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PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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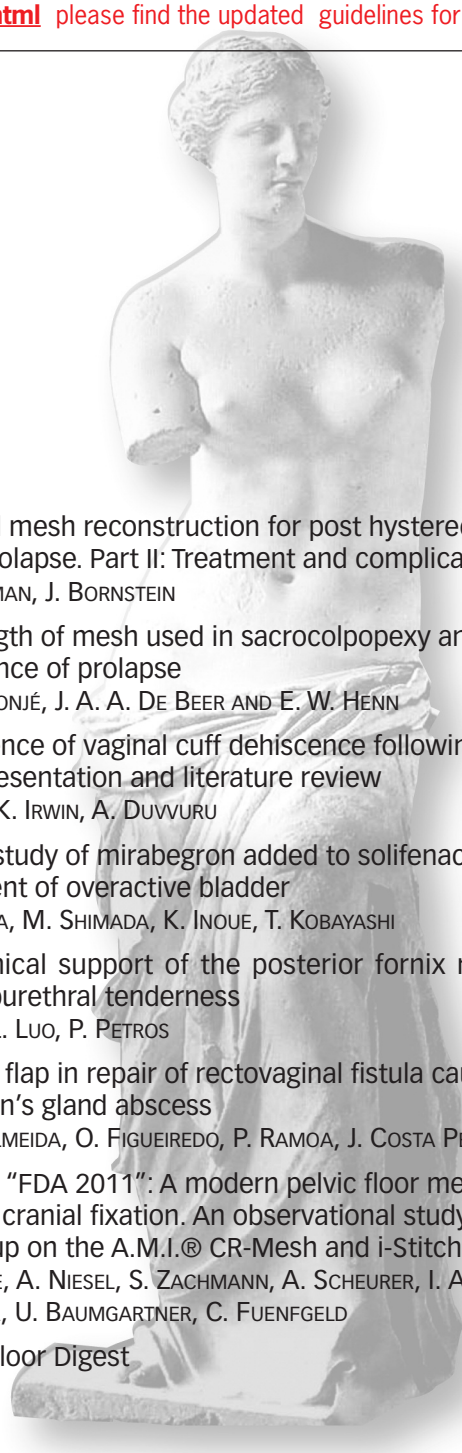

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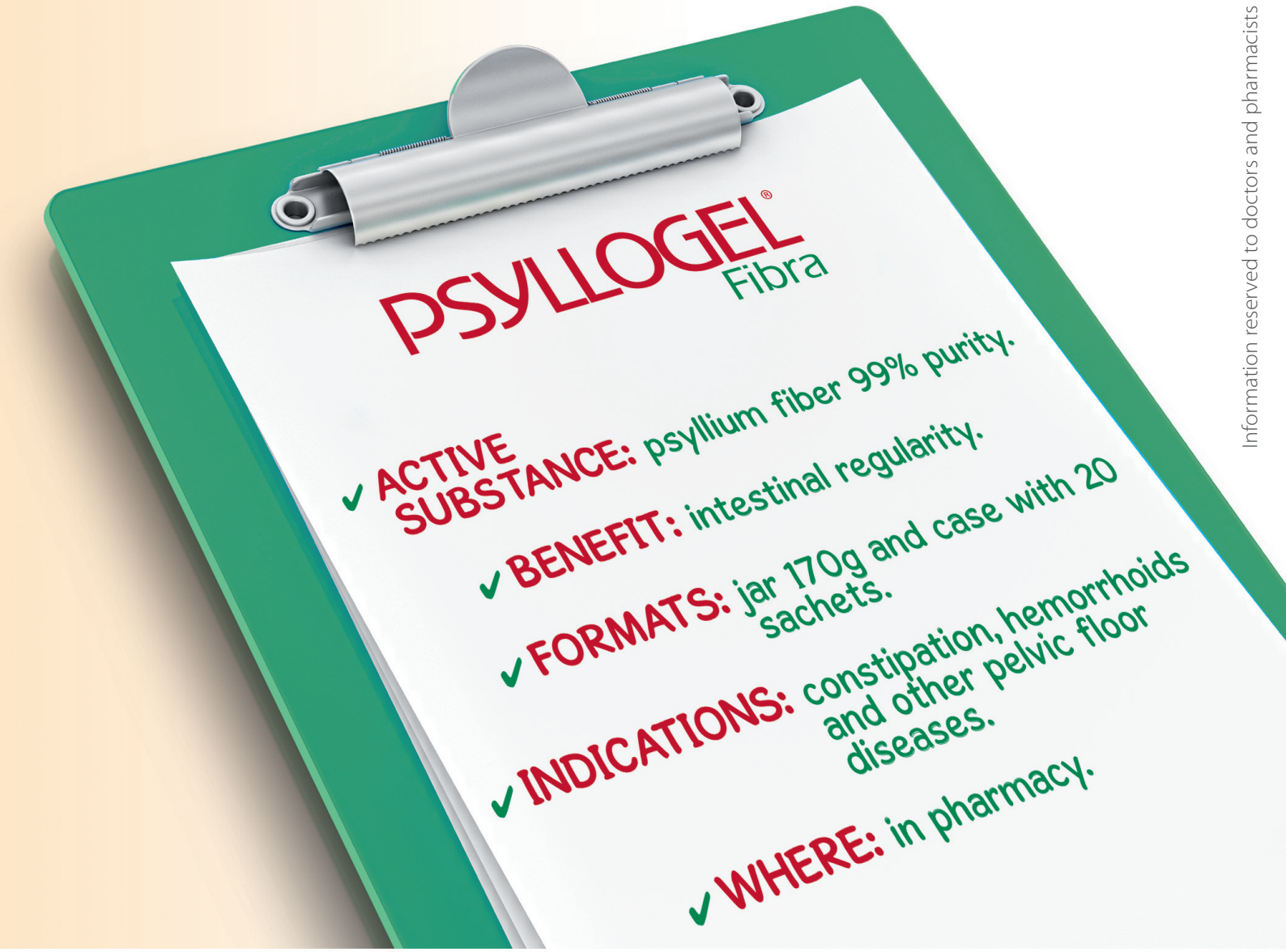

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A multidisciplinary pelvic floor journal

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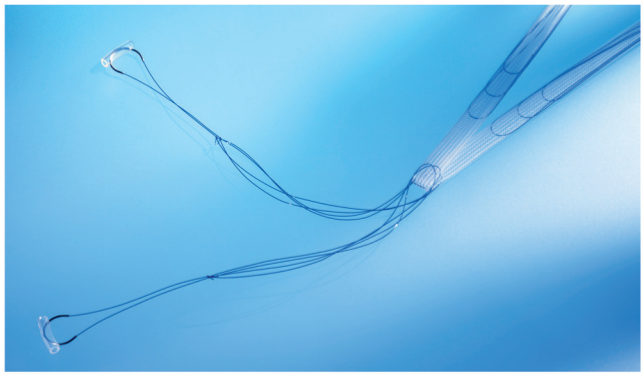

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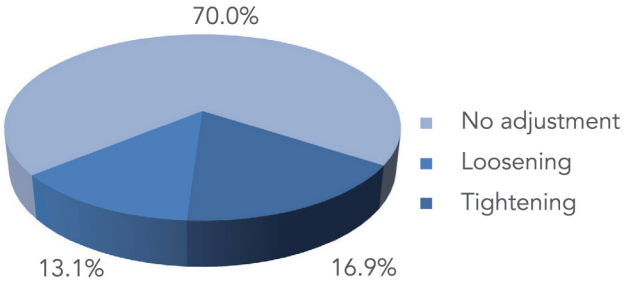

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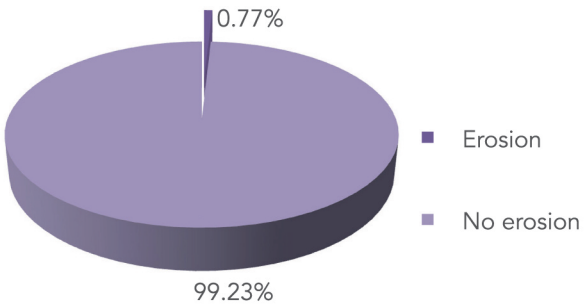

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10th - 13th October 2013 | Cliftons Conference and Training Centre | Sydney, Australia

This year the International Society for Pelviperineology returns to Sydney for our Annual Conference from October 10th to 13th 2013.

The venue is Cliftons Conference and training Centre at 60 Margaret Street Sydney which is a new modern facility in the centre of Sydney only 2 minutes walk from Wynyard railway station. There are several hotels within walking distance of the venue.

As usual a number of local and International speakers will provide an update of the latest developments and controversies in Pelvic medicine and surgery.

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EDUCATIONAL COURSE FOR UROGYNECOLOGISTS AND COLORECTAL SURGEONS ON THE POSTERIOR COMPARTMENT OF THE PELVIC FLOOR

PADOVA November 22-23, 2013
Università degli Studi di Padova

Course Director: Giuseppe Dodi
Honorary Presidents: Raffaele De Caro, Rodolfo Milani, Massimo Porena
Scientific Commitee: Alvise Frasson, Erica Stocco

Friday, November 22
Cadaver Pre-Course: Pelvic Floor Anatomy

14.00 Registration
14.30-15.30 Introduction to the pelvic floor anatomy and the Integral Theory System (ITS)

15.30-18.30 Practical session for surgical techniques

Saturday, November 23

08.00 Registration

08.15 Course Presentation
Lectures:
08.30-09.00 Pelvic Floor Anatomy
09.00-10.00 Pelvic Floor Physiology, the Integral Theory System
10.00-10.30 Diagnosis: Ultrasound, ABS, Solid Sphere Test, Trifunction

10.30-10.45 *Coffee Break*

10.45-13.00 **Workshop: Surgery for genital POP**
- **laparoscopic / robotic assisted approaches**
- **fascial transvaginal procedures**
- **prosthetic transvaginal procedures**
- **Tissue Fixation System (TFS)**

13.00-14.00 *Lunch*
Video presentations on surgical techniques and on-line anatomy

14.00-15.30 **Round Table: Comparison of Surgical Procedures in POP**
Results, complications, legal aspects

15.30-16.30 **Interactive lectures: Surgery of Rectal Prolapses and total POP**

16.30-16.45 *Coffee Break*

16.45-17.15 **Rectovaginal Fistula Surgery**

17.15-17.45 **Sacral Neuro Stimulation for pain and functional disorders after pelvic floor surgery**

17.45-18.30 **Final interactive overview of the Integral Theory System and practical applications**

Professor Peter Petros (Sydney, Australia) will give important contributions to the meeting. The Integral System is a total care system which states that POP, bladder & anorectal dysfunctions mainly arise from lax suspensory ligaments. Through the Integral Theory System (ITS) the dynamic anatomy translates to practical clinical management (dysfunction, diagnosis, surgical and non-surgical management of conditions such as urgency, nocturia, pelvic pain, abnormal emptying, constipation and idiopathic fecal incontinence).
The meeting will contribute substantially to the understanding of the following: anatomical mechanisms of causation for pelvic floor damage related to pregnancy, evidence-based management of female urinary incontinence, anatomical basis for obstetric fecal incontinence, female sexual dysfunctions and chronic pelvic pain syndromes.

Registration fee:

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The registration fee includes access to the Course, coffee breaks, lunch and gala dinner (November, 22nd).

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Only for 15 participants there is the possibility to enter the Anatomy Room with a surcharge of € 100,00 + Vat per person.

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Update

Surgical mesh reconstruction for post hysterectomy vaginal vault prolapse. Part II: Treatment and complications

MENAHEM NEUMAN[1], JACOB BORNSTEIN

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Abstract: The post hysterectomy vaginal vault prolapse (PHVVP) occurs with up to 50% of parous women. It was reported to cause a variety of urinary, bowel and sexual symptoms and to necessitate surgical correction in 11% of the female population. Up to 30% of all females suffer from pelvic floor relaxation progressed to a level which has a negative impact upon their quality of life. Hysterectomy results probably with damages to the integrity and blood supply of the endopelvic fascia as well as to the innervation of the pelvic floor musculature. This might potentially contribute to later POP manifestation. Post hysterectomy vaginal vault prolapse challenges commonly the pelvic floor healthcare practitioner, requiring thorough understanding of the pathology and adequate skills for treating it. Various aspects of PHVVP reconstructive surgery a well as operations for the cure of co-existing morbidities as urinary incontinence, vaginal wall prolapse etc. are discussed in depth.

Key words: Post hysterectomy vaginal wall prolapse management.

1. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: THERAPEUTIC GOALS

One should bear in mind the different surgeon's and patient's expectations and desires related to POP therapy. While the practitioner might be satisfied with goon anatomical restoration, the patient looks for the functional recreation mainly. There is a need for a holistic approach towards the patient's anatomical abnormalities and the related functional impairments, including urine and fecal control and sexual intercourse. Patient's un-realistic expectations with the therapeutic process should be identified and adjusted to the known operative curative properties regarding urinary and fecal incontinence, bladder over activity symptoms, sexual functions as well as body image. Co-existing occult urinary female stress incontinence should be diagnosed prior to surgery and dealt with an anti-incontinence concomitant procedure.

2. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: HERNIATION CONCEPT

POP is actually bulging of viscera through weakened pelvic floor and vaginal walls. Terms used to describe the pelvic organ prolapse in general, and particularly post hysterectomy vaginal vault prolapse could be easily replaced by simply stating the specific herniation process. Cystocele and urethrocele are then herniation of the anterior compartment of the pelvic floor. Uterine, uterine cervix and PHVVP prolapse are all central pelvic floor herniation and enterocele, rectocele and perineal body tear are herniation of the posterior compartment of the pelvic floor. Endorsement of this approach improves the understanding of the underlying process and points to the appropriate therapeutic tools elected for cure, based on the knowledge accumulated regarding hernia repair at other regions of the human body.[1]

3. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE RECONSTRUCTION: ARCHITECTURAL DESIGN

Comprehensive pelvic floor anatomic-functional approach should be based upon solid long lasting suspension of the vaginal vault apex to well established pelvic sustained structures. Among such are the ATFP (Arcus Tendineus Fascia Pelvis) and the sacro-spinous ligament. The first lays along the lateral border of the levator ani muscles, from the inferior pubic ramus and the obturator membrane anteriorly to the ischial spine posteriorly and the second connects the iscial spine to the sacrum. Another anchoring option is the pre-sacral fascia, which longitudely covers the sacral vertebra and provides a solid structure which might serve as a suspensory point to secure the vaginal apex to. Attaching the vaginal vault to one of these ligaments will yield a long lasting apical support, permitting restoration of the impaired pelvic floor and organs functions. Some advocates the pre-sacral fascia, as it is easily reached it is reached easily via the peritoneal cavity, either by laparotomy or by laparoscopy, while others are against because of relatively high rates of intra and post operative bleeding potential, prolapse recurrence and difficult vaginal access. The ATFP, being relatively easily accessed via vagina is elected by some for vaginal vault support, and others will go for the SS ligament, saying this is the most stable pelvic structure, hence providing the best and longest standing support. Deep pelvic dissection, wider than for the ATFP, is necessary for reaching the SS. The cardinal and the utero-sacral ligaments are other potentially usable supportive pelvic anchoring points, yet not easily identified and often obscure. Unfortunately, there is no comparative data to guide any evidence based decision making regarding the preferred pelvic supportive connective tissue, rather than experts opinions.

4. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE: NON-MESH REPAIR

The PHVVP non mesh repair operations are mainly done via vaginal approach as the abdominal rout might frequently requires mesh to bridge the gape between the vaginal apex and the anchoring point at the pre-vertebral fascia. For sexually non active women, whenever the vaginal sexual functions might be sacrificed, colpectomy or vaginal obliteration (Le Fort operation) is a therapeutic option. These relatively safe and simple operations are carried out vaginally, yet prolapse recurrence rate was not established. The vaginal capacity is significantly and irreversibly reduced with these operations. If sexual intercourse function should be preserved, the vaginal capacity is to be maintained. Then are the commonly performed vaginal vault prolapse non-mesh repair done by apical suspension to the SS ligament. The sacro-spineous fixation operation requires deep para-rectal pelvic dissection and is eventually related to significant intra-operative bleeding. This operation was reported to be complicated by post-operative dispareunia, buttock pain, urinary and fecal incontinence, cystocele and rectocele formation, altered defecation and constipation, bladder injuries,

urinary retention and infections. The most troubling disadvantage reported to be attached to this operations is an acceptably high recurrence rate. Neither simple colporrhaphy, with or without plication of the utero-sacral ligaments, nor sacro-spineous and sacral colpopexies, seem to be the preferred procedures for repairing vaginal prolapse. Some authors observed that these surgical modalities are associated with an to up 58% recurrence rate in terms of objective POP scoring and prolapse related subjective symptoms while others reported on a recurrent surgery rate for pelvic floor reconstruction of 30%. True surgery related QoL improvement was never well addressed with these operations.[2-8]

5. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE SURGICAL SUSPENSION WITH MESH IMPLANTS FOR RECURRENCE RATE REDUCTION: JUSTIFICATION AND REASONABILITY

Given that recurrence rate following traditional vaginal apex re-suspension it unacceptably high and that underlying causative genetic, traumatic and surgical co-factors contributes to progressive weakening of the endo-pelvic fascia, one would endorse a recurrence reducing surgical method. The mesh implant concept was previously proven as recurrence reduction method with abdominal wall hernia repair and was later implemented for the pelvic floor herniation repair as well.[9]

6. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE SURGICAL SUSPENSION WITH MESH IMPLANTS SPECIAL PERSPECTIVES

Unlike with abdominal wall hernia vertical mesh repair, the vaginally horizontal implanted meshes are under relatively high level of physical pressure. This makes the vaginally implanted meshes prone to further prolapse, unless well secured to solid pelvic structures as the SS, the pre-sacral fascia, the ATFP or the utero-sacral ligaments. The vaginally implanted meshes are covered by thin and fragile layer of mucosa in comparison with the thick abdominal wall coverage; hence erosion and mesh exposure are possible post operative complication. Anti erosive surgical steps are to be taken in order to minimize mucosal erosion and vaginal mesh protrusion hazard. Among these anti erosive steps are the well respected tension free principles for herniation repair, for both – vaginal wall tissue and mesh. Refrain from excessive vaginal mucosa trimming and dissecting below the sub-mucosal fascia to preserve blood supply and nerve endings might contribute to reduce the post-operative tissue tension as well, avoiding ischemia, mal healing and tissue necrosis, thus reducing the mesh exposure incidence. There is much importance of replacing significant and sufficient parts of the endo-pelvic fascia, beyond the borders of the defected endo-pelvic fascia and pelvic floor herniation process, with the artificial synthetic fascia which is the mesh. This is best done by well spreading the mesh from one pelvic side-wall to the other, from the urethra and bladder neck to the vaginal apex, through the posterior compartment all the way down to the perineal body. Then are the pelvic organs not supported with the defected endo-pelvic fascia any more but rather with the fascia replacing synthetic mesh. Wide dissection is generally required for achieving proper repair and meticulous support ensuring. Ligament through passing with the mesh arms is the preferred anchoring method, as it probably yields long lasting support in comparison with suture mesh fixation methods. The pre-operative surgical field sterilization achieved with abdominal operations could never be gained with vaginal surgery, as this will be never exceed the level of "clean-contaminated" sterilization degree, due to inability to totally disinfect the vagina. Hence, especially anti-infectious designed new mesh types were requested. Macro-porous and mono-filament meshes discourage bacterial growth and nesting and thus are best used for vaginal pelvic floor reconstruction.

7. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE SURGICAL SUSPENSION WITH MESH IMPLANTS FOR RECURRENCE RATE REDUCTION - EVOLUTION OF THE CONCEPT

Though the best approach for restoration of vaginal apical support among the commonly utilized abdominal and vaginal routes remains controversial, the utero-sacral, SS, ATFP and Sacral ligaments vault suspension are the most anatomical among the repairs. Hence, it is most unlikely that these ligament supports for the vaginal apical prolapse will create a predisposition to future anterior or posterior vaginal vault defects or compromise vaginal function. Given that vaginal vault herniation is the result of separation of the pubocervical fascia from the recto-vaginal and paracolpion facia, resulting in an apical enterocele, it should be corrected by meticulous herniorraphy including reattachment of the vaginal vault to one of the above mentioned ligaments. Early attempts to apply the well accepted approach of simple mesh implantation with abdominal wall herniorrhaphy for recurrence rate reduction to the POP repair surgery ended with disappointing results. The failure and mesh exposure rates were extremely high and these attempts were stopped. The reasons for failure were better understood later, as the intra-abdominal forces directed to the pelvic floor implanted mesh and the relatively poor mucosal coverage were acknowledged. These considerations encouraged the design of an innovative procedure for the correction of the apical vaginal support defect, through replacement of the utero-vaginal ligament encoding with a synthetic sling, positioned at the levator plate level space via vaginal approach to the para-rectal area, performed in a daycare setting. The novel Posterior Intra-Vaginal Sling (PIVS), entailing minimal invasiveness via a vaginal approach together with anatomical restoration of the uterosacral ligament suspension of the vaginal apex, performed in a daycare set-up. Magnetic resonance imaging showed that significant improvements in the restoration of the vaginal configuration were achieved in patients who underwent PIVS. The PIVS operation facilitates uterine conservation, even in the event of advanced uterine prolapse. The restoration of the uterosacral ligaments support enables the surgeon to re-suspend the uterine isthmus, hereby avoiding the necessity to perform vaginal hysterectomy for the treatment of uterine prolapse. Thereafter further developments occurred: the mesh against slings debate rose up; questioning whether the preferred way for POP repair is replacing the specific broken endo-pelvic ligaments with synthetic sling is adequate. Others felt that the whole endo-pelvic fascia should be replaced with large mesh from one side-wall to the other and from the pubic bone towards the sacrum is desired, similar to the way mesh implants are used with abdominal wall herniation repair and ending with large mesh size. The best mesh pelvic fixation points and fixation method are another field of uncertainty with POP vaginal mesh implantation: the SS, ATFP, pre-sacral and the sacro-uterine ligaments were all advocated as suitable for pelvic mesh anchoring with variety of fixation methods. Some feel very strongly that the only long lasting fixation method is passing wide mesh arms through the ligaments, others simply sutured the mesh to ligament and various stapling devices were introduced as well. All the above mentioned influence the needed width of pelvic dissection, hence the needed training and skills as well as the potential operative hazards.[10-15]

8. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - PRINCIPLES OF MESH RECONSTRUCTION

The support facilitating and enhancing mesh should be secured to the vaginal apex on one edge and to the elected supportive structure – the SS, utero-sacral, pre-sacral or the ATFP ligaments on the other edge. The mesh should substitute the herniation causing weakened fascia that led to prolapse of the central, anterior and/or posterior pelvic floor compartments. Thus, the post hysterectomy vaginal vault prolapse, as well as the frequently co-existing cystocele and/or entero-rectocele are to be properly corrected simultaneously. In case of co-existing cystocele should the mesh provide support to the whole anterior pelvic floor compartment and be secured also to the anterior end of the ATFP, while with co-existing entero-rectocele should the mesh provide support to the posterior pelvic floor compartment and be secured also to the perineal body. These additive secures will serve to stabilize better the mesh and avoid displacement and recurrent prolapse.

9. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - SURGICAL PEARLS

Tension free concept for the mesh placement and attachment as well as the mesh covering tissue should be kept in mind at all times when reconstruction of damaged pelvic floor is undertaken. This will reduce tissue ischemia, tissue necrosis, mal healing and later mesh exposure. Preservation of viable blood vessels and nerve endings by deep and full thickness infra-fascial lateral dissection of the vaginal wall will contribute for mesh exposure reduction. This is remarkably facilitated with hydro-dissection which is helpful for getting into the true vesico-vaginal and recto-vaginal spaces leads to lower erosion rates. A non-ischemic colpotomy closing suture knotting and minimization of the vaginal through cut are also valuable anti ischemic measures. Extensive mucosal trimming for tissue tailoring while normal dimensioned vaginal recreation might end with tensioned vagina, thus to further mesh exposure. Important is meticulous mesh flattening before vaginal cut assembling, to avoid post operative infra-mucosal mesh folding and pain, including dysmenorrheal. Mesh position securing, either by ligament passing mesh arms or with suturing, should ensure that the mesh is properly spread to replace the whole herniation causing defected endo-pelvic fascia.

10. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE VERSUS REPAIR OF VAGINAL VAULT PROLAPSE WHILE THE UTERUS IS IN SITU

The un-removed uterus offers the surgeon solid central pelvic encoring points such as the cervical ring or the uterus itself. These organs might then both be attached to various solid structures at the pelvic side-walls, as the SS, sacro-uterine, ATFP or the pre-sacral ligaments. Being connected to the cervico sacral, cardinal and cervico-pubic ligaments provides the spared cervical ring extra sustainability for the pelvic floor, arising out of recruitment these web architecture structures to the pelvic reconstruction. This perspective challenges the widely endorsed practice of reflective appointment for vaginal hysterectomy with any uterine prolapse diagnosis, trained at many centers and performed routinely around the globe. Solid data regarding the question whether should the prolapsed uterus be removed are not available currently. Yet, some level 2 evidence supports the preservation of the prolapsed uterus or the uterine cervix at least, potentially guiding a change with the common attitude of automatic indication towards vaginal hysterectomy whenever POPS is present. The direct disadvantages of hysterectomy regarding pelvic floor reconstruction are the damages to the endo-pelvic fascia integrity, vasculature, blood supply and innervation and the deprivation of the advantage of using the cervical rind and the web of connected ligaments for providing extra strength to the pelvic floor architecture. All these are extremely important for maintaining further pelvic floor sustainability and functions. Performing hysterectomy concomitantly with mesh pelvic floor reconstruction increases significantly the risk of post operative mesh vaginal exposure and the need for further operative intervention to cure this complication. Not rare is the occurrence of vaginal shortening after hysterectomy, to such degree that impairment of sexual intercourse. Except of the negative influence on the pelvic floor structure and functions, entails vaginal hysterectomy many operation related complication, some of are health and life threatening, and it might also physiologically mutilate the disregarded hysterectomised patient's body image and self esteem. Minimally invasive novel methods for the treatment of menorrhagia, endometrial polyps and uterine myomas as well as increasing public awareness against preventable hysterectomies lead towards preservation of the prolapsed uterus.[16-25]

11. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE REPAIR-VAGINAL VERSUS ABDOMINAL APPROACH

There are two surgical access routes for reconstructive pelvic surgery to correct POP: the abdominal approach (either by laparotomy or via laparoscopy) and the vaginal approach. Though the best approach for restoration of vaginal apical support among the commonly utilized abdominal and vaginal routes remains controversial; the pelvic ligament vault suspension is the most anatomical among the repairs. Hence, it is most likely that the utero-sacral, SS, ATFP and Sacral ligament support for the vaginal apical prolapse will yelled a long lasting vault suspension and restoration of the vaginal functions. For the last decade, various surgical modalities for curing POP through reconstruction of the pelvic floor have been advocated, mainly modification of the colpo-sacral and colpo-sacro-spinal fixations, using vaginal or abdominal approaches, via laparotomy or laparoscopy. These operations where associated with well documented complications such as mesh erosion, dispareunia, buttock pain, urinary and fecal incontinence, altered defecation and constipation, bladder injuries, urinary retention and infections, cystocele and rectocele formation and protrusion, and other disadvantages such as long operative time, slow return to normal living activities and great costs. Given that the vaginal vault herniation is the result of separation of the pubo-cervical fascia from the recto-vaginal and para-colpion fascia, resulting in an apical enterocele, it should be corrected by meticulous herniorrhaphy with reattachment of the vaginal vault to the utero-sacral ligaments. The vaginal approach for POP reconstructive operations is associated with fewer complications and results in a shorter rehabilitation period than the abdominal route, whereas hysterectomy is widely performed concomitantly whenever the uterus is significantly prolapsed. However, there is no clear evidence supporting the role of hysterectomy in improving surgery outcome. The new minimally invasive procedure for apical prolapse suspension, as the posterior intra-vaginal slingplasty (PIVS) for correction of advanced uterine prolapse, enables uterine preservation. The issue of vaginal hysterectomy within the context of POP was addressed earlier with regard to the potential additive curative effect in terms of reduction of the POP post-operative recurrence rate and the influence of future quality of life. No advantage was attached to hysterectomy in the

surgical cure of POP. Replacement of the broken utero-sacral ligaments applying PIVS provides adequate uterine re-suspension, hereby permitting uterine preservation while treating advanced uterine prolapse.[26-30]

12. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE REPAIR - LAPAROSCOPIC APPROACH

Laparoscopic suspension of prolapsed uterus or prolapsed vaginal vault is feasible and has durable curative results, yet it requires advanced laparoscopic skills and an experienced laparoscopic center as sever damage might occur to the surrounding organs during operation. This is done by suturing mesh to the anterior and posterior aspects of the vaginal vault and securing it to the longitudinal sacral ligament at the level of sacral 2nd or 3rd spine. Post operative dispareunia is claimed to be reduced in comparison with vaginal reconstruction but this was not proved. the advanced laparoscopic surgical skills required for laparoscopic sacro-colpopexy include deep pelvic floor tissue dissection capability as well as familiarity with suturing and knot tying. Thus, this procedure is reserved only for the very well trained end experienced laparoscopists. However, when properly performed is the laparoscopic approach for sacrocolpopexy claimed to be as effective as the abdominal one, while the operative time is significantly longer and hospitalization, blood loss and rehabilitation period are much reduced. due to the necessitated meticulous and proper prior training remained the laparoscopic sacral colpopexy unpopular at many medical centers.[31-35]

13. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - ISOLATED APICAL SUPPORT DEFECT MESH REPAIR

When the apical vaginal vault is prolapsed while the lower segment of the anterior and posterior vaginal walls are well suspended, apical correction only is needed. This might be achieved either via the abdominal cavity by laparotomy or by laparoscopy, or vaginally. The abdominal approach permits exposure of the pre-sacral longitudinal fascia for suspension of the prolapsed vaginal apes, yet frequently implanted mesh is required for bridging over the anatomical gap in-between the two structures. One mesh end is to be fixed to the pre-sacral exposed and bare 4 to 6 square cm. of fascia, avoiding the rectal vessels. The other mesh edge is fixed to the exposed vaginal apical wall. Often the bladder and the rectum must be dissected away from the vaginal apex for about 6 to 8 square cm. permitting adequate and sufficient mesh appliance in order to provide long standing support. Permanent sutures should be used for the mesh to soft tissue fixation. The suture must not be too tight to reduce the occurrence of tissue ischemia, necrosis and breakdown. Other possible fixation methods are staples, yet safety and durability were not reported. At the end the mesh is to be covered with peritoneum to avoid later intestinal damage. Vaginal apical suspension might also be achieved via vaginal approach, either using the ATFP or to the SS ligaments as anchoring points. The ligaments are reached via colpotomy, para-rectal or para vesical dissection and ischial space development. Displacement of the bladder, rectum and small bowels might be necessary for ligamentary palpation or visualization. Occasionally is the vaginal vault long enough for direct suturing to the suspensory ligament, yet – mesh implants are probably important for avoiding recurrence. Unless done bilaterally, which is a rather complicated operation, vaginal axis lateral deviation is induced, causing further potential dispareunia. The durability of this operation is not well established. Many advocates mesh implantation for sustained correction of vaginal vault prolapse, when performed via vagina. The mesh should be fixed either to the ATFP or to the SS ligaments on both lateral pelvic sides and to the vaginal apex medially.

14. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - APICAL AND ANTERIOR VAGINAL WALL SUPPORT DEFECT MESH REPAIR

When the apical vaginal support defect is combined with anterior vaginal wall defect (cystocele), should the apical reconstruction (chapter 22) be followed with anterior vaginal wall reconstruction to complete the pelvic floor repair. This might be done by classical anterior Colporrhaphy most of the times, if only the potential supportive characteristics of the Vesico-vaginal endo-pelvic fascia are judged to be sufficient for long lasting prolapse correction. There are not any existing objective tools to guide such decision, hence must the surgeon base his preferred approach upon clinical impression related to the tissue nature and personal and family history. Elects the surgeon to perform a classical anterior Colporrhaphy, should he make a longitudinal medial anterior wall cut and free the vaginal wall from the bladder Detrusor muscle. Then should he place some transverse sutures to approximate both sides of the vesico-vaginal endo-pelvic fascia to recreate a dissent support for the bladder, trim the un-necessary mucosa to tailor a vaginal at normal capacity and length and close the surgical cut. Should the surgeon decide that the particular pelvic floor might be not appropriate for homologous repair, might a mesh implantation be desired. With such situation, might the surgeon consider adding mesh reinforcement for the anterior vaginal wall reconstruction to the apical support operation. The mesh should preferably cover the whole anterior wall fascial supportive defect, and be spread from one pelvic side wall to the other, from anterior to posterior, to replace literally the whole anterior compartment pelvic endo-pelvic fascia and prevent recurrent prolapse. Achieving proper mesh placement requires then a rather large paravesical dissection, along with the bony pelvis up to the iliac spins laterally and posteriorly and to the pubic bone upwards. The mesh should be flattened properly to prevent further lump formation and vaginal pain. The mesh and the overlying whole thickness and well blood supplied vaginal mucosa should be left totally tension free to avoid tissue ischemia, mal-healing and mesh exposure. The mesh should be well attached to solid intra-pelvic ligament to prevent support brake down. The mesh should be also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments to recruit the endo-pelvic ligaments for improved supportive results. Mesh fixation to the para-urethral tissue is desired as well to promise latter stabilization of the construction. Normally, mucosal trimming is avoided or limited with mesh implants to reduce the possible tissue tensioning and ischemia.

15. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - APICAL AND POSTERIOR VAGINAL WALL SUPPORT DEFECT MESH REPAIR

When the apical vaginal support defect is combined with posterior vaginal wall defect (recto-enterocele), should the apical reconstruction (chapter 14) be followed with posterior vaginal wall reconstruction to complete the pelvic floor repair. This might be done by classical posterior Colporrhaphy, if only the potential supportive characteristics of the recto-vaginal endo-pelvic fascia are judged to be sufficient for long lasting prolapse correction. There are not any existing objective tools to guide such decision, hence must the surgeon base his preferred approach upon clinical

impression related to the tissue nature and personal and family history. Elects the surgeon to perform a posterior Colporrhaphy only, should he make a longitudinal medial posterior wall cut and free the vaginal wall from the rectum and enterocele herniation peritoneal sac. Then should he place a tobacco-pouch round suture to reduce the enterocele herniation and some transverse sutures to approximate both sides of the recto-vaginal endo-pelvic fascia to recreate a dissent support for the rectum. The distant levator muscles are to be approximated in a similar way to form a functional perineal body. The un-necessary mucosa is trimmed to tailor a vagina at normal capacity and length and then the surgical cut the closed. Should the surgeon decide that the particular pelvic floor might be not appropriate for homologous repair, might a mesh implantation be desired. When such occurs, should the surgeon add to the apical support operation posterior vaginal wall mesh reinforcement. The mesh should preferably cover the whole posterior wall fascial supportive defect, and be spread from one pelvic side wall to the other, from anterior to posterior, to replace literally the whole posterior compartment pelvic endo-pelvic fascia and prevent recurrent prolapse. Achieving proper mesh placement requires then a rather large para-rectal dissection, along with the bony pelvis up to the iliac spins laterally and posteriorly and to the perineal body anteriorly. The mesh should be flattened properly to prevent further lump formation and vaginal pain. The mesh and the overlying whole thickness and well blood supplied vaginal mucosa should be left totally tension free to avoid tissue ischemia, mal-healing and mesh exposure. The mesh should be well attached to solid intra-pelvic ligament to prevent support brake down. The mesh should be also secured to the fascial ring of the uterine cervix or to the vaginal apex at the insertion point of the former sacro-uterine ligaments to recruit the endo-pelvic ligaments for improved supportive results. Mesh fixation to the perineal body is desired as well to promise latter stabilization of the construction. Normally, mucosal trimming is avoided or limited with mesh implants to reduce the possible tissue tensioning and ischemia.

16. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - APICAL, POSTERIOR AND VAGINAL HIATUS SUPPORT DEFECT REPAIR

When the apical vaginal support defect is combined with posterior vaginal wall defect (recto-enterocele) and with widely opened vaginal hiatus should the apical and posterior compartment reconstruction (chapter 15) be followed with reconstruction of the perineal body to complete the pelvic floor repair. This might be done by classical perineorrhphy most of the times, if only the potential supportive characteristics of the recto-vaginal endo-pelvic fascia are judged to be sufficient for long lasting correction of the relaxed tissue. When the ano-vaginal septum is extremely poor, both sides the levator plate recruitment might be necessary for erection of solid perineal body and reducing the vaginal opening dimensions. Was the posterior wall reconstruction made with mesh, could the perineal body reconstruction be use for further covering the mesh, hence reducing the post operative mesh exposure hazard.

17. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - APICAL, ANTERIOR AND POSTERIOR VAGINAL WALL SUPPORT DEFECT REPAIR

When the apical vaginal support defect is combined with anterior and posterior vaginal wall defects (cysto-recto-enterocele), should the apical reconstruction (chapter 13) be followed with anterior and posterior vaginal wall reconstruction (chapters 14&15) to complete the pelvic floor repair.

18. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE - REPAIR OF APICAL SUPPORT DEFECT COMBINED WITH STRESS URINARY INCONTINENCE

When the apical vaginal support defect is combined with mid urethral supportive defect (occasionally forming urethrorocele), should the apical reconstruction (chapter 22) be followed with an anti urinary incontinence procedure, usually a mid urethral support reconstruction to complete the pelvic floor repair. One of the trans-obturator or retro-pubic TVT slings might be chosen better than the newly developed “mini slings”, in case that an anterior mesh was implanted, as the required deep para-vesical dissection might impair the tissue ability to harbor these mini-sling’s tips and they might not be well fixed.

19. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION - MESH CHOICE

Accurate diagnosis of all the prolapse features and site specific support requirements identification are mandatory for proper mesh choice. It is the presence of isolated apical supportive defect only at the central pelvic floor compartment or any additional anterior and/or posterior compartments prolapse that determine the requested mesh shape. It is the coexistence of urinary stress incontinence that indicates the need for additional mid-urethral support. The elected mesh or combination of meshes should be providing support for all the prolapsed pelvic floor sites. One must beer in mind that some commercially available anterior compartment meshes are designed for cystocele repair only while others provides the possibility to suspend the prolapsed uterus by cervical ring attachment, thus permitting it to be preserved. Other meshes provide support the mid urethra, concomitantly with anterior compartment reconstruction, hence avoiding the need for additional tape to support the mid-urethra separately. The later ones cure not only the anterior compartment prolapse only but the uterine prolapse and/or stress urinary incontinence simultaneously with the cystocele repair. Other meshes are designed for posterior compartment reinforcement, some of provides the possibility to support the prolapsed uterus or vaginal apex at the same time. Whenever there is a need to treat several sites of pelvic supportive defects more than one mesh might be needed. There should be a dissent and convincing published body of evidence to prove the safety and efficacy of the specifically chosen mesh. The surgeon must be properly trained with any new mesh by an experienced trainer and familiar with potential hazards' including prevention and management of these. The mesh texture need to be as soft and light as possible, none shrinking, small in dimensions, yet sufficient for complete replacement of all defected parts of the endo-pelvic fascia and pelvic floor herniation. Thorough defected endo-pelvic fascia substitution with the artificial fascia is crucial for insuring long lasting support. Host against graft and graft against host reaction formation should be ruled out according with any particular mesh prior to usage, so should any mesh related bacteria nesting or harboring. This is generally the case with type 1 mono-filament macro-porous knitted meshes, not interfering with macrophages migration. Long lasting anchoring method were reported to involve ligament through passing mesh arms, thus the particular mesh attachments to the pelvic chosen supportive points should be proved before hands for long lasting support, preferably with mesh arms through

ATFP or SS ligaments anchoring. Mesh and arm delivery systems for mesh individually prepared or pre-cut kits should be proven to yield the desired correct mesh and arms placement at the pelvic floor. Some pre-cut meshes might be too small to provide the necessary complete coverage of the whole fascial defects, thus easier to place because less dissection is required. Others might provide relatively easy arm placing devices, but at the price of improper arm passage at the deep ligaments of the pelvis for appropriate high support. These meshes might be prone to operative failure and recurrent prolapse. One should not be tempted for these easy to apply kits but rather go for the highly curative ones. Bio meshes where not proven to yield any advantage over the synthetic ones and one should not endanger his patients with bio-hazards. Smilingly, the absorbable meshes where not reported to entail any superiority and one should ask himself is there any potential benefit of a vanishing mesh in herniation repair at all. The list of available commercially manufactured products expends fast and the existing ones are regularly re-shaped, thus there is no point in referring to any particular currently available mesh. With this atmosphere of many newly designed meshes popping up almost monthly, one must be extra couches when choosing his own mesh. Of huge importance is solid clinical data, proving high cure rate and low rate of complications of mild nature. One should seek for proper training before adopting any new operation and maintain his skills with frequent operation performance.[36]

20. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION RELATED COMPLICATIONS: A. INTRA-OPERATIVE COMPLICATIONS

Superficial or deep bleeding might occur during operation, related to arterial or venous breakdown. While dissecting or at needle insertion might the neighboring viscera be perforated; this could involve the urethra, the bladder – at the ureteral orifice or remote from there, the small or large intestine. **B. early post-operative:** at the post operative course might partial or complete bladder outlet obstruction present, field infection could be evident, hematoma formed, vaginal, pelvic or at the thigh pain could appear- with or without neurological deprivation. **C. late post-operative complications:** chronic vaginal, pelvic or at the thigh pain and dispareunia were reported to complicate prolapse reconstructive surgery, with or without neurological deprivation, so was also vaginal mesh protrusion and bladder or rectal mesh protrusion. There is some unclearness whether the last ones occurred during or after the operation. Sacral abscess formation and vesico and recto-vaginal fistula are severe and health threatening post operative complications related to POP reconstruction. Mesh exposure has been described to complicate the postoperative course of these procedures in about 15% of the patients, other complications are relatively rare, yet important because of their potentially sever consequences. All the above mentioned complications were reported to complicate the abdominal as well as the vaginal operations, with type 1 or non type 1 mesh.

21. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION - REDUCING OPERATIVE COMPLICATIONS RATE

Proper training, skill maintaining and good surgical technique keeping are always the golden keys for any operative complication rate reduction. **Avoiding intra-operative bleeding:** hydro-dissection first, than dissecting at vessel free anatomical planes will reduce vessel breakage and bleeding. So will sharp dissection and proper needle passing through a-vascular tissues. **Avoiding intra operative urethral, bladder and intestinal injury:** meticulous dissection, according with standardized and pre-designed surgical steps and respecting anatomy alternating adhesion and fibrosis related to prior surgeries, might contribute to avoiding visceral operative damage. **Avoiding early post operative bleeding:** proper and meticulous intra-operative hemostasis and use of coagulation inducing agent when indicated will definitely reduce post operative bleeding potential. So might the usage of vaginal tampon. **Avoiding post operative pain:** post operative vaginal and pelvic pain and dispareunia might be reduced with proper placement and flattening of the mesh and with tension free surgical technique for both – tissue and mesh. Radiated thigh and leg pain are reduced by properly passing the mesh arms within the pelvic structures – away from neighboring situated nerves. **Avoiding post operative urinary obstruction:** urinary obstruction will be widely avoided by proper non tension mesh placement at the bladder neck level. **Avoiding post operative mesh exposure:** choosing the type-1 mesh for bacterial infection avoiding, vessel and innervation sparing full thickness vaginal wall dissection, shortening the vaginal surgical cuts as much as possible, meticulous hemostasis, non tensile mucosal closing, minimal mucosal trimming – all these will reduce tissue ischemia, necrosis, mal-healing and risk for mesh exposure. **Avoiding post-operative vaginal mesh bladder or rectal mesh protrusion or fistula formation:** meticulous anatomically wise dissection at the proper inter organ planes as well as tension free surgical techniques for both – tissue and mesh and blood vessels preservation will prevent late visceral mesh injury.37

22. POST HYSTERECTOMY VAGINAL VAULT PROLAPSE MESH RECONSTRUCTION - MANAGEMENT OF RELATED COMPLICATIONS: INTRA-OPERATIVE BLEEDING

Apply direct pressure upon bleeding zone, either manually or by packing, if needed - use advanced hemostatic agents or place hemostatic sutures to secure the broken blood vessels, consider selective arterial embolization or pack and finish the procedure. Note: bleeding might be extra-peritoneal, thus large in volume, be ready for blood transfusion, **Intra operative urethral injury:** vaginal repair is possible with 3 different anatomical tissue layers: urothelium, connective tissue and vaginal mucosa. Visualize urethral patency; keep the bladder drained for a week, continuing the mesh placement is optional. **Intra operative bladder injury:** evaluate damage with cystoscopy whenever bladder injury might be suspected. Unless ureteral orifice is involved - vaginal repair is possible, otherwise repair abdominally. Correction is best performed with 3 different anatomical tissue layers: urothelium, connective tissue and vaginal mucosa. Consider use of ureteral catheter; visualize ureteral patency, keep the bladder drained for a week. Controversy exists regarding mesh implantation after cystotomy, continuing the mesh placement is optional only if the bladder injury is mild in nature and leakage is not anticipated. **Intra operative small intestine injury:** if minor – repair and proceed with operation, otherwise – repair but refrain from mesh placement. **Intra operative large intestine injury:** if small – repair, otherwise consider diversion and colostomy. Abort procedure and do not implant mesh to avoid infection and protrusion. **Early post operative bleeding:** if patient is stable hemodynamicaly - use vaginal tampon and monitor vital signs as well as Hematocrit levels and ultrasonic imaging of the hematoma. Consider hematoma evacuation only if clinically significant, provide

preventive antibiotics. **Early post operative pain:** to a certain level of post operative pelvic pain is frequent and successfully dealt with by oral analgetics. When excessive or referred pain is evident, suspect nerve involvement or pelvic hematoma, take necessary diagnostic steps and act accordingly by removing the mesh or evacuating the hematoma. **Early post operative urinary obstruction:** complete post operative urinary obstruction is rarely improved with expectancy, thus early intervention to relieve increased mesh tension is indicated. This is easily achieved by re-opening the primer surgical cut at the anterior vaginal wall, clamping the mesh on midline sides and gentle downpulling, avoiding urethral damage as well as exaggerated mesh loosening. If just partial obstruction is diagnosed, and the residual urine volume is only moderately increased, recatheterization is probably sufficient as spontaneous relief occurs frequently. **Post-operative vaginal mesh protrusion** - small mesh exposures, occurring after abdominal colpo-sacro-pexy or vaginal reconstruction, might it be subject to local estrogens for a month time. There after - surgical removal is indicated if persistent. With large mesh exposures or with non type 1 mesh surgical removal should be performed as first measure as conservative treatment would be fruitless. **Late post-operative pain:** mesh exposure or retraction and vaginal tissue fibrosis might cause vaginal, pelvic, buttock or thigh pain, with or without neurological deprivation. Local treatment with estrogen and anti inflammatory might reduce pain, otherwise intervention should be considered for exposed mesh removal or mesh tension release. Chronic irradiated pain to lower extremity, especially when combined with neural deprivation, calls for mesh arm removal. This is not easy to perform and entails limit results. **Late post-operative discharge:** chronic vaginal discharge might be due to mesh exposure or vaginal granulation tissue formation; thus removal of these is indicated. **Post-operative dispareunia:** mesh exposure or vaginal wall tissue fibrosis should be suspected, especially if the partner is inconvenient during sexual intercourse as well. Thus, removal of these is indicated. **Post-operative vaginal mesh bladder or rectal mesh protrusion and vesico or recto-vaginal fistula:** These should be dealt with surgical therapy. The mesh should be removed and injured viscera should be treated. Surgeons should be familiar with and well trained for managing these complications, yet one should seek for proper assistance with decision making as well as with the requested surgical measures.[38-44]

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TABLE 1. – Surgical mesh reconstruction for post hysterectomy vaginal vault prolapse.

	Non Mesh Operations		Mesh Operations		
	Vaginal Obliteration and Colpectomy	Sacro Spineous fixation	Vaginal	Abdominal	Laparoscopic
Skill requirements	Average vaginal skills	Advanced vaginal skills	Advanced vaginal skills	Average abdominal skills	Advanced laparoscopic skills
Complication rate	Low grade	Medium grade	Medium grade	Medium-high grade	Medium-high grade
Operative time	Relatively short	Relatively short	Relatively short	Relatively long	Relatively long
Rehabilitation time	Relatively short	Relatively short	Relatively short	Relatively long	Relatively short
Cure rate			Relatively high		
Cure durability	Presumably long	Presumably long	Presumably longer	Presumably longest	Presumably long
Cure of coexisting other POP features	Feasible		Feasible	Relatively complicated to perform	
Post operative vaginal sexual intercourse	Sacrificed		Low rate of dispareunia		

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Original article

The length of mesh used in sacrocolpopexy and subsequent recurrence of prolapse

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Abstract: Objective: to determine the incidence of recurrent prolapse in different length categories of mesh along the vagina at sacrocolpopexy, performed in the division of urogynaecology in a university teaching hospital. Patients and Methods: A retrospective analysis was done from a urogynaecological data base, reviewing 301 patients who underwent sacrocolpopexy. They were analysed twice: firstly for the anterior mesh and secondly for the posterior mesh. Both anteriorly and posteriorly, they were categorized into three groups: with mesh from the vaginal vault, from the mid-vagina and from the vaginal introitus, both anteriorly and posteriorly, extending to the sacrum. The recurrence rate for prolapse was determined for each category. Results: Of the 301 patients, all were followed postoperatively for a mean period of 34 months (range 9-63 months). For each category, the recurrence rate for prolapse was as follows: anterior from vault (A1) 15.4% (n=26), from mid-vagina (A2) 8.3% (n=193), and from introitus to sacrum (A3) 2.4% (n=82). Posteriorly, the recurrence rates were as follows: from vault (P1) 23.7% (n=38), from mid-vagina (P2) 22.8% (n=44) and from introitus (P3) 3.2% (n=219). Statistically significant differences were found between A1 and A3, as well as between P1 and P3. Conclusion. With extension of the mesh along the vaginal walls during sacrocolpopexy, the incidence of recurrent prolapse decreased significantly.

Key words: Length of Mesh; Sacrocolpopexy; Prolapse; Recurrence.

INTRODUCTION

Randall and Nichols introduced abdominal sacrocolpopexy (SCP) in 1971.[1] Subsequently, SCP, together with sacrospinous fixation (SSF), has become the most commonly performed surgical procedures for middle and posterior compartment pelvic organ prolapse.[2] SCP delivered slightly better results concerning recurrent prolapse with equal quality of life results, but the operative time and peri-operative morbidity were increased, compared to SSF.[2-4] In a more recent study, however, recurrent prolapse was similar for SCP and SSF.[2]

Abdominal SCP is a procedure where the vaginal vault is suspended to the anterior longitudinal ligament of the sacrum. Synthetic mesh or other forms of suspension material are used.1 It adequately elevates and supports the vaginal vault, but not the anterior and posterior vaginal walls. Therefore, the incidence of post-operative anterior and posterior compartment prolapse was quite high and occurred in more than 25%.[5,6] Gradually, a need was recognised for extending the mesh along the anterior and posterior vaginal walls for increased support.[6,7] However, the optimal length of mesh along the anterior and posterior vaginal walls for the prevention of recurrent vaginal prolapse has not been determined. This study was designed to calculate different lengths of mesh along the vagina with recurrent prolapse as the main end point. Secondary end points were quality of life and mesh erosion.

