineum or bladder neck.

Demographic data of the 42 patients are shown below (Table 1).

All patients operated with this procedure underwent full clinical assessment including pelvic organ quantification (POPQ) examination and a 3 dimensional pelvic ultrasound. Each patient prior to surgery and again 3 months after surgery completed a series of quality of life questionnaires. Ongoing follow-up is planned with annual review and quality of life assessment.

TABLE 1: Demographic data.

Age: 39 – 86 (Mean age 67)
Previous repair surgery 28 patients
Previous hysterectomy 13 patients

All 42 patients in this study presented with a significant pelvic organ prolapse (POPQ stage 3 or 4). Three patients also required a hysterectomy for other pathology and two patients had a co-existing rectal prolapse.

TABLE 2: Procedures performed

Anterior CR Mesh 12 patients
Posterior CR Mesh 9 patients
Anterior and Posterior CR Mesh 21 patients

## RESULTS

Surgery was successfully completed in all 42 patients. The range of follow-up was 4 – 15 weeks. There were no significant intraoperative complications. No patients needed blood transfusion and there was no evidence of any surgical morbidity. No patient suffered from any bladder or urethral injury. There was no incidence of bowel injury.

Initial postoperative assessment showed restoration of apical support in all 42 patients. Two patients also had resolution of their rectal prolapse. One patient reported a slight deterioration of anterior wall support at 3 months postop in association with mild stress incontinence. There was no incidence of early mesh erosion or defective healing. All patients reported significant resolution of the symptoms of prolapse. Three patients, two of which required a concurrent hysterectomy complained of severe postoperative pain and in one patient this was still present after 6 weeks. No assessment was made of sexual function at this stage due to the short length of follow-up. This aspect will be reported in future reviews. Two patients reported de-novo stress incontinence.

## DISCUSSION

The early outcomes of 42 patients who underwent CR Mesh implantation show a reduction in the incidence of mesh erosion and no early evidence of defective vaginal wound healing.

Ongoing data collection and quality of life assessments after longer follow up will clarify long-term outcomes and facilitate the planning of comparative trials. Early results indicate that the combination of this technique together with



the new lightweight low density macroporous CR mesh will result in at least equal outcomes for patients and a significant reduction in mesh related complications.

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## APPENDIX 1

### A.M.I. ADVANCED PELVIC FLOOR REPAIR SYSTEM using CR-Mesh and AMI suture instrument DETAILED PROCEDURE INSTRUCTIONS (version 2.1)

These detailed step by step instructions describe a total vaginal reconstruction procedure using a CR-Mesh prosthesis in both anterior and posterior vaginal compartments including restoration of Level 1 apical support using the AMI Suture instrument.

Prior to commencing surgery an intra-operative assessment is made and the surgeon decides whether anterior, middle and posterior compartments are to be repaired. The procedure is performed through an anterior, posterior or both incisions. If a hysterectomy has been performed then the vault epithelium should be left intact for at least an anterior-posterior length of 4cm.

#### STEP 1: ANTERIOR INFILTRATION

Dilute normal saline 100-200mls in Local Anaesthetic ( e.g., xylocaine 1%) +/- adrenalin.

Pull down the cervix to visualize the anterior vaginal wall and infiltrate with the saline mixture. Choose a point half way between the vault and the cervix and inject 20 mls at a depth of 2-4 mm. The subcutaneous tissues should expand evenly in every direction. If the infiltration seems to expand locally only at the site of infiltration then the needle needs to be a little deeper. Inject another 20-40ml at about the same point. Inject the fluid centrally so that it spreads laterally and hydrodissects under the fascia in all directions.

#### STEP 2: ANTERIOR INCISION

This is a full thickness vertical incision initially 2-3 cm long in the central portion of the anterior vaginal wall. The incision is deep enough to reach the dark clear layer under the fascia created by the hydro-dissection. The incision is extended distally to the transverse vaginal sulcus at the level of the bladder neck and proximally to a point 2cm from the cervix or vault.

The anterior vaginal incision is further developed by reflecting the central tissue overlying the bladder away from the skin edge. This done by starting the lateral dissection at the midpoint of the incision. Do one side at a time. The surgeon's assistant or nurse holds the epithelial edge laterally on each side with two Allis or Littlewood forceps. The surgeon holds the central tissues medially with his forceps and extends the lateral dissection to the sulcus on each side and proximally to the cervix or vault. Distally, the bladder neck also needs to be dissected free from the overlying epithelium but at this stage the dissection is limited to the superficial space under the skin to avoid penetrating the venous plexus in each vaginal sulcus until the last possible moment in order to reduce potential bleeding.

#### STEP 3: POSTERIOR INFILTRATION

Pull the cervix up to visualize the posterior vaginal wall and infiltrate at a point 3-5cm distal to the posterior cervix in a similar manner to the anterior vaginal wall.

#### STEP 4: POSTERIOR INCISION

Start the incision 3-4cm distal to the cervix at the site of infiltration and extend the incision towards the perineum once the correct layer under the fascia is identified and entered. Be wary of an enterocele close to the cervix. As the incision reaches the perineum be careful of causing any rectal damage as the rectum may be caught up in the scar tissue associated with previous perineal repairs or episiotomies. Do not use blunt dissection to reflect the rectum off the perineal body.

The proximal end of the posterior vaginal incision should be 1-2cm from the cervix or 2-3cm from the vaginal vault. At each end of the incision dissection is performed to provide good access to the back of the cervix, the perineal body and distal levator muscles. Complete this dissection at this time as it will be difficult to complete once the mesh is in place.

#### STEP 5: PREPARE THE CERVICAL RING

The cervical ring is the central support structure of the upper vagina. If the uterus is absent then a cervical structure has to be recreated as described below.

##### A. UTERUS PRESENT

Place a single 2/0 monofilament polypropylene suture in the anterior and posterior cervix under the skin edge at the cervical end of each vaginal incision. Ensure that a good strong bite of cervical connective tissue is included in these sutures. Each suture is then held by a clamp which can be placed to rest temporarily on the suprapubic area. These sutures should be long enough to not fall down into the operative site.

##### B. UTERUS ABSENT

The epithelium and fascia of the vault is preserved for an antero-posterior length of at least 3cm. This enables a central structure to be created which is made up of a body of fascial tissue behind the intact vault held together by three double 2/0 monofilament polypropylene sutures which are passed from the anterior to posterior vaginal incision using a large Mayo needle.

The six sutures are passed carefully from the anterior vaginal incision to the posterior vaginal incision without button holing the vault or damaging any viscera. The three pairs of sutures are tied above and below the vault to firmly hold the fascia behind the vault. The first pair of sutures are tied in the midline and then the two lateral pairs are tied 1-2cm on each side of the midline.