PATIENTS AND METHODS

From the urogynaecologic data base of the Department of Obstetrics and Gynaecology, University of the Free State in Bloemfontein, South Africa, 301 consecutive patients were selected for inclusion in the study based on abdominal SCP with available follow-up data. The only exclusion criterion was uncertainty about the extent of mesh along the vagina. The data base was constructed from data forms completed for every patient on discharge from hospital and during follow-up. The following data were collected for each patient: demographic information, previous surgery, complaints, findings on examination, current surgery and complications peri-operatively. The follow-up data were gathered from forms completed at each follow-up clinic visit. These covered complaints, findings on examination and complications such as mesh erosion. The forms were verified during weekly staff meetings and the data entered into a computer data base (Epi-Info 6.0; CDC, Atlanta, Georgia).

The patients were classified into six groups according to length of mesh along the vagina, either anteriorly or posteriorly. The groups are listed in Table 1 and illustrated in figure 1. Group A1 was a special category created for analysis purposes only, where no mesh was placed anteriorly of the vagina; only posteriorly (any length). Where mesh was attached to the vaginal vault only, it was categorized as P1.

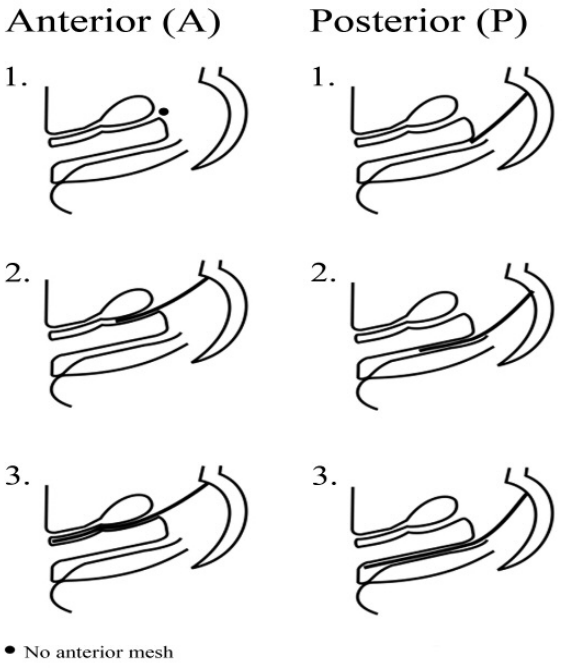

Figure 1. – Mesh length categories representing the six subgroups A1–3 and P1–3.

Bladder symptoms were based on careful clinical history taking and clinical examination. Multichannel urodynamic investigations were not utilized because a minority of patients were subjected to this procedure.

Staging was done according to the pelvic organ prolapse quantification system (POP-Q).[8] On follow-up, recurrent prolapse was regarded as prolapse stage 2–4. Patients who did not return for follow-up, were contacted (mainly by telephone) and requested to present themselves for follow-up.

The surgical technique for the A3/P3 categories was as follows. A laparotomy was done, followed by a cystostomy. With a finger in the bladder and deviation of the vaginal vault posteriorly, a space was created in the vesicovaginal fascia to the level of the bladder neck. A suprapubic catheter was inserted when the cystostomy was closed. The second step was mobilization of the rectum from its medial side and the rectovaginal space was partly opened. From below, a midline incision was made over the distal half of the anterior vaginal wall following hydrodissection. The solution used was 200ml saline with two 1ml ampules of ornipressin. Following a midline incision, the vesicovaginal space was opened between the distal urinary tract and the vagina, until the space already made from above, was reached. A mesh measuring 15 X 3 cm was inserted from below. The mesh used was either Vypro (polyglactin and polypropylene 1:1; Johnson and Johnson, Brussels, Belgium) or Ultrapro (polyglecaprone and polypropylene 1:1; Johnson and Johnson, Brussels, Belgium). Distally, it was fixed para-urethrally at the level of the mid-urethra. The vagina was closed. Posteriorly, a similar incision was made following hydrodissection. The rectovaginal space was opened. This space was connected with the space already made from above. Following a posterior repair (where necessary), a second mesh strip (15 X 3cm) was inserted from below and attached distally to the perineal body. The vagina was closed. Abdominally, the two strips of mesh were fixed to the vaginal vault and then to the sacrum at S1. The rectum was pulled upwards and fixed to the mesh on its anteromedial side. Finally, the peritoneum, which was trimmed, was closed over the mesh and the abdomen was closed.

When shorter lengths of mesh was used (P1, P2 and A2), the mesh was introduced abdominally and fixed to the vagina. A posterior repair was done seperately where necessary.

Only two surgeons were involved (HSC and JAAdeB), with both following the same techniques. The choice of the length of mesh to be inserted depended on two factors: the surgical experience of the surgeons and the degree of vaginal prolapse. With increasing experience, the surgeons more readily extended the length of mesh along the vaginal walls when a SCP was indicated. When stage 3-4 prolapse was present in the anterior and/or posterior compartments, the length of mesh increased as well.

In the early phases of the study, mesh was placed only on the side of the prolapse. Following the observance of cases where prolapse subsequently developed in the opposite (unaffected) vaginal compartment, mesh was inserted routinely on both sides of the vagina. This may be seen as a preventative step in preventing future prolapse on the unaffected side.

The length of mesh for each case was determined retrospectively during the analysis. Every patient's file contained a detailed operative report from which it was determined what the length of mesh was.

On follow-up, recurrent prolapse was regarded as prolapse stage 2-4. Patients who did not return for follow-up, were contacted (mainly by telephone) and requested to present themselves for follow-up.

Statistical analysis consisted of the chi-squared test for categorical data (Fisher's exact test for small numbers) with 95% confidence intervals (CI). The study was approved by the Ethics Committee of the Faculty of Health Sciences, University of the Free State.

RESULTS

The median age of the 301 patients was 58 years, with a range of 35-86 years. The median parity was three (range 1-8) and 93.4% of the patients were Caucasian. Previous surgery for pelvic organ prolapse was performed in 38.3% of the patients. These variables did not differ significantly between the six subgroups.

TABLE 1. – Classification of patients and description of subgroups according to the length of mesh along the anterior and posterior vaginal walls.

Group	Subgroup	Description
Group A Mesh anterior of the vagina	A1	No mesh anterior of the vagina; only posteriorly from the vault to the sacrum (any length).
	A2	Mesh placed anterior of the vagina, from the mid-vagina to the sacrum.
	A3	Mesh placed anterior of the vagina, from mid-urethra to sacrum.
Group P Mesh posterior of the vagina	P1	Mesh from the vaginal vault (posteriorly) to the sacrum.
	P2	Mesh placed posterior of the vagina, from the mid-vagina to the sacrum.
	P3	Mesh placed posterior of the vagina, from the perineal body to the sacrum.

TABLE 2. – Pelvic organ prolapse pre-operatively among sacrocolpopexy patients.

Prolapse (Stage 3 and 4)	Group*											
	A1 (n=26)		A2 (n=193)		A3 (n=82)		P1 (n=38)		P2 (n=44)		P3 (n=219)	
	n	%	n	%	n	%	n	%	n	%	n	%
Anterior compartment	22	84.6	122	63.2	55	67.1	38	100	20	45.5	141	64.3
Middle compartment	16	61.5	93	48.2	26	31.7	24	63.2	32	72.8	79	36.0
Enterocele#	7	26.9	96	49.7	41	50.0	8	21.1	23	52.3	113	51.6
Rectocele#	8	30.7	74	38.3	26	31.7	17	44.7	10	22.7	81	37.0

TABLE 3. – Incidence of recurrent prolapse among sacrocolpopexy patients.

Subgroup	Compartment	95% confidence interval (CI)	
	Anterior (cystocele)		
A1 (n=26)	4 (15.4%)	-3.3% ; 25.5%	1.9% ; 31.2%*
A2 (n=193)	16 (8.3%)		
A3 (n=82)	2 (2.4%)	-10.9% ; 0.9%	
	Any compartment		
A1 (n=26)	6 (23.1%)	-4.2% ; 28.5%	1.4% ; 35.1%*
A2 (n=193)	27 (14.0%)		
A3 (n=82)	6 (7.3%)	-2.1% ; 13.5%	
	Posterior (enterocele)		
P1 (n=38)	4 (10.5%)	-15.0% ; 14.2%	2.3% ; 22.8%*
P2 (n=44)	5 (11.4%)		
P3 (n=219)	3 (1.4%)	-3.1% ; 22.6%*	
	Posterior (rectocele)		
P1 (n=38)	5 (13.2%)	-12.8% ; 17.3%	3.5% ; 25.5%*
P2 (n=44)	5 (11.4%)		
P3 (n=219)	4 (1.8%)	-2.6% ; 22.2%	
	Any compartment		
P1 (n=38)	9 (23.7%)	-16.9% ; 19.4%	2.9% ; 30.4%*
P2 (n=44)	10 (22.7%)		
P3 (n=219)	20 (9.1%)	-2.7% ; 28.2%*	

*p ≤ 0.05; difference between groups is statistically significant.

On examination pre-operatively, 82.7% of the patients presented with anterior compartment prolapse, 70% with middle compartment prolapse and 72% with posterior compartment prolapse (POPQ stages 1-4) (the figures were mutually inclusive). Table 2 shows the types of stage 3 and 4 prolapse in each subgroup. There were no statistically significant differences between these groups.

Follow-up data were available for all patients with a median duration of follow-up of 34 months (range 9-63 months). The median duration of follow-up for the six subgroups were as follows: A1 40 months, A2 27 months, A3 20 months, P1 48 months, P2 45 months, and P3 24 months. The incidence of recurrent prolapse within the six subgroups is summarised in Table 3. In group A (mesh placed anteriorly of the vagina or no mesh anteriorly), the differences between A1 and A2, as well as between A2 and A3, were not statistically significant, both for recurrent anterior compartment prolapse and any type of recurrent prolapse (including the posterior compartment). However, the difference between A1 and A3 was statistically significant, both for recurrent anterior compartment prolapse and any type of prolapse (Table 3). Similarly, a statistically insignificant difference in recurrent prolapse was found between P1 and P2, as well as between P2 and P3, but the difference between P1 and P3 was statistically significant, both for recurrent posterior compartment prolapse and any type of prolapse (Table 3).

Post-operative quality of life is summarised in Table 4 in terms of bladder symptoms, obstructive defecation and dyspareunia. Although no statistically significant differences were found between the subgroups, there was a tendency towards more cases of overactive bladder (urinary urge) symptoms with increasing length of mesh along the vagina, both for mesh anteriorly and posteriorly of the vagina. Mesh erosion also increased with increasing length of mesh, although the differences between the subgroups were not statistically significant (see Table 5).

DISCUSSION

This study was retrospective in nature, although the initial data collection was done prospectively (for the data base). SCP consisted of mesh from the vaginal vault to the sacrum in the early phases of the study. With increasing experience and the awareness of recurrent vaginal prolapse following SCP, the length of mesh was increased along the vaginal walls, first posteriorly and later on to both the anterior and posterior sides of the vagina. Following the publication of Sullivan's "total pelvic mesh repair",[7,9] the length of mesh was extended to the vaginal introitus (full vaginal length) (Figure 1).[10-12] This study confirmed that by extending the length of mesh along the vagina, the incidence of recurrent prolapse decreased. Extension only to the mid-vagina did not make a difference.

Hilger et al. noted recurrent prolapse in 26% of their patients when mesh was placed from the vaginal vault to the sacrum.5 This group also reported a gradual extension of the mesh along the vaginal walls as their experience increased. Several other groups reported similar experiences,[3,6,13] but none was as well documented as in this study.

Intra-operatively, morbidity mainly involved blood loss and trauma to other organs. These were not determined in this report, but previous reports from the same data base on other aspects of SCP, reveiled a blood loss of less than 300ml per patient. Injury to the bladder and rectum occurred in less than 2% of cases.[10-12, 14]

The increasing success in preventing recurrent vaginal prolapse must be weighed against morbidity, both intra- and post-operatively. In this study, the figures for postoperative morbidity was high: overactive bladder symptoms in 24-42% of patients, stress urinary incontinence in 15%, ob-

TABLE 4. – Post-operative morbidity among sacrocolpopexy patients.

	Group											
	A1 (n=26)		A2 (n=193)		A3 (n=82)		P1 (n=38)		P2 (n=44)		P3 (n=219)	
	n	%	n	%	n	%	n	%	n	%	n	%
Overactive detrusor symptoms	9	34.6	46	23.8	34	41.5	7	18.4	15	34.1	67	30.6
Stress urinary incontinence	5	19.2	44	22.8	30	36.6	9	23.7	17	38.6	53	24.2
Obstructive defecation	4	15.4	24	12.4	16	19.5	6	15.8	8	18.2	30	13.7
Dyspareunia	0	0	21	10.9	8	9.8	1	2.6	7	15.9	21	9.6

TABLE 5. – Occurrence of mesh erosion and repeat surgery required among subgroups.

	Group*											
	A1 (n=26)		A2 (n=193)		A3 (n=82)		P1 (n=38)		P2 (n=44)		P3 (n=219)	
	n	%	n	%	n	%	n	%	n	%	n	%
Mesh erosion	0	0	17	8.8	11	13.4	1	2.6	4	9.1	23	10.5
Suburethral sling	3	11.5	8	4.1	12	14.6	4	10.5	3	6.8	16	7.3
Anterior vaginal repair	0	0	3	1.6	0	0	0	0	2	4.5	0	0
Posterior vaginal repair	0	0	6	3.1	9	11.0	4	10.5	3	6.8	30	13.7
Repeat SCP	3	11.5	5	2.6	1	1.2	4	10.5	2	4.5	3	1.4
Incisional hernia repair	1	3.8	8	4.1	1	1.2	2	5.3	0	0	8	3.7

structive defecation in 12-20% and dyspareunia in 3-11% (Table 4). If a patient was seen several times postoperatively and any of these symptoms or signs occurred at any time, she was labelled with it whether it persisted, improved or cleared later on. The symptoms were also not graded. Over time the authors applied several modifications to the surgical technique in order to decrease postoperative morbidity. Unfortunately, these were not well documented and can't be reported on in detail.

Mesh erosion occurred in 3-14% of cases without a significant difference between the groups (Table 5). Most of these (97%) were minor in nature and treated in the consulting room by excision of the mesh followed by an estrogen containing vaginal cream. Efforts were made to decrease this incidence, but it was not possible to report on the success of these efforts.

A possible confounding variable is the increase of experience by the authors (HSC and JAAdB) over time. The more often a surgeon performs an operation, the better he/she gets at it. Since the length of mesh was increased over time, improved expertise could have contributed towards the lower incidence of recurrences. However, the absence of a decreasing trend in variables like overactive bladder and obstructive defecation with increased lengths of mesh do not support this possibility. We therefore conclude that improved expertise over time could have had an influence, but the increased length of mesh was most probably the more important factor.

In conclusion, by extending the length of mesh along the vaginal walls, less recurrent vaginal prolapse was encountered. However, the increase in morbidity with longer lengths of mesh is of concern, even though it was statistically insignificant. The overall incidence of post-operative morbidity was high and needs further investigation to clarify this important issue.

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Case report

Recurrence of vaginal cuff dehiscence following hysterectomy: case presentation and literature review

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Abstract: This report presents a case of a recurrence of vaginal cuff dehiscence in a 34 years old woman following a total laparoscopic hysterectomy for chronic pelvic pain. Vaginal intercourse at 7 weeks postoperatively was the precipitant in both instances of the dehiscence. Vaginal cuff dehiscence following hysterectomy is rare and recurrence is incredibly scarce.

Key Words: Abdominal Hysterectomy; Recurrence of Vaginal Cuff Dehiscence; Total Laparoscopic Hysterectomy.

INTRODUCTION

Vaginal cuff dehiscence (VCD) is a rare complication following hysterectomy and recurrence is incredibly scarce.

CASE REPORT

A 34 year old woman (gravida 7 and para 3) presented to the Emergency Department (ED) of Royal Darwin Hospital (RDH) with a history of worsening abdominal pain following her child jumping on her abdomen. The pain was worse with straining and coughing. She had two episodes of vomiting and discomfort on opening her bowels. She had engaged in sexual intercourse seven days prior to her presentation and reported yellow vaginal discharge and lower abdominal pain since that time. Examination revealed generalised abdominal rebound tenderness and the presence of copious clear fluid freely flowing from the vaginal cuff (VC). There was a defect on right side of the VC with no bowel seen herniating through the defect. This patient was a smoker of an average built.

This patient had a total laparoscopic hysterectomy (TLH) for chronic pelvic pain in a different Australian state approximately 14 weeks prior to the above presentation. Her records indicated that the VC was opened using laparoscopic coagulating shears and closed vaginally with 0-maxon sutures. The patient was advised to avoid vaginal intercourse for a minimum of six weeks. It was reported that when she was reviewed five weeks postoperatively that she complained of some abdominal discomfort and on examination she had soft abdomen and the laparoscopic port sites were well healed. The histology of the uterus revealed no abnormality.

The patient had vaginal intercourse seven weeks following the TLH. She felt a 'popping' sensation intra-coitally followed by sharp abdominal pain and vaginal loss of approximately 30-60mL of fresh blood followed by a copious yellow brown discharge. Then she presented herself "for the first time" to the ED of RDH. Abdominal examination revealed generalised abdominal tenderness and speculum vaginal examination revealed pink coloured small bowel in the vagina, indicating VCD and evisceration. The patient had an exploratory laparotomy under the care of the specialist on duty who documented the bowel was healthy, maxon suture at VC was not intact and was removed and VC was sutured with interrupted number 1 Vicryl. The patient was given appropriate course on antibiotics and was discharged home on the 5th postoperative day after being advised to avoid vaginal intercourse until she was next reviewed. At her review 5 weeks later her treating specialist noted no vaginal discharge and appropriate healing of VC. She was instructed to avoid intercourse for a further four weeks, despite this, she had intercourse one week later, resulting in her current above presentation.

The recurrence of vaginal cuff dehiscence (RVCD) was managed with laparotomy by the principal author. A 4-5cm long defect was confirmed at the right side of the VC (Figure 1). The bowel that was firmly adherent to the posterior vaginal edge was mobilised. Also the bladder was mobilised away from the anterior vaginal edge. Both organs were carefully and adequately mobilised using sharp and very gentle blunt dissection. This mobilisation allowed adequate debridement to obtain fresh vaginal edges. The defect was closed using interrupted stitches with adequate bites that were 1 cm apart and 1 cm from the vaginal edges. A small needle with 3.0 Vicryl (polyglactin) suture material was used to minimize trauma to the relatively inflamed and weak vaginal tissue. Prophylactic antibiotics cover was started preoperatively and continued on for five days postoperatively. The patient was commenced on oral hormone replacement therapy (HRT), Premarin, 0.625mg on the second postoperative day when she became adequately mobilising. She was discharged home on the 5th postoperative day and was advised to continue on HRT for a period of six months, cease smoking and abstain from vaginal intercourse for 6 months. She was scheduled for reviews at 3 and 6 months with the principal author.

On review at 3 months, she was asymptomatic. She was encouraged to continue with the above plan. When she was

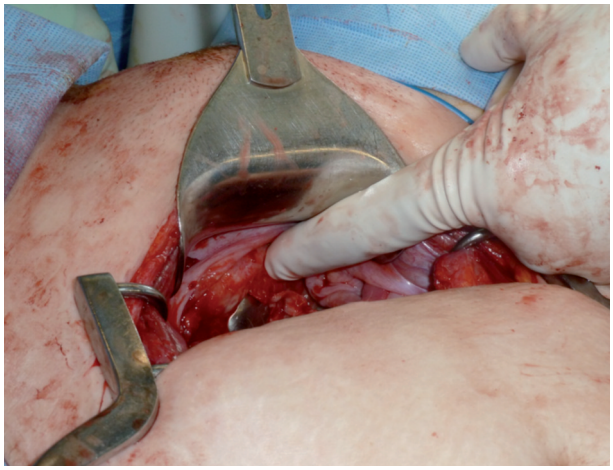

Figure 1. – Recurrent vaginal vault dehiscence "a metal probe in the vaginal vault is showing the defect in the right side of vaginal cuff".

reviewed 6 months postoperatively, she reported resuming intercourse 2 months before the visit (4 months after the repair). Since then, she has had regular intercourse 1-2 times per week with no pain or bleeding. On examination, the VC was well healed and supported. The patient was discharged from the clinic and advised to report back if any problem.

DISCUSSION

VCD is a rare complication of hysterectomy. By year 2011, approximately 120 cases of VCD had ever been reported in the literature[1] and notably only two case reports documenting a recurrence have been identified by the authors.[2,3] The incidence of unreported cases is unknown.

The overall rate of VCD following hysterectomy is 0.24%.[4] Chan et al[5] reported a rate of VCD of 1.59% following TLH compared with no cases of dehiscence following vaginal hysterectomy (VH) or total abdominal hysterectomy (TAH) in their retrospective analysis of 1224 cases. Ceccaroni et al6 analysed data from 8635 hysterectomy patients and noted laparoscopic hysterectomy was associated with a significantly higher incidence of dehiscence (0.8%) than both TAH (0.25%) and VH (0.15%). Likewise Agdi7 observed a significantly higher incidence of VCD after TLH (1.14%) than after TAH (0.1%) and VH (0.14%).

It is suggested that the use of electro-cautery for colpotomy in TLH may lead to tissue necrosis and prolonged devascularisation, reducing the potential for adequate cuff healing and thus an increased risk of dehiscence.[4-6, 8-10] Suturing techniques have also been implicated in the higher rates of dehiscence with TLH. It is suggested that laparoscopic knot pushers may cause fraying and weakening of the suture, predisposing to VCD.[4,5,9] It is also thought that laparoscopic magnification can distort the view and result in shallow suture placement and thus inadequate closure.[4, 5, 11]

It is unclear if the increased risk with laparoscopic hysterectomy is related to the technique of suturing. While some authors found that the choice of route[10,12] (vaginal or laparoscopic) or method of suturing1[0] (interrupted or running) was not statistically significant in affecting dehiscence rates, Uccella et al[11] reported that laparoscopic and robotic sutures were associated with a rate of VCD three and nine times that of trans-vaginal colporraphy. To minimise the risk, some authors have recommended the use of double layer[5,13] interrupted sutures[5] when closing the VC during a TLH, while Shen et al[14] reported no significant difference in frequency of dehiscence between one or two layers closure.

The type of suture material used has also been debated. Hur[4] suggests the use of a delayed absorbable monofilament suture. Chan et al[5] supported the use of a monofilament suture and questioned the use of Vicryl sutures in TLH. Dauterive et al[8] and Bikkendaal et al[10] hypothesise that regardless of the suture material, there is a primary healing defect as a result of excessive coagulation.

The most common precipitant of VCD in premenopausal women is sexual intercourse.[4-8, 12, 15, 16] This patient VCD occurred twice when she had vaginal intercourse 7 weeks postoperatively. Surgical wounds in general will attain up to 40% of maximal strength within the first month postoperatively although strength will continue to increase for as long as a year.[17] Timing of the resumption of sexual intercourse must therefore take into consideration the prolonged healing process. The general recommendation is to avoid the "early resumption" of coitus[4,5,8,9,12,16]; however, specific time frames vary. Hwang[12] recommended avoidance of intercourse until the postoperative examination identified a completely healed VC incision, although we question how it is possible clinically to identify the degree of healing that would withstand the intercourse. Hur4 suggested delaying sexual intercourse for a period of six to eight weeks after total hysterectomy and a minimum delay of 12 weeks after a repair of VCD. Dauterive[8] and Nick et al[9] also suggest eight weeks of "pelvic rest" following TLH. However longer periods of abstinence would not prevent spontaneous dehiscence.[4,10]

There is no agreement on how women with VCD should be managed. A recent review of the literatures reported 51% of VCD were repaired vaginally, 32% abdominally, 2% laparoscopically and 10% using a combined approach; only 5% were allowed to heal by secondary intention.[13] Some authors have recommended closure of VCD with delayed absorbable monofilament suture in an interrupted fashion.[1,4] The use of postoperative HRT has been suggested to maximise wound healing following gynaecological surgery[5], although evidence of its efficacy is limited.[4]

A literature search on RVCD was conducted which revealed only two case reports, only one of which is a true RVCD. This case was reported by Ferri[2] (1996) and is of a 65 year old woman who presented with a relapse of VCD seven months after repair for initial dehiscence and twelve months after vaginal hysterectomy for uterine prolapse. There was no obvious precipitant in this case. The repair of the first VCD was achieved via a median laparotomy with uterosacral ligament plication. The recurrent defect was repaired using interrupted Vicryl sutures and polytetrafluroethylene mesh. The patient had no reported complications at 12 months post operatively.

The second case was of a 31 year old woman who originally underwent laparoscopic assisted vaginal hysterectomy and bilateral salpingo-oophorectomy for endometriosis.[3] The peritoneum and vaginal cuff were closed using 0 chromic sutures. At the first attempt of sexual intercourse, six weeks post-operatively, VCD and evisceration occurred. The defect was repaired vaginally using a double layer closure with interrupted 0 Vicryl sutures. Six months later, the patient underwent an exploratory laparotomy for investigation of severe pelvic pain that revealed persistent endometriosis and scarring of the VC with multiple bowel adhesions and thus a partial vaginectomy was performed and VC closed with 0 vicryl. Four months later, the patient presented with a RVCD after intercourse. The defect was repaired using interrupted Polydioxanone suture in an overlapping mattress technique followed 5 months later by abdominal sacrocolpopexy using synthetic Prolene mesh to prevent future evisceration. Obviously, a potential confounder in Jurus[3] report is the additional vaginectomy during laparotomy the patient underwent before the relapse of VCD and thus could independently have played a role in causing the dehiscence.

CONCLUSION

As there is such limited information available reporting on RVCD following hysterectomy, it is difficult to draw solid conclusions with regard to the risk of recurrence, and how to best avoid and manage this problem. The authors view is that in management of VCD or RVCD, it is very important to obtain fresh vaginal edges by good debridement of both edges of the vagina that may require adequate mobilisation of the bladder and bowel. It may be equally important to use interrupted sutures with adequate bites, administer prophylactic antibiotics intraoperatively and postoperatively, administer estrogen postoperatively and advise the patient to delay vaginal intercourse for at least 12 weeks.

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Original article

A pilot study of mirabegron added to solifenacin in the treatment of overactive bladder

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Abstract. Objectives: The ß$_3$ adrenergic receptor agonist mirabegron was clinically indicated as a new therapeutic drug for overactive bladder (OAB) in Japan in September 2011. However, mirabegron has yet to be investigated in detail in this context. To further characterize this agent, we administered 25 mg of mirabegron as add-on therapy to female patients with confirmed OAB who displayed persisting OAB symptoms despite receiving solifenacin and investigated clinical efficacy by comparing overactive bladder symptom scores (OABSS) and residual urine volume and determining whether adverse drug reactions were worsened at Weeks 4, 8, and 12.Methods: Participants in the study comprised 20 female patients with persisting symptoms of OAB despite solifenacin treatment and with OABSS ^{3}3 (and urgency score ^{3}2). Mean age was 73.4 years (range, 44-90 years). Results: OABSS totals were significantly improved at Week 4 and had decreased on average by 3.95±2.11 by Week 12. At Week 12, 16 (80%) of subjects achieved a reduction of ^{3}3 points in total OABSS, and no subject showed worsening of adverse drug reactions. Urge urinary incontinence resolved in 6 of the 12 affected subjects (50%). No significant differences were present in residual urine volume, no subject reported worsening of dry mouth or constipation as an adverse drug reaction, and no subject was discontinued from treatment. Conclusions: Used concomitantly with an anticholinergic drug, mirabegron produced an excellent therapeutic effect in OAB and presented no safety concerns. This combination could provide a new option for patients showing OAB refractory to anticholinergic drugs or severe OAB.

Key words: OAB; Mirabegron; Solifenacin; OABSS; UUI.

INTRODUCTION

The International Continence Society in 2002 defined overactive bladder (OAB) as a symptom syndrome characterized by urinary urgency with frequency, nocturia, and urge urinary incontinence.[1] The ß$_3$ adrenergic receptor agonist mirabegron was first clinically indicated as a new therapeutic drug for OAB in Japan, receiving this designation in September 2011, but in this context has yet to be investigated in detail. Currently phase III testing is underway in the European Union on the concomitant use of the ß$_3$ adrenergic receptor agonist mirabegron with anticholinergic drugs.[2] The concept of anticholinergic drugs as combined therapy with mirabegron has never been studied previously. To increase the understanding of mirabegron, we investigated the efficacy of add-on mirabegron administered to female OAB patients who had persisting OAB symptoms despite receiving solifenacin treatment and who were unable to take a higher dose or were forced to take a lower dose of solifenacin because of adverse drug reactions.

We tried this study as Pilot Study.

PATIENTS AND METHODS

Subjects enrolled in the study were female OAB patients in the Department of Urology, Kobayashi Hospital (an affiliate hospital of Showa University Northern Yokohama Hospital) who experienced improvement but still had persisting OAB symptoms following 3 months of treatment with the anticholinergic drug solifenacin, who still satisfied the diagnostic criteria for OAB after treatment (i.e., urgency score 2 and total of 3), and who were unable to take a higher dose or were forced to take a lower dose of solifenacin because of adverse drug reactions. Subjects were given 25 mg of mirabegron with solifenacin once daily after breakfast for 12 weeks. Subjects were evaluated in Weeks 4, 8, and 12. OABSS, number of night-time episodes, and residual urine volume were determined, and worsening of adverse drug reactions was monitored. The Wilcoxon signed-ranks test was used to evaluate OABSS, and a paired t-test was used to analyze residual urine volume data. Values of $p<0.05$ constituted a significant difference. Informed consent was obtained from all patients.

RESULTS

Backgrounds, OABSS, residual urine volume, and symptoms prior to mirabegron treatment of the 20 subjects enrolled in the study are shown in Table 1. Significant improvement was seen in the OABSS items of "daytime frequency" and "urge urinary incontinence" beginning at Week 8, "nocturia" beginning at Week 12, and "urinary urgency", as the number of night-time episodes, and OABSS total beginning at Week 4. Mean OABSS total had decreased by 3.95±2.11 by Week 12. Ten (50%) of the subjects in Week 4 and 16 (80%) in Week 12 had achieved a

TABLE 1. – Pre-treatment symptoms.

Background		
Age	73.4	(44-90)
Solifenacin		
10mg	1	(5.0%)
5mg	11	(55.0%)
2.5mg	8	(40.0%)
OABSS		
mild(0-5)	0	0
moderate(6-11)	18	(90%)
severe(12-15)	2	(10%)
OABSS Total score	8.75	±2.27
Daytime frequency	0.95	±0.69
Nocturia	2.3	±0.92
Urinary urgency	3.7	±0.92
Urge urinary incontinence	1.8	±1.82
OAB wet	12	(60.0%)
Dry mouth	11	(55.0%)
Constipation	2	(10.0%)
Post Voiding Residual (Rate)	13.4ml	±39.23

reduction of 3 in OABSS total, and no subject showed worsening of adverse drug reactions. Urge urinary incontinence resolved in 6 of the 12 subjects (50%) with urge urinary incontinence at baseline. Residual urine volume did not differ significantly (Figure 1). No subjects reported worsening of dry mouth or worsening of constipation as adverse events, and no subject was discontinued from treatment.

DISCUSSION

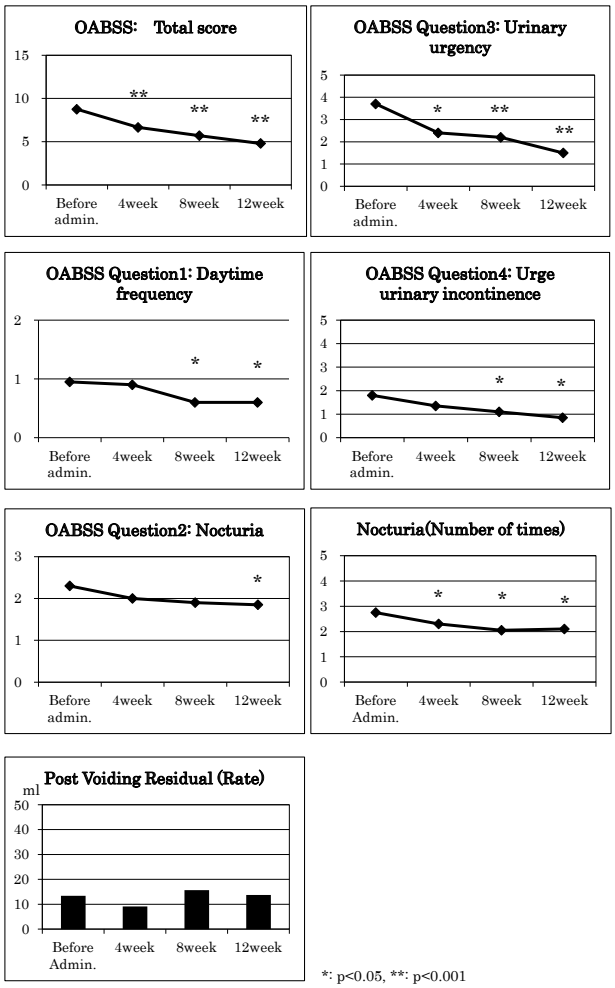
The prevalence of OAB in Japan is 12.4% among individuals 40 years old, increasing to 37% in individuals 80 years old. Twenty-three percent of affected individuals seek medical help for OAB.[3] Urodynamic investigation is not needed to diagnose OAB, which can be diagnosed on the basis of the presence of urinary urgency as a symptom. A diagnosis of OAB is made when there is at least one weekly episode of urinary urgency as assessed with the OABSS, with a total OABSS score 3.[4] Gotoh et al. reported that the minimal clinically important change in total OABSS score is -3 points.[5]

The mechanism of urinary urgency has been characterized. Expansion of the bladder causes the release of various factors from the epithelium of the urinary tract. Prostaglandins (PG), tachykinin (TK), adenosine triphosphate (ATP), and acetylcholine (Ach) stimulate sensory C-fibers, and nitric oxide (NO) and vasoactive intestinal peptide (VIP) suppress sensory nerve activation. Under pathological conditions, changes in these factors occur. Sensory nerve (primarily C-fiber) stimulation promotes the voiding reflex. This is one postulated cause of OAB.[6] Anticholinergic drugs inhibit acetylcholine, which in turn inhibits stimulation of sensory C-fibers and thereby inhibits urinary urgency. The most widely distributed adrenoceptor in the human bladder is the ß3 receptor.7 The release of NO is promoted by ß3 agonists via the ß3 adrenergic receptor, enhancing the suppression of sensory C-fiber activation. G protein concurrently released from the ß3 receptor activates adenylate cyclase, facilitating the breakdown of ATP into cyclic adenosine monophosphate. This breakdown of the ATP-stimulating sensory C-fibers suppresses urinary urgency. The therapeutic efficacy of ß3 agonists on OAB derives from these two pathways.