It is impossible to recreate the cervical ring in this way if the fascia behind the vault is broken down to link the anterior and posterior incisions. Ensure adequate tissue is left to facilitate this step. Care is also taken not to tie these sutures too tight and compromise the tissue held in the sutures or bunch up the overlying epithelium excessively.

Once the three pairs of sutures are tied above and below the vault all six clamps holding these sutures are placed out of the way on the suprapubic area.

#### STEP 6: OPEN THE PARARECTAL SPACE

First ensure that the central rectal tissues under the posterior incision have been dissected away from the lateral vagina and adequate access to the back of the cervix and the perineal body has

been achieved. The lateral dissection should extend to the sulcus on each side.

This dissection is completed by getting an assistant to hold part of the edge of the posterior vaginal incision using two Allis clamps held apart and retracting the central tissues with a pair of forceps held by the surgeon. The Allis clamps are moved around the skin edge in segments until the lateral dissection is completed. By lifting up the central tissues with a forcep while the assistant provides counter traction using two Allis forceps the correct plane can be seen and usually the yellow fat associated with an enterocoele is identified in the pararectal tissues.

Use a single index finger to probe the upper lateral aspect of the dissection on each side aiming in the general direction of the ischial spine which should be palpable through the fascial tissues overlying the pelvic sidewall. In some cases the fascia falls away easily with this digital examination and the ischial spine can then be felt clearly together with the arcus ligament above and the sacrospinous ligament below. Remember that with the patient lying on her back in the lithotomy position the arcus and sacrospinous ligaments will be vertical in their orientation above and below the ischial spine respectively.

If this dissection is not straightforward and relatively easy then use the index finger to sweep up and down over the lateral sacrospinous ligament and the arcus ligament until a defect is created in the fascia.

If this also proves to be unsuccessful then introduce a pair of scissors into the upper lateral aspect of this dissection on each side and open the fascia with the scissors by using a push-open-withdraw technique. Do not cut tissue with the scissors. Use the index finger to open up the fascial defect created by the scissors.

Sometimes opening this fascia can be quite difficult. Resist the temptation to use excessive force or sharp dissection. Rather, repetitive push-open-withdraw technique with scissors should be effective. Sometimes counter-traction using 2-3 clamps on the skin edge will facilitate this dissection.

#### STEP 7: CREATE THE POSTERIOR APICAL ATTACHMENTS

The apical attachments are created using 2/0 monofilament polypropylene sutures placed in position using the AMI Suture instrument.

Apical attachments are placed on each side in the medial posterior aspect of the sacrospinous ligament immediately adjacent to the sacrum/coccyx. This placement is only possible with a narrow instrument such as the AMI Suture Instrument which can access this medial position on the sacrospinous ligament.

#### TECHNIQUE OF SUTURE ATTACHMENT USING AMI SUTURE INSTRUMENT

The AMI Suture instrument is loaded with a 2/0 monofilament polypropylene suture. Once the surgeon is confident that he has adequate access to the attachment point an index finger is placed in position on the ligament through the incision and the loaded suture device is slid along this pre-positioned finger. Once the surgeon can feel the suture instrument is in the correct position the index finger is used to push the instrument tip into the body of the ligament. The assistant steadies the handle of the suture instrument and the surgeon uses his free hand to release the suture from the holding point on the handle. During this time the surgeon keeps pressure on the tip of the instrument with his index finger so that it does not become dislodged from the ligament prior to completing the fixation.

The handle of the suture instrument is then slowly closed until a click is felt which indicates the suture has been harpooned. The ring pull handle is then slowly withdrawn until it is locked in the second position.

Only then can the index finger holding the tip of the instrument on to the ligament be released. The suture instrument then has to be lifted forward to disengage the tip from the ligament without dislodging the suture from the instrument.

Once it is withdrawn the suture can be released from the second position on the instrument and the suture is pulled through and held with a large clip. Pull firmly on the suture to ensure that the attachment is strong. It is better for the suture to break or the tissue to give way at this stage when the attachment can be easily repeated.

The posterior sutures are then clipped to the drapes with a distinctive large clamp. These are the only sutures in the procedure that need to be specially identified.

Notes:

1. There is a potential for damage to the suture when using the AMI Suture instrument and this is more of a problem for some surgeons due to their technique.

a. Always ensure that the suture has been released from the handle before closing the device as any tension in the suture could lead to the suture being cut.

b. Use the instrument smoothly and slowly. Do not close the instrument rapidly or it might also cut the suture at this point.

c. When placing the suture in the instrument do not centre the suture. Attach the suture to the tip of the AMI Suture instrument away from the midpoint of the suture so as to ensure that any point of potential weakness or damage to the suture is not at the midpoint.

d. After placing the suture in position around the ligament tie it gently without tension to ensure that if one of the threads was to break the other will still be able to be used (The Bath Knot).

e. Some surgeons would prefer to use a 2/0 braided polyester to place the suture and then use the braided polyester to pull the 2/0 monofilament polypropylene into position.

*Standard practice for apical attachments:*

#### A. UTERUS PRESENT

In the presence of the uterus two apical attachments are performed on each side through the posterior incision and there is NO apical attachment through the anterior incision.

These sutures will eventually pass through the cervix to be tied anterior to the cervix so that the cervix is pulled back to the sacrum and uterine retroversion is corrected.

These sutures are clipped to the drapes with large clamps. Make sure that this is always done using DISTINCTIVE LARGE CLAMPS to signify that these attachments are through the posterior vaginal incision. The two attachments on each side are made to the same area on the ligament, i.e., the medial posterior surface of the ligament.

#### B. UTERUS ABSENT

When the uterus is absent two separate apical attachments are performed on each side of the pelvis with one passing through the posterior vaginal incision and one through the anterior vaginal incision. These sutures will later be attached separately to the anterior and posterior CR Mesh on each side.

Again, it is critical that these sutures are distinguished from each other by always placing a distinctive large clamp on the posterior apical attachments and a small clamp on the anterior apical attachment as once the mesh has been pulled into position it will be difficult to identify which suture is which.

Once these sutures are in place they are clipped to the drapes on either side to keep them away from the operative field.

NOTE: Vault or cervical attachments are lying freely on the suprapubic area whilst the apical attachments are clipped laterally to the drapes.

#### STEP 8: OPEN THE PARAVESICAL SPACE

This dissection is not performed until the steps above have been completed due to the possibility of bleeding from the venous plexus when entering the paravesical space lateral to the paravaginal sulcus.

By delaying this step until this point in the procedure the potential for bleeding is reduced. This bleeding could potentially slow down the previous steps and lengthen the operation. Bleeding due to damage to the paravaginal venous plexus is usually easily controlled once the anterior mesh is pulled into place.

Each side of the dissection is done separately. The assistant grasps the edge of the vaginal incision with two Allis forceps and a Briesky or similar retractor is used to inspect the vaginal sulcus and ensure that it is not buttonholed.

The dissection is behind the fascia initially (in the vagina) but passes through the fascia at the pelvic side wall as the sulcus is reached. It is at this point that bleeding is more likely to occur.

The lateral dissection should always be commenced midway between the urethra and the vaginal apex. It is initially sharp

dissection behind the fascia and this is facilitated by hydrodissection. The fascia is breached to enter the paravesical space with scissors using a push-open-withdraw technique.

Once the paravesical space is opened the dissection needs to be extended along the incision to allow a Sims speculum to be placed between the vaginal incision and the bladder (into the paravesical space) to enable inspection of the pelvic side wall. The lateral support tissue of the urethra is reflected medially by extending the dissection anteriorly with blunt dissection pushing the urethra medially and sharp dissection cutting laterally.

The ischial spine, arcus ligament and sacrospinous ligament(SSL) are identified and the SSL is explored through the anterior incision to facilitate attachment of the anterior apical suspension sutures. (As mentioned above these anterior apical sutures are only inserted when there is no uterus).

#### **STEP 9: PREPARATION OF BLADDER NECK AND ANTERIOR CERVIX**

The anterior vaginal dissection is completed by preparing the bladder neck and anterior cervix for subsequent placement of the CR Mesh.

The bladder neck is prepared by dissecting free the lateral supports of the upper urethra using blunt and sharp dissection as described above. This should be done until the surgeon's index finger can pass lateral to the urethra and easily feel the inner surface of the obturator fossa at the level of the clitoris without being restricted by a band of connective tissue lateral to the urethra.

The anterior cervix has already been prepared to accept the anterior mesh and this task is completed by ensuring that there is good access to the strong fibrous tissue of the anterior cervix with a flap of epithelium of at least 1cm to cover the attachment point.

#### **STEP 10: PRELIMINARY STEPS TO ATTACH CR-MESH**

Prior to attaching the CR Mesh to the anterior and posterior vaginal apex preparation is completed so as to enable the attachment to be done smoothly without confusion or suture entanglement.

Before commencing check that the following have been done:

1. Anterior and posterior vaginal incisions have been completed with preparation of the bladder neck and perineum.
2. Cervical ring has been prepared for attachment of the CR Mesh with pre-placement of sutures. This is either a single 2/0 Prolene suture in the front and back of the cervix or three pairs of 2/0 Prolene sutures tied around the central fascia behind the vault.
3. Four apical attachment sutures are in position with correct clamps used for identification. Distinctive large clamps are placed on the apical attachments through the posterior vaginal incision while smaller clamps identify any apical attachments through the anterior vaginal incision.
4. The operative field is made tidy with removal of extraneous instruments, suture material and needle holders and their return to the scrub sister.
5. At this point drapes can be refreshed and gloves changed if necessary.

#### **STEP 11: PLACEMENT OF POSTERIOR CR MESH**

First unpack and unfold the CR Mesh. Identify the proximal and distal ends as well as the FRONT and BACK of the mesh. The proximal sling passes through the mesh and attaches laterally to the back of the mesh with a nylon holding suture.

The mesh is positioned by the surgeon 4-5 cm in front of the vagina and held in the anatomical position by the assistant(s) who hold the proximal corner of the mesh on each side. The proximal 1-2 cm of the mesh is folded over to create a double layer.

The back of the mesh is orientated to face the rectum while the front of the mesh faces the vaginal lumen.

The Mesh is held by the assistant(s) until attached to the cervix or vault. It is important that they not release the Mesh until this attachment is complete.

The CR Mesh is attached differently depending on the presence or absence of a cervix. The following sections are potentially the most confusing and difficult parts of this procedure.

#### **A. UTERUS PRESENT**

First a single Allis forcep is attached to the skin edge of the posterior incision on each side 2cm lateral to the midline and these two clips are allowed to fall down behind the mesh. They will be important in a subsequent step but for now they sit in the background.

The surgeon first passes the solitary 2/0 monofilament polypropylene suture which has been pre-positioned in the posterior aspect of the cervix through the proximal end of the mesh in the midline 2-3mm from the edge of the mesh. The posterior cervical suture passes through this point from the FRONT of the mesh to the BACK. A clamp is used to hold the suture behind the mesh and this clamp is also allowed to fall down behind the mesh which is held in position by the assistant(s). The assistant(s) must not release the Mesh at this point.

Both of the pre-positioned apical (medial sacrospinous) attachment sutures are then passed through the two layers of the posterior CR Mesh from the BACK of the mesh to the FRONT 2-3 mm from the folded proximal edge of the mesh and about 1cm lateral to the central cervical attachment suture that is already being held by the clamp hanging behind the mesh in the midline. Try to ensure that each suture of the apical attachments passes through a different hole in the mesh.

NOTE: The cervical attachment sutures and the apical sacrospinous attachment sutures pass through the proximal part of the CR Mesh in opposite directions.

A large Mayo needle is then used to pass the two pairs of apical attachment sutures through the cervix from back to front on each side. These sutures emerge through the anterior cervix and a LARGE DISTINCTIVE clip is placed on the end of each pair of sutures. All four apical sutures should be positioned from the back of the mesh through the mesh then through the cervix to emerge through the anterior incision. Throughout this procedure the assistant(s) have continued to hold the posterior mesh in position.

The proximal end of the mesh is lifted up to lie flush with the posterior cervix and the midline suture is tied firmly from behind to lock the central upper (proximal) folded edge of the mesh to the cervix in the midline.

The assistant(s) can now release the corners of the mesh and carefully lift up and hold laterally the two pre-positioned Allis clamps holding the skin edge of the posterior incision 2cm lateral to the midline on either side.

The surgeon can then add a 2/0 Vicryl or similar suture to secure the mesh to the fascia under the skin over the posterior cervix lateral to the apical attachments that pass through the cervix to emerge anteriorly.

The posterior aspect of the cervix will be secured to the posterior mesh by the following:

1. the midline suture which has been tied firmly to hold the proximal edge of the posterior CR Mesh to the posterior cervix.
2. the two pairs of apical attachment sutures which pass from behind the posterior CR Mesh on each side to emerge 2-3 mm from the proximal edge of the mesh and 1cm lateral to the midline and then pass through the body of the cervix to emerge from the anterior aspect of the lower cervix.
3. a fascial attachment suture lateral to the above sutures which also holds the proximal edge of the mesh onto the posterior cervix or fascia

The apical sutures which emerge through the anterior cervix are clipped but not tied.

Once this attachment is complete the surgeon should ensure that the main body of the mesh is lying flat and the two lateral slings are also lying flat in the anatomical position.