Options for OAB treatment include pharmacotherapy, interferential low-frequency therapy, and botulinum toxin injection. Pharmacotherapy is the most widely used option. OAB guidelines give most anticholinergic drugs a recommended grade of A.[1,4] Adverse drug reactions to anticholinergic drugs, however, include dry mouth and constipation due to muscarinic receptor inhibition and urinary disturbances, and urinary retention due to the extended suppression of bladder hyperactivity. These adverse drug reactions occur more frequently than is commonly thought and are sometimes not reported to the attending physician.[8] Doctors must weigh the likely benefits of treatment against the potential adverse reactions to these drugs when administering treatment. Ito et al. found that dry mouth and constipation are more severe in untreated OAB patients than in non-OAB patients. Anticholinergic drugs must be given with care to OAB patients, who are already at increased risk of oral dryness and constipation, because of the potential to reduce patient quality of life and cause potential poor compliance.[9] The shortcomings of anticholinergic drugs led to the development of drugs with different mechanisms of action and fewer adverse drug reactions. The ß3 agonists do not act on cholinergic receptors and therefore do not cause adverse drug reactions such as dry mouth and constipation as frequently as anticholinergic drugs. Although a direct comparison with anticholinergic drugs is not possible, the general impression is that the efficacy of ß3 agonists is somewhat inferior (Table 2).[10,11] Anticholinergic drugs have been found to be effective beginning in the early stage of treatment.[12] When an anticholinergic drug was used with mirabegron, total OABSS had improved by Week 4 and continued improving through Weeks 8 and 12.

In Japan, 5.80 million people suffer at least one urge urinary incontinence episode per week, and 3.40 million have at least one episode daily.[13] Urinary incontinence resolved in 50% of subjects receiving 5 mg or 10 mg of solifenacin in a Japanese phase III study.[11] In the STAR trial, urinary incontinence resolved in about 60% of solifenacin group patients.[14] In research conducted by Suzuki et al., urinary incontinence resolved in 28.6% of patients switched to solifenacin because

Figure 1.



*: p<0.05, **: p<0.001

TABLE 2. – An effect and side effect incidence in the Japanese phase III trial of Mirabegron and Solifenacin.

	Mirabegron 50 mg	Solifenacin 5 mg	Solifenacin 10 mg
Effect			
Urinary frequency (×/24H)	-1.67±2.212	-1.93±1.97	-2.19±2.09
Urgency (×/24H)	-1.85±2.555	-2.41±2.88	-2.78±2.82
UUI (×/24H)	-1.01±1.338	-1.45±1.89	-1.52±1.77
Nocturia	-0.44±0.933		
Residual urine	8.76ml → 9.58ml		
Voided volume	+24.3ml ±35.5ml	+35.8ml ±43.4ml	+43.6ml ±44.5ml
Side effects			
Oral aridity	1.70%	41.30%	
Constipation	2.90%	19.80%	
Blurring of eyes	0%	5.20%	
Difficult voiding	0.10%	4.00%	
Vertigo	0.20%	2.40%	

of a failure to respond adequately to imidafenacin.[15] Treatment with once-daily mirabegron achieved improvements in urge urinary incontinence in a Japanese phase III study of the drug. In the present add-on study, urge urinary incontinence resolved in 6 of the 12 affected patients (50%), indicating the beneficial effect of add-on mirabegron.

During voiding, acetylcholine normally binds to muscarinic receptors to suppress adenylate cyclase activity and thereby promote bladder smooth muscle contraction. The ß$_3$ agonists activate adenylate cyclase, but do not result in bladder smooth muscle relaxation associated with the suppression of adenylate cyclase by acetylcholine and therefore do not impact detrusor muscle contraction during voiding.[16] Patients in the present study, who were first treated with solifenacin and were in a state without adenylate cyclase suppression, may have achieved greater relaxation of bladder smooth muscle when ß$_3$ agonist treatment synergistically activated adenylate cyclase. Even so, these patients experienced no changes in residual urine volume or urinary retention. Mirabegron thus may not impact the voiding profile of patients who experience no urinary disturbance and may not cause smooth muscle relaxation in association with anticholinergic drug treatment.

In our study, mirabegron was added to prior solifenacin treatment. To improve safety, beginning treatment with mirabegron may be better, as this agent is associated with fewer adverse drug reactions, but subsequent addition of an anticholinergic drug could result in urinary disturbance. However, in terms of efficacy, beginning treatment with solifenacin as in this study and then adding mirabegron after confirming the absence of urinary disturbance may be better.

The adverse drug reactions associated with anticholinergic drugs lower patient quality of life and sometimes force treatment to be changed, reduced, or discontinued. Concomitant treatment with mirabegron and an anticholinergic drug thus may not only produce greater therapeutic effects in OAB, but, provided concomitant treatment alleviates the symptoms of OAB, may also allow the dose of anticholinergic drug to be reduced and therefore reduce adverse drug reactions, improving patient quality of life. This combination could become a new option for treating OAB refractory to anticholinergic drugs or severe OAB.

This is the first report anywhere to describe concomitant treatment with a ß$_3$ agonist and an anticholinergic drug. The next logical step is to follow patients to determine long-term treatment outcomes and whether anticholinergic drug doses can be reduced.

And a larger study is required to assess any patient benefit.

A presentation describing this study was given at the 19th Conference of the Neurogenic Bladder Society of Japan.

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Case report

Mechanical support of the posterior fornix relieved urgency and suburethral tenderness

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Abstract: Supporting the posterior vaginal fornix with a speculum blade relieved urgency and suburethral tenderness, the latter consistent with the hypothesis of referred pain from lax uterosacral ligaments.

Key words: Simulated Operation; Virtual Operation; Pelvic pain; Suburethral Tenderness.

INTRODUCTION

We report an unexpected finding, relief of suburethral tenderness on mechanical support of the posterior vaginal fornix.

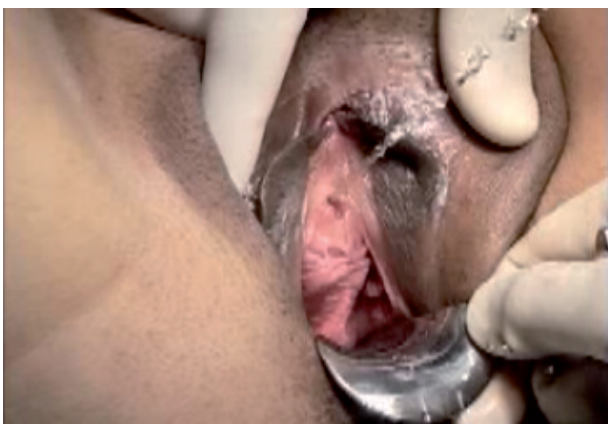
The concept of mechanical support of specific ligaments, was originally introduced to challenge the Integral Theory which stated that stress and urge both derived, for different reasons, from laxity in the vagina or its supporting ligaments.

The midurethral pressure test,[1] (VIDEO 1), tests pubourethral ligament laxity: pressing upwards on one side immediately behind the pubic bone, prevents loss of urine during coughing in women with urinary stress incontinence (USI); it also restores vesicourethral geometry from a funnelled to abnormal shape.[1]

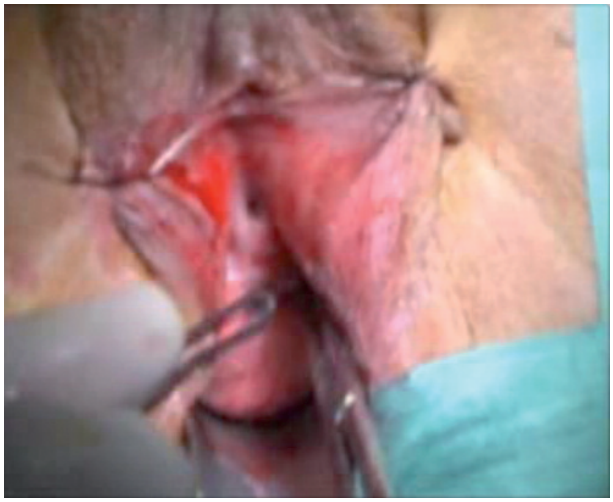
Not so well known are the tests for the origin of urgency. The midurethral pressure test for PUL laxity also controls urgency symptoms in up to 50% of patients who also have USI, (VIDEO 2). Another "simulated operation" for urgency is to gently support the bladder base digitally to diminish urge symptoms (VIDEO 2). The anatomical rationale for these "simulated operations" for urgency is that mechanically supporting the lax ligaments restores the insertion point and therefore, optimum contractility to the directional muscle forces[1] which stretch the vaginal membrane for hypothesized support of the bladder base stretch receptors, "trampoline analogy".

PATIENTS AND METHODS

In October 2012, a 49 year old patient with 2nd degree uterovaginal prolapse attended the Shanghai Jiaotong University affiliated 6th Peoples hospital OPD. She complained of lower abdominal pain (relieved on lying down), frequency and urgency. This patient had anterior vaginal repair 6 years ago, because of 2nd degree cystocele and severe urgency. After the procedure, her symptom of urgency improved, but the symptoms recurred two years ago.



Video 1. – Link for the video: www.pelviperineology.org



Video 2. – Link for the video: www.pelviperineology.org

She was assessed using the Pictorial Algorithm, (Figure 1); 2nd degree uterovaginal prolapse was confirmed, the symptoms suggesting uterosacral ligament laxity. During vaginal examination, extreme tenderness was noted in the suburethral area of vagina immediately below the urethra. There was no hypersensitivity in the hymenal area on testing for vulvodynia. Gentle insertion of the posterior blade of a Cusco speculum into the posterior fornix relieved the feeling of urgency and the suburethral tenderness. The test was repeated twice, each time with the same findings.

DISCUSSION

It has been previously demonstrated that injecting local anaesthetic (LA) in the distal site of the uterosacral ligaments (USL) relieved vulvodynia, lower abdominal pain,[2] and suburethral pain,[3] giving some support to the hypothesis[4] that lower abdominal pain and the pain of vulvodynia may be referred pains from the inability of lax USLs to support the pain fibers contained within the nerve fibers which are stretched by the force of gravity to produce pain; one clinical characteristic of such pain is relief on lying down. We hypothesize the relief of pain in this case was due to speculum support of the apex/ distal USLs.

One criticism levelled at this referred pain hypothesis was that the pain arose from the organ itself and that the LA

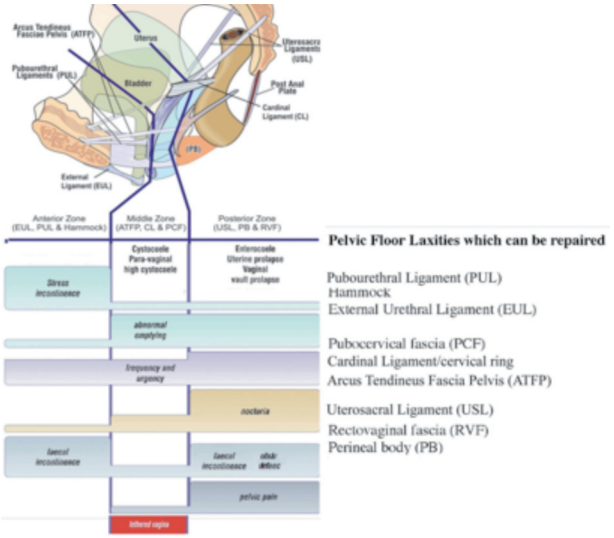


Figure 1. – The **Pictorial Diagnostic Algorithm** summarizes the relationships between structural damage (prolapse) in the three zones and function (symptoms). The size of the bar gives an approximate indication of the prevalence (probability) of the symptom. The symptoms of this patient suggested USL laxity. .

simply anesthetized the afferent pain fibres (S2-S4) from the organ which traverse the USLs.[5] This criticism did not explain relief of pain in the lower abdomen which had a different innervation, the ilioinguinal nerve, T12, L1, nor can it apply to this case.

CONCLUSION

This accidental finding appears to provide some support to the hypothesis of referred pain caused by USL laxity. We hope this report may unlock another avenue for investigation for this difficult problem.

VIDEO 1 Courtesy Professor Palma, Brazil
VIDEO 2 Courtesy Dr Monteiro, Portugal

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Case report

Martius flap in repair of rectovaginal fistula caused by Bartholin's gland abscess

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Abstract: *Background:* The most rectovaginal fistulas (RVF) are acquired. Although a Bartholin's gland abscess isn't unusual in women in reproductive age, RVF is a rare complication. Case: We present a patient with a low RVF. She had a previous history of four episodes of Bartholin's gland abscess. She was undergone LIFT surgery. Two weeks later she had a new Bartholin's gland abscess and three weeks after was diagnosed another RVF secondary to Bartholin's gland abscess. Surgical approached with LIFT surgery was performed and complemented with Martius graft. *Conclusion:* We reported rare case of rectovaginal fistula secondary a Bartholin's gland abscess and treated with Martius graft. With this case the authors highlight the im-portance of multidisciplinary approach and the relevance of interpositional graft techniques.

Key Words: Rectovaginal Fistula; Bartholin's Gland Abscess; Martius Flap; Recurrence.

INTRODUCTION

A rectovaginal fistula is an epithelium-lined communication between the rectum and vagina.1 The most rectovaginal fistulas are acquired although congenital abnormalities do exist.[1,2] The acquired fistulas include aetiologies such as trauma (operative, obstetric, and traumatic injuries), infection, inflammatory bowel disease, carcinoma, and radiation.[1,2]

Two percent of women develop a Bartholin's duct cyst or gland abscess at some time in life.[3] Bartholin gland infection may spontaneously drain causing a low rectovaginal fistula.[2] The treatment of rectovaginal fistula must be tailored to the individual fistula.[1]

CASE REPORT

A 37-year-old patient presented to the colorectal surgeon with a history of passage of fla-tus from the vagina. She regarded a previous history four episodes of Bartholin's gland abscess in last two years. All cases were management with medical or expectant treat-ment. Examination in office revealed a low rectovaginal fistula. A surgical approaches with LIFT (ligation of intersphincteric fistula tract) technique was performed.

Two weeks after LIFT surgery the patient had a recurrence of Bartholin's gland abscess with spontaneous rupture and drainage.

Three weeks later the patient was admitted under the gynaecologist with malodorous vag-inal discharge and perineal pain. A recurrence of the fistula was the first diagnostic hy-pothesis.

A multidisciplinary approached was performed, with colorectal surgeon and gynaecologist.

At operation, a fistulous tract was isolated with probe and the fistula extended from the Bartholin's abscess, traversed the rectovaginal septum to enter the rectum, a new rectovaginal fistula. LIFT surgery was performed it was dissected in a bloodless plane between the internal and external anal sphincters beyond the fistula tract. The tract was then ligat-ed and closed on both the rectal and vaginal side the intersphincteric dissection was then closed at the skin (Figure 1).

A longitudinal incision was made in the left labia major, it was dissected the bulbo-cavernous muscle and its adjacent labial fat pad (the inferior flap pedicle was preserved). The Martius flap was mobilized to the perineal body, underneath the labia minor and an-chored laying on repair fistula site (Figure 2).

The flap was sutured to vaginal edge fistula and the labial major incision was closed with Vycril® rapid 2/0 (Figure 3).

In the follow-up examination (6 weeks and 4 months after), both superficial and deep tis-sues had fully healed.

Histology confirmed an abscess with chronic inflammatory cell reaction.

DISCUSSION

Despite the Bartholin's gland abscess can lead a rectovaginal fistula, in literature review only one case was reported.

We reported the first case of recto-vaginal fistula secondary to a Bartholin's gland ab-scess and treated with a Martius graft.