#### **B. UTERUS ABSENT**

First a single Allis forcep is attached to the skin edge of the posterior incision on each side 2cm lateral to the midline and these two clips are allowed to fall down behind the mesh. Once again, they will be important in a subsequent step but for now they sit in the background.

The surgeon first passes the central 2/0 monofilament polypropylene suture which has been prepositioned in the fascia behind the vault through the proximal end of the mesh in the midline 2-3mm from the edge of the mesh. The posterior central vault suture passes through this point from the FRONT of the mesh to the BACK. A clamp is used to hold the suture and this clamp is



allowed to fall down behind the mesh which is held in position by the assistant(s).

The assistant(s) must now hold the Mesh in position without releasing it until it is firmly secured to the vault.

The lateral vault sutures are now also passed through the mesh from FRONT to BACK approximately 1cm on each side of the central suture. All three clamps holding these sutures are allowed to fall down behind the mesh.

The prepositioned POSTERIOR apical attachment sutures (one on each side) are then passed through the posterior CR Mesh from BACK to FRONT about 2-3 mm from the folded proximal edge of the mesh and just lateral to the most lateral vault attachment suture. Note that the clamps holding the vault attachments will hang down behind the Posterior CR Mesh while the two apical attachments will lie on the front of the mesh so they can later be tied in the vaginal lumen. Try to ensure that each of the posterior apical attachment sutures passes through a different hole in the mesh.

Ensure that the large clamp used to identify each of the posterior apical attachment sutures is repositioned on the end of the sutures once they have been passed through the mesh.

The proximal end of the mesh is then lifted up by the assistant(s) to lie flush with the posterior vault and the vault sutures are tied firmly from behind to lock the upper (proximal) folded edge of the mesh onto the posterior aspect of the vault in the midline.

The assistant(s) can now release the corners of the mesh and carefully lift up and hold laterally the two pre-positioned Allis clamps holding the skin edge of the posterior incision 2cm lateral to the midline on each side.

The surgeon can then add a 2/0 Vicryl or similar suture to secure the mesh to the fascia behind the skin lateral to the apical attachments.

At the end of this part of the procedure there should be the following attachments on the posterior vault:

- the three sutures which have been tied firmly to hold the mesh to the posterior vault.
- the single pair of posterior apical attachment sutures which pass from behind the mesh on each side to emerge 2-3 mm from the proximal edge of the mesh 1cm lateral to the midline and then lie on top of the posterior CR Mesh and can be identified as posterior by the attachment of a large clip.
- a fascial attachment suture lateral to the apical sutures

The apical sutures which emerge through the posterior mesh are clipped but not tied at this point.

Once this attachment is complete the surgeon should ensure that the main body of the mesh is lying flat and the two lateral slings are also lying flat in the anatomical position.

#### STEP 12: PLACEMENT OF ANTERIOR CR-MESH

The CR Mesh is removed from sterile packaging and unfolded so that the FRONT and BACK of the mesh can be identified. The mesh is held by the assistant(s) in the anatomical position with the BACK of the mesh facing the bladder and the FRONT of the mesh facing the vaginal lumen.

##### A. UTERUS PRESENT

First the central anterior cervical attachment suture is passed through the edge of the mesh in the midline passing from the FRONT to the BACK of the mesh.

Both pairs of apical attachment sutures that emerge through the anterior cervix are now passed from the BACK to the FRONT of the anterior CR Mesh and the LARGE DISTINCTIVE clips are allowed to fall down in front of the mesh.

The central suture is tied firmly to hold the mesh onto the cervix in the midline. The apical sutures are left hanging down in the vaginal lumen.

Once the central suture has been secured the assistant(s) can let go of the corners of the mesh and then lift up the two pre-positioned Allis forceps to facilitate placement of any lateral fascial sutures using 2/0 Vicryl or similar suture.

##### B. UTERUS ABSENT

The mesh is orientated with the FRONT of the mesh facing the vaginal lumen and held by the assistant(s) in the manner described above.

The three pairs of sutures attached to the anterior vault are passed through the mesh from FRONT to BACK. The anterior apical

attachment sutures which are identified by the presence of SMALL CLAMPS are passed from the BACK of the mesh adjacent to the vault attachment sutures. They are then able to hang down below the mesh in the vaginal lumen.

The mesh is moved close to the cervix and the three anterior vault sutures are tied pulling the proximal end of the anterior CR Mesh into position attached to the vault. Once in position the assistant(s) can release the mesh and carefully hold and lift up the two Allis forceps attached to the skin edge on either side. Further sutures to fix the mesh to the fascial tissue can then be placed in position if necessary.

At all times through this part of the procedure the surgeon should ensure that the mesh is not twisted and maintains its anatomical position. The assistant(s) must concentrate on holding the mesh still because if they release the mesh at this stage it may be difficult to orientate and could slow the procedure down considerably.

At the end of this step both anterior and posterior mesh should be lying flat over the perineum with the four apical sutures lying between the two meshes and able to be identified by their different clamps.

#### STEP 13: PLACEMENT OF PROXIMAL TRANSOBTURATOR SLINGS

The proximal transobturators are placed in position without moving the mesh from its resting position at the end of the previous step.

First make a small vertical skin incision 1cm above the ischial tuberosity on each side.

Next, check that the Sims speculum and small Briesky retractor are sitting on the perineal table ready to be placed in position. Attach the pulling suture of the first sling to be positioned onto a needle holder and also rest it on the perineal table.

Hold the A.M.I. TVA tunneller with both hands and pass it through the proximal medial aspect of the obturator fossa. This is done by holding it in a horizontal position and sliding the tip into the subcutaneous tissue and then for 1-2cm onto the pelvic bone before lifting the handle 90 degrees to penetrate the obturator fossa. At this point transfer the alternative index finger into the paravesical incision and guide the TVA tunneller medially through the arcus ligament 1cm anterior to the ischial spine.

The assistant surgeon then holds the TVA tunneller so that the surgeon can carefully place the Sims speculum into the paravesical dissection and then under the tip of the tunneller. The Briesky retractor is then placed in position to retract the bladder medially and ensure good vision of the tunneller tip. Using the pre-positioned needle holder the pulling suture of the appropriate sling is carefully attached to the end of the tunneller and the suture pulled through the obturator fossa as far as possible without disrupting the mesh. Once the sling is in position cut the pulling suture off the end of the sling but do not cut the sling or the protective plastic cover at this stage.

The same procedure is then repeated on the other side.

#### STEP 14: PLACEMENT OF THE PROXIMAL TRANSLEVATOR SLINGS

Before placing the translevator slings the anterior and posterior CR Mesh and associated clamps and sutures have to be carefully lifted up out of the way and onto the suprapubic area. First remove any retractors or speculums from the vagina. Lift the anterior CR Mesh up and lie it down on the suprapubic area starting with the distal sutures (level 3 attachments) then the four apical sutures, then the posterior mesh and its associated distal sutures, then finally the posterior proximal levator slings that are about to be placed in position.

Make a small skin incision approximately 3cm lateral and 3cm posterior to the anus on each side. Use the A.M.I. TVA tunneller to pass through the ischiorectal fossa from below and with the alternative index finger resting on the inner surface of the levator muscle guide the tip of the tunneller through the levator 2cm medial and below the ischial spine. Attach the pulling suture and pull the translevator slings through as far as possible without moving the mesh.

Cut the pulling suture off the end of each sling but do not cut the sling or protective plastic cover at this stage.

#### **STEP 15: SECURE THE UPPER VAGINAL ATTACHMENTS**

If necessary due to a deep narrow vagina it is sometimes appropriate to commence the posterior vaginal skin closure suture at this time as access to the posterior fornix may be difficult when everything is pulled up into position. Use a 2/0 Vicryl or equivalent suture for this purpose.

Use a speculum to visualize the vaginal apex and then grasp the cervix or vault with an Allis forceps. Carefully push the vault back into the pelvis with this instrument. The assistant should make sure that the main body of the mesh does not get caught on anything during this process.

Whilst holding the cervix or vault in the correct position carefully pull on the four upper vaginal slings to take up any laxity. **DO NOT USE THE TRANSOBTURATOR OR TRANSLEVATOR SLINGS TO PULL THE CERVIX OR VAULT INTO POSITION.**

#### **STEP 16: FIX APICAL SUTURES**

When these sutures are being tied ensure that the vaginal apex is held down into the pelvis by using either a speculum or retractor at all times. This ensures that the vaginal length is maximized.

##### **A. UTERUS INTACT**

Place the speculum in the posterior fornix to ensure good vision. There are four apical sutures that need to be tied anterior to the cervix.

First pull each suture into position in turn until the cervix is sitting nicely in its new position. Once all four sutures have been tensioned complete the job of securing them with at least 7 knots on each suture as monofilament polypropylene has a tendency to unravel and these attachments are critical to the success of the procedure.

##### **B. UTERUS ABSENT**

There are two posterior apical attachment sutures and two anterior. These sutures should be carefully pulled into position before tying with the two anterior sutures left relatively loose compared to the two posterior ones. Once again, tie all four sutures with at least 7 knots to avoid them unraveling.

Note: The four apical suspension sutures are not meant to pull the vaginal vault or cervix up and attach it to the sacrospinous ligament. rather, they are designed to replace the uterosacral ligament and suspend the apex from its' normal anatomical origin.

Excessive tension on these attachments will increase the amount of postoperative pain and limit the mobility of the upper vagina.

Once the four apical sutures are secure gently pull on the transobturator and translevator slings then cut off the distal ends of each sling half way along. Carefully remove the protective plastic sheaths but do not remove the nylon holding sutures at this time.

The upper vagina is now secure.

#### **STEP 17: POSTERIOR MESH ADJUSTMENT**

During this part of the operation a large Briesky retractor should be used to hold the vagina open and hold the anterior mesh out of the way. This instrument will also ensure that the vaginal length is maximized when adjusting the mesh.

First check that the perineal dissection performed early is adequate. Grasp the posterior skin edge 2cm lateral to the midline on each side and pull the vagina open to visualize the posterior mesh. Check the mesh has not been twisted or caught in any of the earlier sutures.

If only one assistant is available secure the two Allis forceps holding the vaginal epithelium with towel clips. Prepare a 2/0 PDS suture to secure the mesh to the midline and hold one side of the distal end of the mesh. The assistant surgeon holds a retractor deeply into the posterior fornix to maximize the vaginal length with one hand and the other side of the distal mesh with the other. The surgeon can then cut the distal mesh in the midline until he reaches the perineal body where the mesh is secured with a single 2/0 PDS suture in the midline. Once this suture has been placed in position the assistant can remove the anterior retractor unless it is still needed to keep the anterior mesh away from the operative field.

#### **STEP 18: PERINEAL SLINGS**

The divided posterior CR Mesh distal to the attachment to the perineum in the midline forms two slings which pass posteriorly through the perineum, around the anus and emerge from the same skin incision as the proximal translevator sling

The pulling suture of the distal mesh on each side is attached to the TVA Tuneller and this instrument is then passed laterally at the distal end of the levator muscle adjacent to the perineal body for a maximum distance of 1cm. It is then turned posteriorly to pass lateral to the anus and exit the skin through the same incision as the proximal translevator sling. This is done on each side.

When passing the TVA tunneller posteriorly on each side be sure to remain very superficial, just under the skin, as the rectal artery and vein cross the path of this instrument adjacent to the anus but at a deeper level.

The perineal slings are pulled through and if necessary lateral holding sutures are added at the edge of the mesh in the vagina to ensure that the mesh lies smoothly and does not curl up or move to a different position. Cut off the excess mesh and the pulling suture from each distal sling to leave 2-3cm of mesh on each side.

#### **STEP 19: BLADDER NECK**

Place an Allis forceps on the skin edge on either side of the bladder neck to lift up the anterior vaginal skin incision so as to visualize the bladder neck and paraurethral tissues. Make sure a speculum or Briesky retractor is placed in position posteriorly to hold the vaginal apex deep back into the pit of the sacrum while any anterior vaginal measurement and adjustment of the mesh is performed.

Ask your assistant(s) to hold the distal corners of the anterior CR Mesh while you cut the mesh in the midline to reach the bladder neck. The midpoint and length can be marked by placing a small clamp on the mesh to identify this point. Use a 2/0 PDS or equivalent suture to secure the mesh to the paraurethral tissues close to the bladder neck on either side.

#### **STEP 20: DISTAL TRANSOBTURATOR SLINGS**

First ensure that there is adequate dissection lateral to the bladder neck and that a finger placed through the incision between the mesh and the vaginal side wall adjacent to the bladder neck can reach the inner surface of the obturator foramen.

The TOA Universal tunneller is used with an outside in approach to enter the vagina from a skin incision at a point 1cm medial to the skin fold at the level of the clitoris.

Hold the TOA Universal tunneller in a vertical position with the tip inside the skin incision. Use the free hand to place an index finger on the undersurface of the obturator membrane by passing it through the vaginal incision lateral to the mesh. Place the thumb of the same hand on top of the TOA tunneller and use it to feel the tunneller passing adjacent to the bone to enter the upper medial aspect of the obturator.

Use the other hand holding the handle of the tunneller to move the handle 45 degrees lateral and then rotate the tunneller onto the tip of the index finger inside the vaginal incision then guide the needle out into the vagina. Be careful not to perforate the vaginal epithelium in the sulcus by keeping close contact with the tip of the needle at all times.