The major supportive structure between the vagina and rectum is recto-vaginal septum. The Bartholin's gland and duct are located bilaterally within the bulbo-cavernous muscle just lateral to the attachment of the recto-vaginal septum.[4]

There are many approaches reported for repairing a simple recto-vaginal fistula.[1]

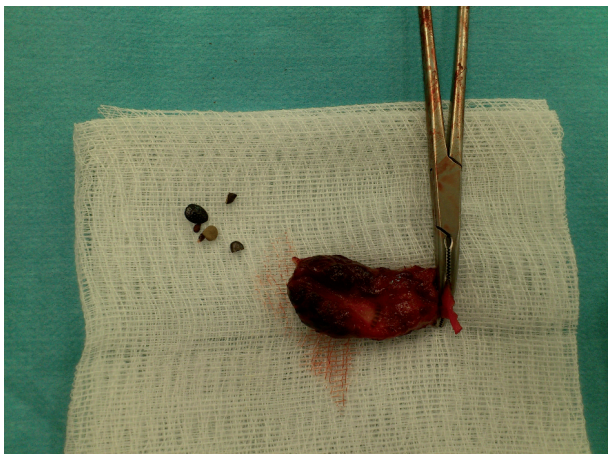

Figure 1. – Recto-vaginal fistula.

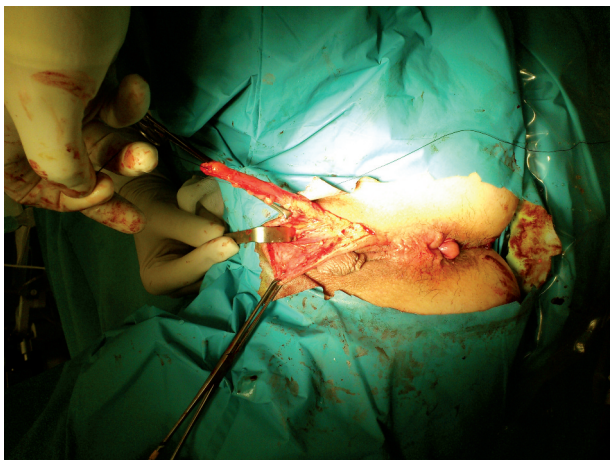

Figure 2. – Martius Flap.

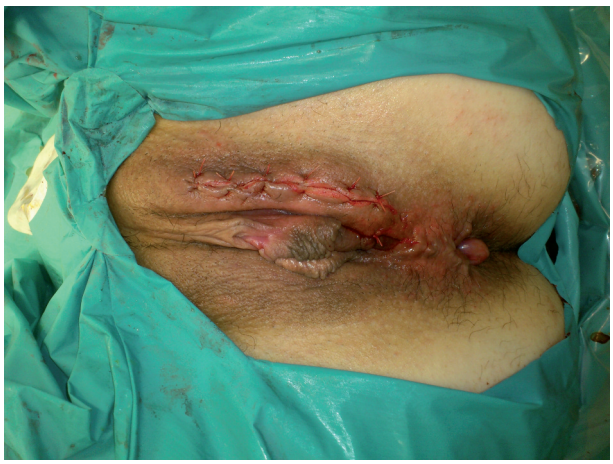

Figure 3. – Final result.

The LIFT approaches that was developed for the treatment of intersphincteric anorectal fistulas has been adopted for treatment of recto-vaginal fistulas.[2]

Although the description of many surgical approaches for the treatment of low recto-vaginal fistulae (LRVF), all are associated with a high recurrence rate and a poor function.[5]

Multiple factors may lead to a recurrence of recto-vaginal fistula such as post-operative infection, extensive scarring with poor blood supply, inflammation pre-operatively, and technically inadequate repairs.[1]

In addition to some techniques for complex recto-vaginal fistulas, other procedures may be utilized, such other well vascularized tissue as an interpositional graft. Tissue used in-clude the bulbo-cavernous, gracilis, omentum, gluteus maximus, sartorius and rectus ab-dominus.[6] The most used interpositional graft technique is the Martius graft. This tech-nique involves mobilization of the bulbo-cavernous muscle with its labial fat pad and tunnelling it to be interposed between rectum and vagina.[6] It carries a success rate be-tween 60-85%.[5,6]

The Martius flap repair has been well described in patients with recto-vaginal fistulas secondary to radiation injury. The purpose of tissue transfer procedures in patients with recto-vaginal fistulas is to provide healthy tension-free, well-vascularized tissue in the area of repair.[6]

White et al. performed fourteen Martius procedures on twelve patients with radiation-induced recto-vaginal fistulas. Eleven patients had successful closure of their fistulas with this procedure, and no operative complications occurred.[6,7]

Chi L. et al. reported nine patients were refereed for Martius surgery, seven of the nine patients had undergone between one and six fistula repair session prior grafting procedure with multiples aetiologies. No recurrence was reported during de follow-up period and all patients had normal faecal continence. Only one patient had mild dyspareunia and no fur-ther surgical treatment needed.[8]

A Bartholin's gland abscess led to chronically inflamed, scarred, and poorly vascularized tissue, which inhibited wound healing.[4]

We used the Martius flap based on patient previous history: first she had Bartholin's gland abscess, second she had undergone a fistula repair 5 weeks ago and third she had a previous history of four episodes of Bartholin's gland abscess.

With this case the authors highlight the importance of multidisciplinary approach and the relevance of interpositional graft techniques.

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Original article

Caution "FDA 2011": A modern pelvic floor mesh with a new form of cranial fixation. An observational study with 6-month follow-up on the A.M.I.® CR-Mesh and i-Stitch

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Abstract: Mesh-augmented pelvic floor surgery, which continues to be the subject of considerable discussion and attention, has not (yet) reached the surgical gold standard. The last 15 years have seen the development of an extensive range of materials and instruments, with the introduction of several revolutionary new methods. However while many of these concepts are a step in the right direction, they are not yet free of risks and complications. A reconstructive technique first demonstrated by Farnsworth was designed to offer full, 3-level support, while allowing individual adjustment of the mesh size and customised cranial fixation. Preliminary results also promised low erosion rates. During April 2008 and March 2010, we carried out an observational study in seven different clinics to evaluate this technique with respect to selected parameters. The study comprised 186 patients with an average age of 65.8 years, who underwent anterior, posterior or total repair with the A.M.I. CR-Mesh. At a follow-up time of 3-6 months, 92.5% of patients were satisfied with the procedure. The most frequent complications were post-operative de novo stress urinary incontinence (SUI) (7.5%) and cystitis (3.7%). Erosion occurred in 3.2% of patients. The authors found the method and materials to be a significant and valuable addition to the range of treatments in mesh-augmented pelvic floor surgery.

Key words: FDA updates; Pelvic floor repair; Prolapse surgery; Urogynecology; Vaginal meshes.

INTRODUCTION

The very topical discussion resulting from FDA-Updates[1, 2] on the use of mesh for vaginal surgery has prompted consideration of alternative methods and materials, which may provide counter-arguments for many of the claims made by the FDA. The need for sufficient therapeutic procedures to treat pelvic floor defects and prolapse disorders is undisputed and, due to the current demographic development and better education on the subject that is now helping to break existing taboos, the number of patients is increasing. Statistics show that in Germany, more nappies are produced for adults than for children.[3]

While the field of urogynaecology struggled time and again during the first 100 years with unsatisfactory long-term results, more recent times have been characterised by the quite revolutionary development of new methods born with the introduction of the tension-free suburethral slings (TVT) by Ulmsten and Petros in 1995. The relevant anatomy, and in particular the cranial fixation, can be seen in Figures 1-3. The techniques, materials and instruments that

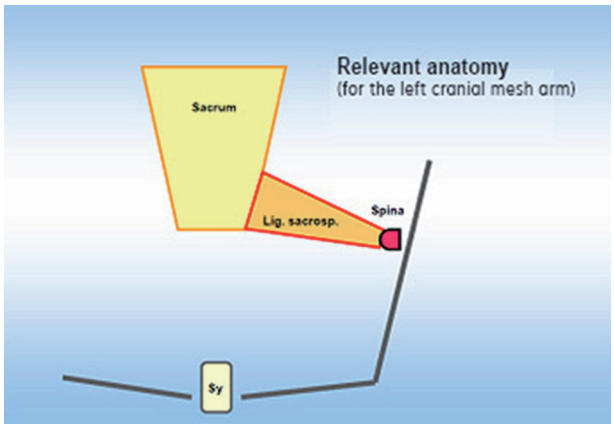

Figure 1. – Relevant anatomy.

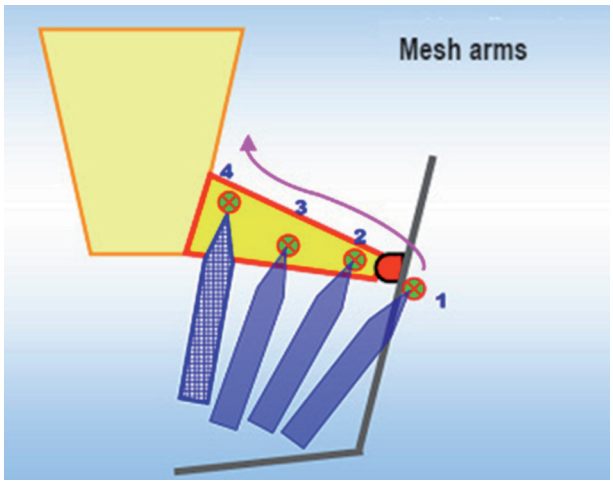

Figure 2. – Cranial passage of mesh arms (fixation point initially at 1, today at 4).

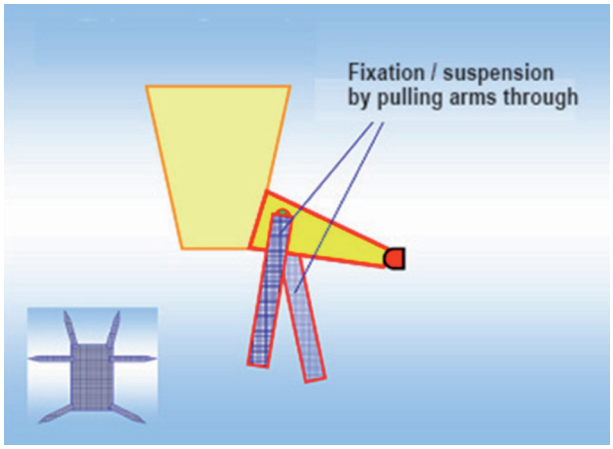

Figure 3. – Passage / fixation of mesh arms.

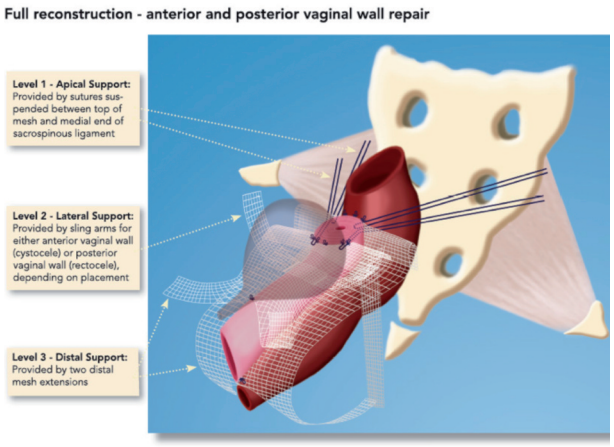

Figure 4. – Technique according to B. Farnsworth.

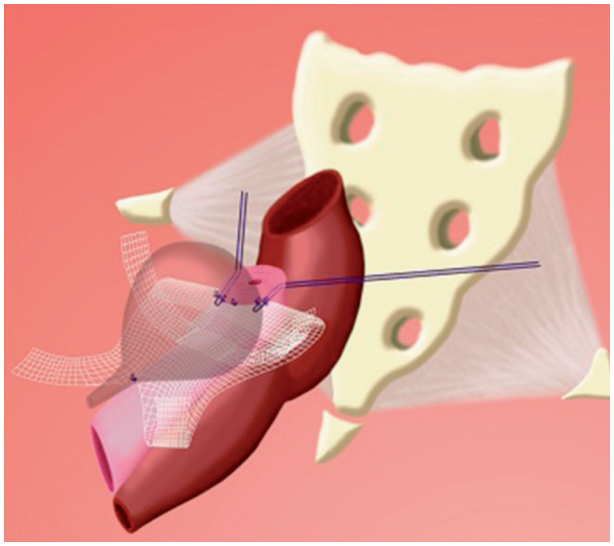

Figure 5. – Anterior repair (cranial suture suspension subsequently replaced by fixation/suspension of mesh arms).

followed all had their own particular emphasis, and some also brought defining and groundbreaking modifications. In particular the transobturatoric approach (Delorme) served as a stimulus for the industry's activity, and the result was the further advancement of many existing slings and meshes, as well as the introduction of many new ones. Time and again, the significant progress made in terms of effectiveness combined with high success rates achieved by renowned centres provided the impetus for an expansion of the methods, and to some extent also their uncritical use on a broad scale.

We now have an extensive range of innovative procedures, materials and instruments. However, the most recent developments – namely the mini-slings and the first meshes using a purely transvaginal approach – show that while these concepts represent positive progress in many respects, particularly in terms of minimal invasiveness, they are not yet free of risks and complications. In particular the long paths required for placement of the 6-arm meshes primarily used today (for the most part "blind passages" through the pelvis), fixation of the arms – in the case of transobturatoric meshes and slings – to the area of femoral muscle attachment in the upper thigh muscles, as well as a predominant lack of individualised mesh size and fixation, leave many questions unanswered. The "surgical gold standard" for mesh-augmented pelvic floor surgery has thus not yet been found. The road from armless pieces of mesh or patches, on to meshes with 2, 4 or 6 arms with greatly differing fixation techniques, and further on to "unfixed" placement of meshes by means of long-term tamponades, shows the uncertainty of the developers.

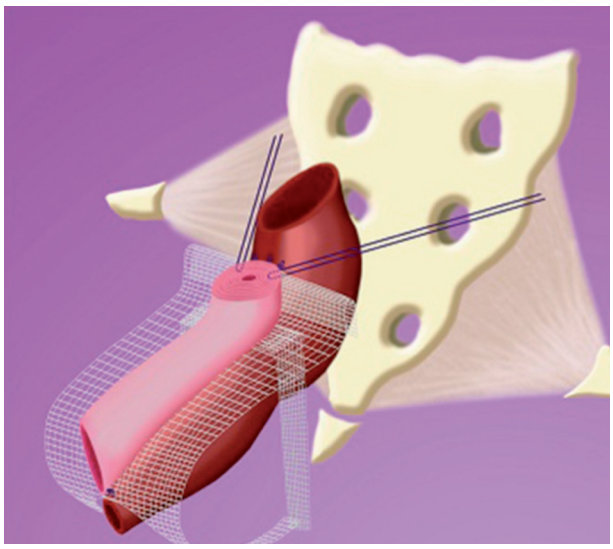

Figure 6. – Posterior repair (cranial suture suspension subsequently replaced by fixation/suspension of mesh arms).

Since 2008 a physiological reconstructive technique has been propagated, in particular by B. Farnsworth, who repeatedly emphasised the significance of sufficient, individually-customised cranial fixation and better suspension (Figure 4-6). Preliminary results from other authors have also shown a very low erosion rate occurring with use of this special mesh and surgical technique.[4] However widespread acceptance of this innovative method was hindered – at least in Europe – by the complexity of numerous individual steps and the inconsistency of still combining a transvaginal with a percutaneous approach.

Our aim was to evaluate this technique with respect to preparation, fixation and customisation.

MATERIALS AND METHODS

During the period from April 2008 to March 2010, the authors evaluated the Farnsworth technique in an observational study comprising seven centres and 186 patients. The average age was 65.8 years and 25.6% of patients had previously undergone pelvic reconstruction surgery (Table 1). The uterus was preserved in 52.2% of patients, and removed in 28% during the same intervention. The remaining 19.8% had previously undergone a hysterectomy. Indic-

Table 1. – Patient Population and Case History.

Number of cases	186 patients, 237 meshes (average 31 patients/clinic; range: 4- 7)	
Age of patients	65.8 years (Range: < 50 yrs.: 4.8%; 51-65 yrs.: 42.5%; 66-80 yrs.: 47.9%; > 80 yrs.: 4.8%)	
Case history (%)	After hysterectomy with no further prolapse/defect surgery	17.7
	After hysterectomy with further prolapse/defect surgery	21.3
	Previous prolapse/defect surgery but no hysterectomy	4.3
	No previous surgery	56.7
	Primary reconstruction	74.4
	Secondary reconstruction / revision surgery	25.6

TABLE 2. – Surgery Performed and Operating Times

Surgery performed	n	Operating time (mins)
CR-Mesh + HE	28.0	
CR-Mesh with preservation of uterus	52.2	
CR-Mesh with previous hysterectomy	19.8	
Anterior mesh only	54.3	
+ HE	12.4	82
Preservation of uterus	31.7	63
Previous hysterectomy	10.2	59
Posterior mesh only	12.4	
+ HE	5.9	81
Preservation of uterus	2.7	54
Previous hysterectomy	3.8	49
Anterior and posterior mesh	33.3	
+ HE	9.7	111
Preservation of uterus	16.7	103
Previous hysterectomy	7.0	74

ations for using the A.M.I. CR-Mesh were as follow: anterior and posterior level II defect in combination with level I defect, isolated level I defect, POP-Q III/IV, wish to preserve uterus, long vagina, sexually-active patient.

Operating times ranged from 49-82 minutes for a single mesh with or without hysterectomy, and from 74-111 minutes for a total repair with two meshes, with or without hysterectomy. A total of 237 meshes were placed. 54.3% of patients underwent anterior repair only, 12.4% posterior and 33.3% total repair (Table 2).

Surgery was performed according to the technique described by Farnsworth,[5] the main steps of which can be summarised in simplified form as follow:

- Preparation of the surgical site in the traditional manner as for anterior, posterior or total repair.
- Placement (for both anterior and posterior meshes) using the i-Stitch instrument of a PP 0 suture on both sides of the sacrospinous ligament, as high and as medial as possible, for level I suspension. This eliminates the need for extensive dissection (Figure 7-10).
- Suspension of the lateral, sleeved mesh arms to the side pelvic wall to provide support at level II.
- Individual customisation of the mesh by cutting the arms with no sleeves down to the correct length. These arms are placed at the bladder neck or around the anal sphincter complex for level III stabilisation.

The focal point of the technique is suspension rather than fixation, and the mesh is designed to establish:

- Stable, individually-customised cranial suspension at level I;
- Firm, but springy muscular suspension and stabilisation at level II;
- A wide, stable connection at level III.

The investigators were asked to evaluate the method and materials in terms of preparation, fixation / suspension using the i-Stitch, individual adjustment of the mesh and physiological repair.

RESULTS

Intra- and post-operative complications, the most common of which were cystitis (7.5%) and de-novo stress urinary incontinence (3.7%), can be seen in Table 3. The cystitis was treated conservatively and subsequently resolved,

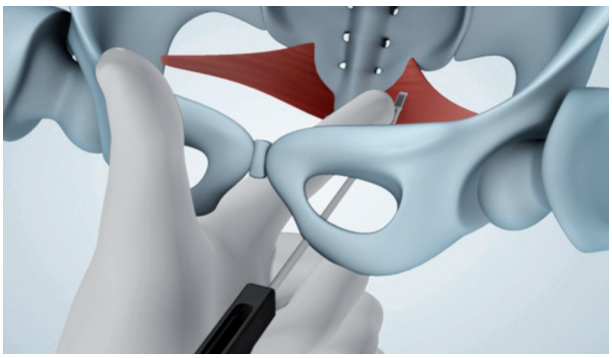

Figure 7. – Suture placement using i-Stitch (1).

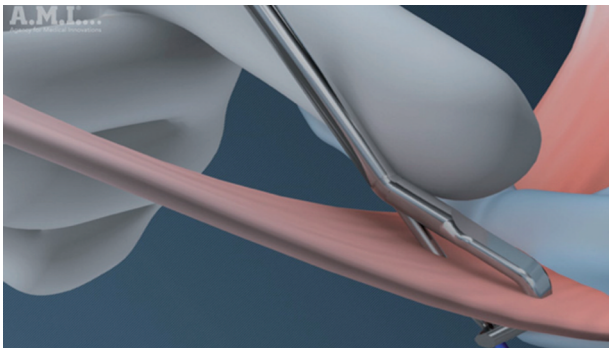

Figure 8. – Suture placement using i-Stitch (2).

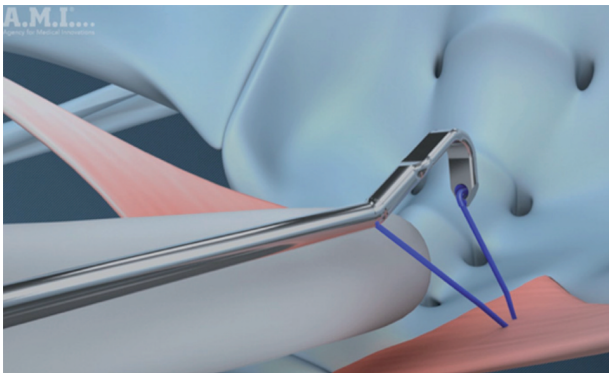

Figure 9. – Suture placement using i-Stitch (3).

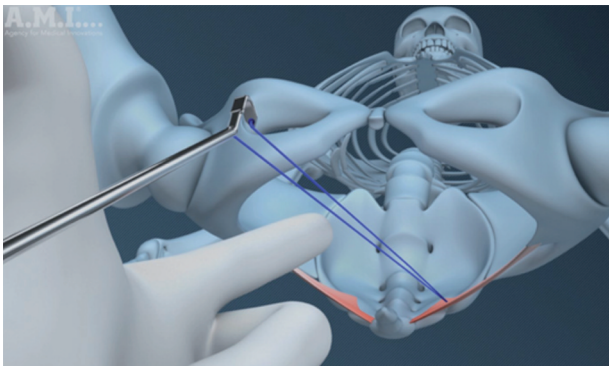

Figure 10. – Suture placement using i-Stitch (4).

while the patients experiencing de-novo SUI received secondary therapy. There was one recurrence of cystocele (0.5%) and one case of de-novo cystocele after implantation of a posterior mesh (Table 3). Multiple cases of short-term urinary retention were successfully treated with conservative therapy. Of the six cases of erosion (3.2%), three were treated with conservative therapy and three patients underwent revision surgery.

TABLE 3. – Complications Intra- and Post-Operative.

Intra-operative bladder lesions	1.6%
Intra-operative intestinal lesions	0.5%
Post-operative cystitis	7.5%
Infected haematoma	1.1%
Post-operative de-novo SUI	3.7%
Recurrence of cystocele	0.5%
De-novo cystocele after posterior mesh	0.5%
Mesh erosions	3.2%

The satisfaction rate, measured according to whether the patient was satisfied with the functional result and would recommend the procedure to others, was 92.5%.

The findings of the investigators in terms of the materials can be summarised as follow:

- The size and shape of the mesh implant allow it to be cut down to suit the individual patient with no difficulty (Figure 11).
- Despite the wide dimensions of the implant, it is easy to handle and the soft texture makes it gentle on the patient. The material is lightweight and isoelastic, while still retaining its shape and stability.
- Even around the edges, the mesh cannot be felt post-operatively and therefore represents no disturbance for sexually-active patients
- The i-Stitch instrument is an innovative solution for suture fixation, allowing easy access to all structures with minimal dissection.
- The authors' recommendations for modifications to the tunnelling instruments have subsequently been implemented.

The authors find the method to be complex and difficult to perform, with a very flat learning curve. However it offers several notable advantages:

- Optimal, high cranial-medial fixation by means of sutures placed using the i-Stitch, with no excessive preparation and no visualisation of the ligament necessary.
- True, individually-customised apical suspension.
- Optimal adjustment to the patient's individual vaginal length.
- Preservation of the central vaginal serosa (by median knot fixation of the lateral arms to the mesh body).
- As a result of the specific mesh characteristics and best possible preservation of the physiological vaginal axis, a notably low erosion and de-novo dyspareunia rate.
- Minimal disposable material.

DISCUSSION

Data contained in the Cochrane analyses 2010 and 2011,[6,7] which along with other publications formed the basis for the FDA warning, require closer scrutiny. There are only two studies relating to quality of life, one study analyses the results obtained with a pre-cut mesh (Perigee), which is applied without the essential apical fixation and therefore implies complications such as mesh shrinking, sintering, creasing, erosions and dyspareunia etc.

Two further studies are based on meshes, which are cut to size instead of pre-cut, but again do not have any form of apical fixation. As qualified by Murphy et al. in,[8] of the seven randomised studies comparing mesh repair with traditional surgical techniques, six studies were designed to evaluate only anatomical and not subjective outcome, five showed anatomical advantages for mesh surgery while only one study showed no advantage, and only one study contained an analysis of the subjective and objective outcomes. This analysis showed the mesh to achieve better results according to both criteria. In terms of sexuality, only one study showed a significantly worse dyspareunia score in the non-mesh group, while all the other publications showed no difference between the two. All in all, this collection of literature can therefore be considered as very heterogeneous.

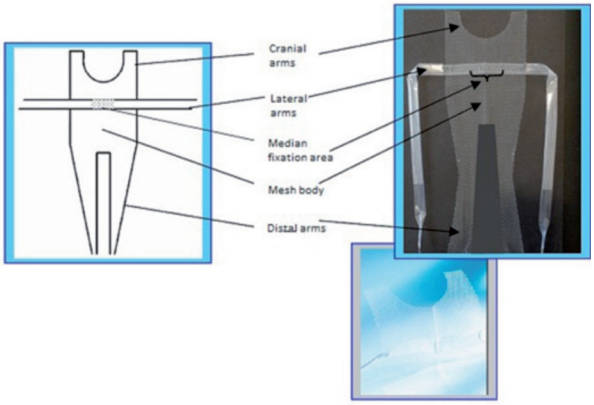

Figure 11. – A.M.I. CR-Mesh (left: basic mesh shape; right: mesh with hexagonal pattern).

Tunn[9] also commented objectively:

- There was no differentiation made between the varying qualities of mesh.
- There is no conclusive proof that the complications cited are connected with the mesh implant.
- No mention is made of the fact that similar complications (e.g. dyspareunia) may also arise with prolapse and urinary incontinence surgery which does not involve a foreign body.
- Mesh erosion in the vagina was named as the most frequent complication.
- As there can be no doubt that more than only 7,000 meshes are implanted per year, it would be a remarkably low mesh erosion rate.
- More questions were raised than answered.
- Furthermore, there was no acknowledgement whatsoever of the rapid development made in terms of mesh quality and operating technique.
- Patients must certainly be informed about the lack of long-term results and the availability of other surgical alternatives that do not involve mesh. However to be fair, they should also be informed that particularly in case of a recurrence, there is often no sensible alternative to mesh surgery.

Fuenfgeld qualifies matters further, noting that "many of these meshes were implanted during the learning curve with first generation implants and with a suboptimal technique. The experience described can therefore not be considered a correct representation of today's reality. At this point in time, the question therefore arises by implication as to what extent the frequently-cited complications might be reduced or prevented by suitable techniques and materials".[10]

There is no doubt that unsatisfactory progress made by individual patients after mesh operations, the accumulation of complications and the discontinuation of studies due to untenable erosion rates require thorough analysis and considered answers. As such, factually grounded, non-tendential warnings, such as that given by Dietl[11] should certainly be heeded, however on the other hand we would like to concur with the "snapshot" of the current status as described by Lange: "Colposuspension, suburethral slings and now the meshes have been and continue to be the subject of much controversy. There is no doubt that the field of urogynaecology has made enormous progress and taken a giant leap forwards. Despite making many wrong turns along the way, we now have erosion rates which we previously could only have dreamt of. And with all the criticism of incorrect or incorrectly-applied techniques and the human tendency to see everything new as better, one should

also assess conventional methods just as critically instead of glorifying them".[12]

In this respect, the position taken by the Working Group for Urogynaecology and Plastic Pelvic Floor Reconstruction[2] may be helpful, according to which: "... a general overly-careful approach to the materials, which in the meantime are very advanced and also quite varied, would not be conducive to scientific progress and would block further developments..."

This also perhaps another good reason to remind ourselves that slings and meshes for incontinence and pelvic floor defects were not simply the random result of a marketing strategy pursued by the industry, instead they were the result of more than 100 years' development, which has been pushed particularly since the 1960's, and of intensive clinical and scientific research. The progress made in the last few years in terms of material and surgical techniques has contributed to the optimisation of therapy and helped objectify the discussion, and is indicative of the primarily responsible manner in which the problems have been handled. Furthermore, the question as to whether – after some 10 years' experience with mesh fixation by means of tapes pulled through the pelvis using tunnellers – the less invasive types of fixation such as anchor systems or other metal fasteners actually have any advantages, is one still under discussion.

We therefore consider the CR-Mesh technique to represent a significant addition to the current range of treatments in mesh-augmented pelvic floor surgery. It incorporates notable advancements in terms of material and method, which appear to address several of the difficulties experienced with mesh implants in the past. In our experience these developments may contribute to improved post-operative outcomes, particularly in terms of erosion and patient satisfaction.

CONCLUSION

Despite considerable discussion during the last few years about the use of mesh implants for pelvic floor repair, mesh-augmented surgery is an important form of treatment and in many cases the only viable option. The CR-Mesh technique according to Farnsworth is a pragmatic and effective method which enjoys a low rate of complications. In particular the stable cranial fixation / suspension created by means of a reusable suture instrument represents a true innovation. Based on a very positive evaluation of the overall concept, and bearing in mind the low erosion rate and high degree of patient satisfaction, the authors consider the method, mesh and instruments to represent a valuable development in the individualised treatment of pelvic floor prolapse.

ACKNOWLEDGEMENTS AND DISCLOSURES

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Pelvic Floor Digest

Surgical treatment of mixed and urge urinary incontinence in women
W. Jäger, O. Mirenska, S. Brügge. Gynecol. Obstet. Investig., Published online: August 9, 2012,

In this study the Authors analyze whether the surgical replacement of uterosacral ligaments by an alloplastic tape can treat patients with mixed and urge incontinence. In particular they show that vaginal–rectal-sacral fixation (VARESA) and cervical-rectal-sacral fixation (CERESA) are able to cure and to improve the above described symptomatology in 102/135 (77%) and 24/135 (18%) of cases respectively.
In this context the Authors hypothesis is that the association between descensus uteri and urge incontinence could be caused by a defective functioning of the uterosacral ligaments and in this way they refer to the Petros' theory that points out the importance of the posterior compartment for establishing the continence function.[1]
As is known the etiology of urge incontinence is unknown an in this way it is difficult to give an interpretation of the results in the light of the surgical solution used and therefore we are obliged to start from what we can deduce from the current literature. In particular we known that a successful surgical repair of stress incontinence is associated with the cure of urgency incontinence in 50% to 85% of patients suggesting a connection between urethral afferents and the micturition reflex.[2-3]
In this sense Barrington experimentally demonstrated that running water through the urethra or distension of the proximal urethra causes contraction of the detrusor in the cat[4] and Jung showed that in the rats urethral perfusion facilitated detrusor activity, and that intraurethral lidocaine (1%) caused a significant decrease in bladder contraction frequency.[5] These studies suggest that mechanosensitive afferent nerves activated by fluid entering the urethra can increase the excitability of the micturition reflex and that in patients with stress incontinence, in which urine easily enters in the posterior urethra, an involuntary detrusor contraction with urgency to void may be induced. Starting from these considerations, it could be possible that the surgical approach by CERESA or VARESA, by the replacement of uterosacral ligaments by an alloplastic tape, determines not only an anatomical support of the posterior compartment but also a realignment of the urethra with recovery of urinary continence and the resolution of urgency. A perspective MRI study before and after these surgical approaches is advisable to confirm this interpretation from an anatomical point of view.

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Factors associated with exposure of transvaginally placed polypropylene mesh for pelvic organ prolapse
K.P. Gold, R.M. Ward, C.W. Zimmerman et al. Int. Urogynecol. J. 2012; 23:1461-1466.

This case-control study (48 cases, 48 controls) evaluates potential risk factors for mesh exposure following transvaginal placement of polypropylene mesh for POP requiring reoperation. The authors identified bleeding complications at the time of mesh implantation as a risk factor. Multivariable logistic regression analyses were performed to determine if age, smoking, and bleeding complications were independently associated with developing mesh exposure. Women with and without mesh exposures were of similar gravidity, parity, BMI, menopausal status, and had similar rates of medical comorbidities, prior and concomitant urogynecologic surgeries. The complication of excessive blood loss (EBL >500 ml), hematoma formation requiring intervention, or the need for a postoperative transfusion, was found to be a predictor of mesh exposure in both the univariable analysis and the multivariable model, with an adjusted OR of 7.25 (95% CI 1.47–35.66). Sixteen patients (33%) had perioperative complications in the mesh exposure group, including EBL >500 ml (9), posterior vault hematoma requiring drainage,[1] vascular injury with resultant hematoma requiring embolization of anterior and posterior branches of the internal iliac artery,[1] cystotomy repaired at the time of surgery,[2] rectal perforation with repair at the time of surgery,[1] right sciatic pain,[1] and groin and leg pain.[1] Only two controls (4%) had a complication: EBL >500 ml. Age, gravidity, parity, BMI, medical comorbidities, prior and concurrent urogynecologic surgeries, or smoking were not identified as risk factors for subsequent mesh exposure requiring reoperation. The Authors state that it is important to recognize that inconclusive findings are not synonymous with evidence of a lack of association, and larger studies are needed in order to evaluate the impact of these and other potential comorbidities on mesh complications. They also underline that the strengths of their study include its size and the use of a comparison group, with the limitations of a retrospective design, of multiple surgeons of varying skill levels, and the inclusion of surgeries involving mesh placement in different institutions. The use of polypropylene mesh to augment the vaginal repair of POP must then be weighed against the risk of mesh exposure and the potential need for additional surgery. The individual risk-benefit profile of each surgical candidate must be considered. Although it may not be possible to predict which patients will have excessive bleeding at the time of surgery, those who do have this complication need a careful surveillance for mesh exposure in their follow up.
The interest of this article can be related to the "FDA 2011 warning" as recently described by Neuman,[1] were most of the adverse events with prostheses implant are due to mesh exposure and this seems to depend on excessive implanted mesh mass, inappropriate mesh placement, applying exaggerated tension forces on the implant and native pelvic tissue, and lack of appropriate training or sufficient skills maintenance. With EBL one can expect a weaker immune response with bacterial growth and inadequate tissue repair. Furthermore it has to be remembered that the width of the vaginal wall covering the mesh implants is usually rather thin, therefore meticulous surgical measures are required in order to reduce mesh exposure, such as improving the minimal invasiveness of the procedure, reducing tissue damage and bleeding during dissection and mesh placement.

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