Attach the correct pulling suture and hold the mesh in the correct alignment to facilitate it pulling through the obturator successfully. Complete the procedure on the contralateral side.

#### **STEP 21: ADJUSTMENT OF DISTAL TRANSOBTURATOR SLINGS**

The distal transobturator slings are attached to the bladder neck and are similar to a traditional bladder neck sling but they are suspended from the medial anterior aspect of the obturator foramen rather than retropubically.

These slings can be adjusted using a coaptation test, once they have been pulled into position. Excessive tension may result in voiding difficulty, although this is usually temporary.

#### **STEP 22: VAGINAL SKIN CLOSURE**

The anterior vaginal incision is closed with interrupted 2/0 Vicryl sutures. The posterior vaginal incision is closed with a 2/0 Vicryl continuous suture.

#### STEP 23: REMOVE HOLDING SUTURES

Nylon holding sutures are removed from the four proximal slings.

#### STEP 24: TRIM EXCESS SLING AND MESH

All slings and mesh are cut off at the skin. Push the skin down before cutting. Lift the skin edge up after cutting each sling or mesh extension to ensure there is no residual prosthesis close to the surface within each incision.

#### STEP 25: EXTERNAL SKIN CLOSURE

External skin closure is performed using 2/0 Vicryl sutures or Steristrips or Skin adhesive.

#### STEP 26: CYSTOSCOPY

Cystoscopy should be performed if there is any suspicion of bladder trauma or unexplained haematuria. Some surgeons prefer to perform cystoscopy as a routine.

At cystoscopy check the following

- Integrity of the bladder.
- Presence or absence of any signs of obstructed voiding.
- Ureteric orifices with normal flow
- Urethra

#### STEP 27: CATHETER AND PACK

Place a Size14 Silastic catheter in the bladder and connected to a drainage bag at the end of the procedure. This catheter is left on free drainage for 2 days after the surgery.

A vaginal pack or bandage soaked in a suitable cream or fluid such as Betadine, Hibitane or oestrogen is placed in the vagina at the end of the procedure.

#### STEP 28: RECTAL EXAMINATION

Check the rectal mucosa and sacrospinous attachments at the end of the procedure.

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# The neuropelveology: a new specialty in medicine?

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## INTRODUCTION

The pelvis contains not only different organs such as the bladder, rectum or genital organs, but also pelvic nerves. After the central nervous system and spinal cord, no other part of the body contains so many and such important nerves: pelvic nerves are not only involved in sexuality, voiding and storage pelvic organs and locomotion but also in the transport of all sensitive information's generated in the lower limbs and pelvis to the central nervous system. Pelvic nerves damages lead therefore to pelvic visceral dysfunctions, problems with locomotion and different kinds of pain. Unfortunately no specialty deals electively with the pathologies of the pelvic nerves and plexuses!

## PELVIC NERVES ARE OMITTED IN MEDICINE

Reports about pelvic nerves damages secondary to surgical and obstetrical procedures are rare in literature. This is surprising if one considers how many invasive procedures in proximity to the pelvic nerves are performed every day over the world and how many pelvic pathologies do exist which could potentially induce a compression, entrapment or invasion of the pelvic nerves. Incidences of pelvic nerves pathologies are widely underestimated obviously because of lack of awareness that such lesions may exist, lack of diagnosis and acceptance, declaration and report of such lesions. The same phenomenon of "incidence underestimation" is observed with all neurogenic and non-neurogenic pelvic nerves and plexuses pathologies.

The most probable reasons for omission of the pelvic nerves in medicine are the complexity of the pelvic nerve system, the difficulties of etiologic diagnosis and - probably the main reason - the limitations of access to the pelvic nerves for neurophysiologic explorations and neurosurgical treatments. Neurosurgical procedures techniques are well established in nerve lesions of the upper limb but pelvic retroperitoneal areas and surgeries to the pelvic nerves are still unusual for neurosurgeons. Few open-surgical approaches to the sacral plexus have been described by neurosurgeons for treatment for traumatic pelvic plexopathies, but these approaches are laborious and invasive, offer only limited access to the different pelvic areas and expose patients to risk of severe vascular complications. Techniques of nerves neuromodulation to control pelvic pain syndromes and dysfunctions are for the same reasons, limited to spinal cord and sacral nerves roots stimulation that restrict considerably their indications and effectiveness.

## LAPAROSCOPY ENABLES PELVIC NEURO-FUNCTIONAL SURGERY...

All these limitations of access to the pelvic nerves and plexuses can now be overcome with the laparoscopy: development of video endoscopy and microsurgical instruments enables good access to all areas in the retroperitoneal pelvic space, providing the necessary visibility with magnification of the structures and possibility to work with appropriate instruments (figure 1).<sup>1</sup> Using laparoscopic exposure and sparing of the motor autonomic nerves of the pelvic organs, postoperative functional morbidities can be avoided successfully in radical pelvic surgery.<sup>2</sup> Therefore iatrogenic dysfunctions such as bladder retention, chronic

constipation, urinary and faecal incontinence or sexual dysfunctions cannot longer been accepted as a fatality that patients must accept as the "price for a optimal procedure", but must be considered complications that can be avoided by using selective nerve sparing techniques, without compromising the radicality of the procedure. In pelvic pain and/or dysfunctions due to pelvic nerves damages secondary to pelvic surgeries or pelvic pathologies, laparoscopy allows for an exact morphologic, etiologic and functional exploration of the pelvic nerves that can results in an effective treatment. Classical neurosurgical procedures such as nerve decompression and reconstruction are feasible in optimal surgical conditions through this way. Moreover, laparoscopic surgery is the gold standard for treatment of etiologies such as nerve endometriosis or vascular/fibrotic tissue/surgical material nerve entrapment.<sup>3</sup> The laparoscopy is therefore the essential and logical step in the management of pelvic nerve pathologies that must be indicated as soon as possible, before the nerve damage becomes irreversible and before the process of "pain chronification" starts.

## ... THAT OPENS A NEW THERAPEUTIC WAY FOR A LARGE NUMBER OF PATIENTS ...

Laparoscopy is also the only technique that enables selective placements of electrodes to all pelvic nerves and plexus. This technique of **L**aparoscopic **I**mplantation **O**f **N**europrothesis also called "LION procedure", enable both, a morphologic and functional exploration of the nerves before the decision of implantation, and a selective placement under optimal vision of electrodes in direct contact to the nerves.<sup>4</sup> The use of multiple channel electrodes enables stimulation of different pelvic nerves and plexuses at the same time and with a broad variation and combination of electrical currents. So the sacral plexus LION procedure permits to control most of pain syndromes and dysfunctions of pelvic organs (chronic pelvic pain, sacral radiculopathies, pudendal/gluteal/genital pain, urgency syndrome, bladder hyperactivity and/or retention, urinary and faecal incontinence...) and of the lower limbs (phantom and residual post-amputation pain, spasticity and spasms, muscle atrophy...). This evolution also presents new therapeutic options in the management of patients suffering from neurogenic pathologies of the peripheral (multiple sclerosis, polyneuropathies, neuromas...) and of the central nervous system (multiple sclerosis, Parkinson syndromes, stroke...).

## ...AND A REVOLUTION FOR SPINAL CORD INJURED PEOPLES

For spinal cord injured people, since a complete biological cure is unlikely to be developed in the near future, electrical devices are still required to restore functions. The LION procedure enables implantation of electrodes to the different pelvic nerves involved in pelvic functions and locomotion. In this way, pudendal neuromodulation enables relaxation of the bladder during filling phase and micturition when desired, letting patients free from catheterization. The sciatic neuromodulation allows for control of spasticity of the lower extremities by muscle training that constitute in combination with the electrical induced skin blood flow

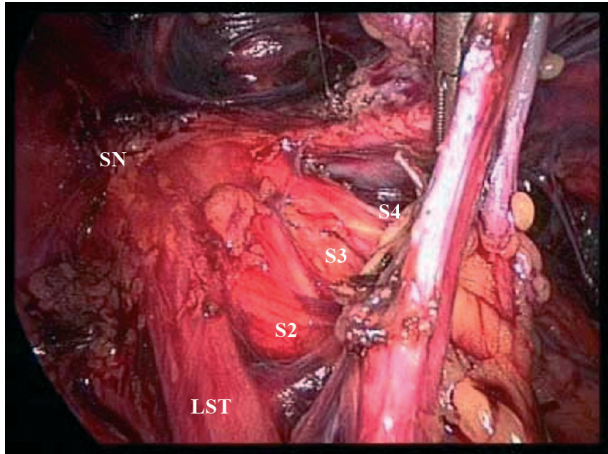


Fig. 1 – Laparoscopic exposure of the left sacral plexus SN: sciatic nerve – LST: lumbosacral trunk – S: sacral nerve root.

improvement, an optimal prophylaxis against decubitus lesions.<sup>5</sup> Blockade of the knees in extension by femoral stimulation with stabilization of the pelvis by concomitant sciatic stimulation enable lower paraplegics (Th7-Th12) to recover an autonomic alternative locomotion. In spina bifida children's, the LION procedure offers a unique method for controlling pelvic floor dysfunction using selective pelvic nerve stimulation and bypassing the points of anatomic abnormalities and scar tissue due to previous dorsal surgeries. Laparoscopic Neuro-Navigation is an essential Technique in this pathology since it grants an exact functional exploration and cartography of the pelvic nerves allowing for a more selective stimulation adapted to specific nerve damages. All these new aspects are the results of pioneering work which has been resumed under the term "neuropeleology". This new specialty in medicine focuses on the prevention, diagnosis and treatments of pathologies of the pelvic nerves and plexuses. The dilemma is that all knowledge required for this approach is dispersed into completely different speciality

areas, which usually have nothing in common: knowledge in neurology, pelvic neuro-anatomy, pathologies of the pelvic organs and training in laparoscopic (neuro-)surgery are mandatory. Nonetheless, because of the huge number of patients who may profit from these new developments, omission of the pelvic nerves in medicine is not any longer acceptable. This evolution will require more exchange of ideas between clinical physicians and basic researchers and should encourage young physicians to involve energy and work in fields of clinical and experimental surgery.

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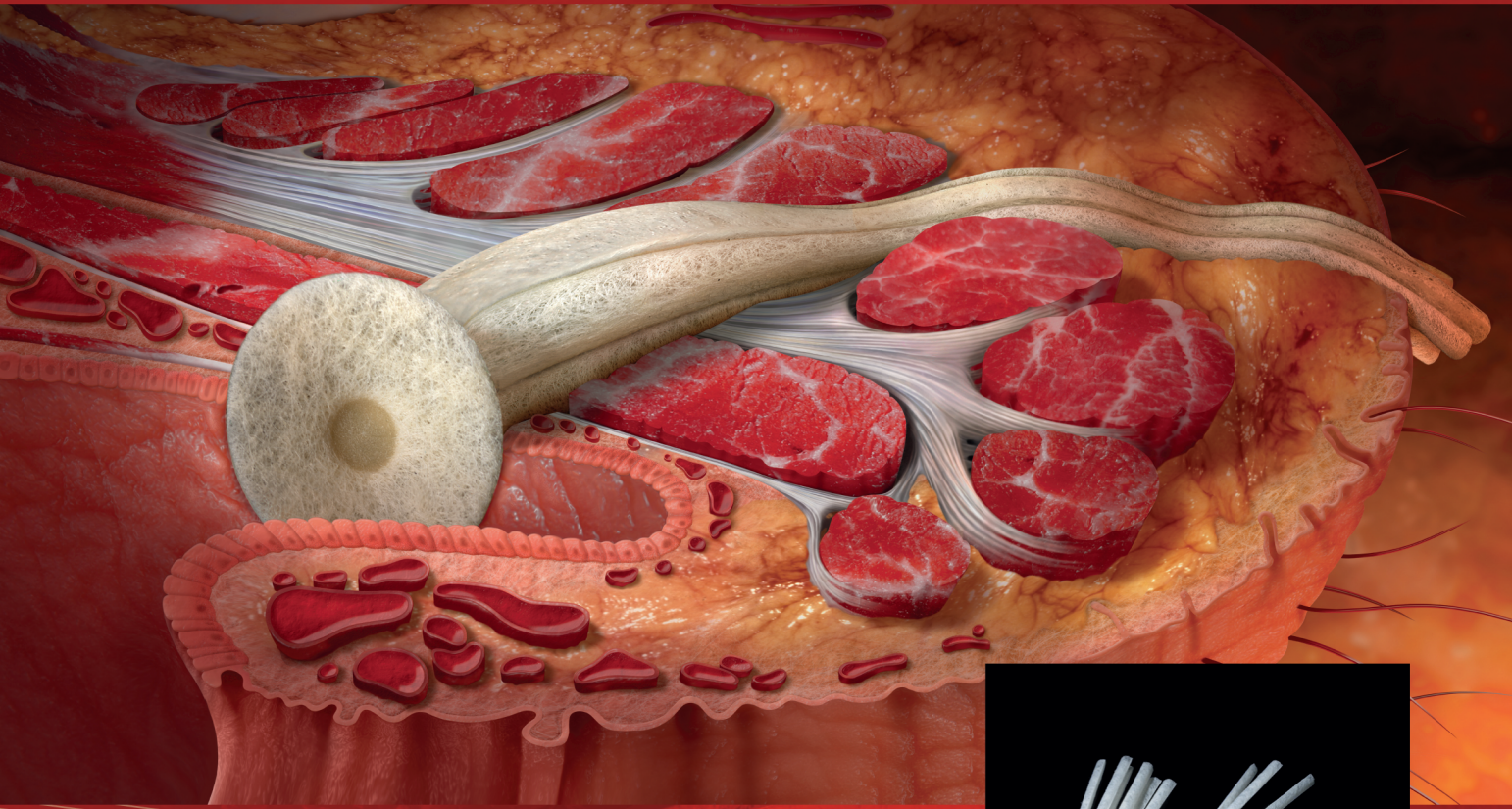


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The Standard Task Force, American Society of Colon and Rectal Surgeons: Practice parameters for the treatment of haemorrhoids. *Dis Colon Rectum* 1993; 36: 1118-20.

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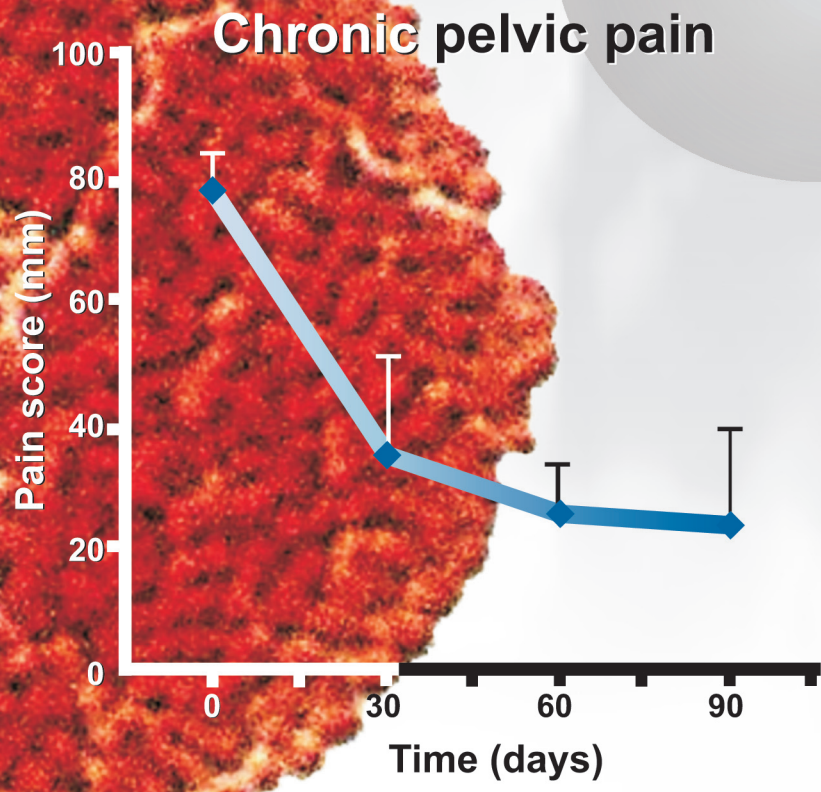
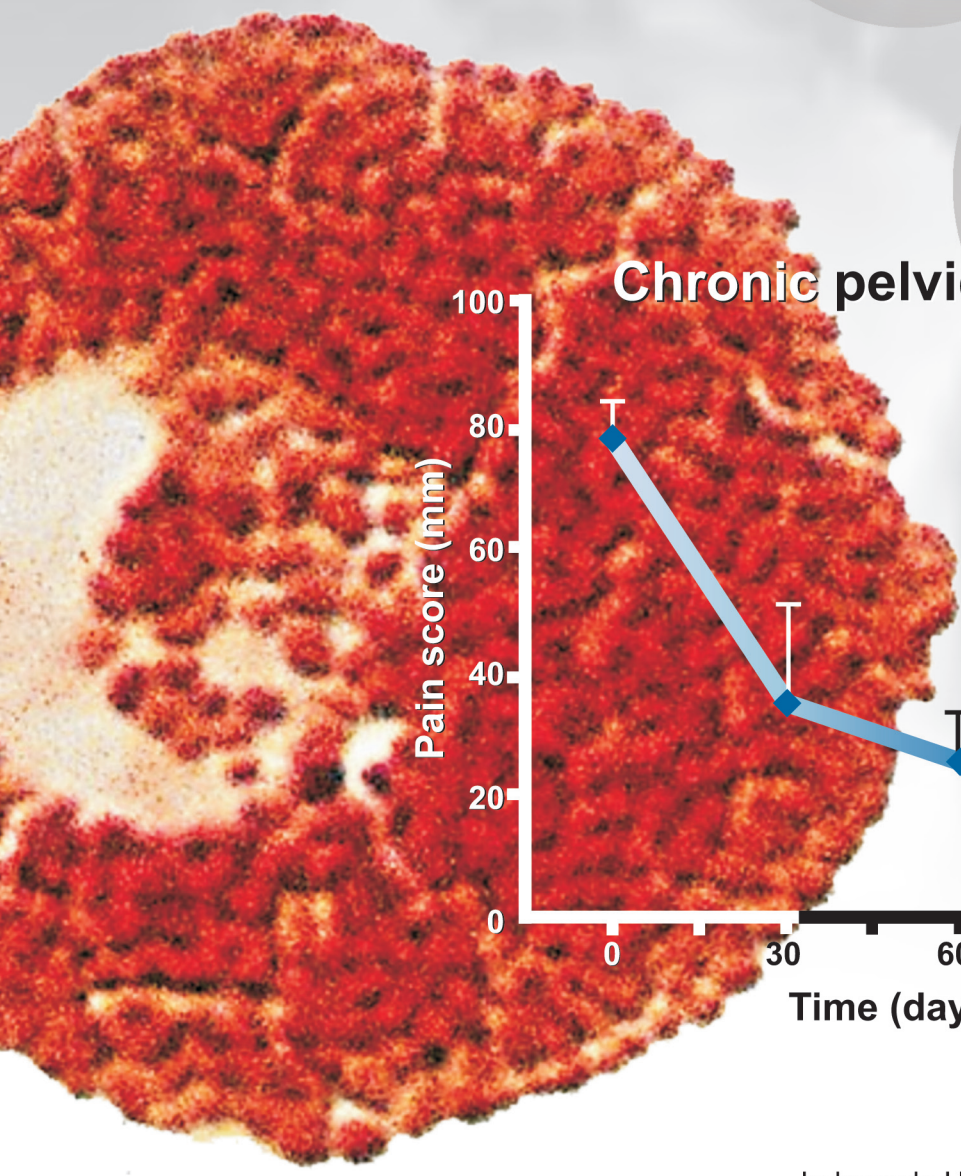
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