#### **Pelvic Floor Digest**

This section presents a small sample of the Pelvic Floor Digest, an online publication (**www.pelvicfloordigest.org**) that reproduces titles and abstracts from over 200 journals. The goal is to increase interest in all the compartments of the pelvic floor and to develop an interdisciplinary culture in the reader.

#### **1 – THE PELVIC FLOOR**

**Variations in stress incontinence and prolapse management by surgeon specialty.** *Anger JT, Litwin MS, Wang Q, et al. J Urol. 2007 Aug 14; epub.* Numerous studies have documented a relationship between provider specialty and outcomes for surgical procedures. In this study the effect of surgeon specialty was determined on outcomes of sling surgery for women with stress urinary incontinence. Early prolapse management by gynecologists corresponded to fewer prolapse repairs in the year following the sling, suggesting that gynecologists are more likely to identify and manage prolapse at the time of the evaluation of urinary incontinence, a strategy that appears to avoid the morbidity and cost of repeat surgery.

**Symptoms of anal incontinence and difficult defecation among women with prolapse and a matched control cohort.** *Morgan DM, Delancey JO, Guire KE, Fenner DE. Am J Obstet Gynecol. 2007 Aug 20; epub.* One-third of women with pelvic prolapse have anal incontinence of flatus on "most" or "every" day or difficult defecation with "most" or "every" bowel movement. This study quantifies the risk for these symptoms comparing women with and without prolapse of similar age, body mass index, race, and hysterectomy status. Length of the perineal body, mean parity, and a positive standing cough stress test are associated with greater symptom severity.

A prospective, randomized controlled trial of the use of an anal purse-string suture to decrease contamination during pelvic reconstructive surgery. *Biller DH, Guerette NL, Bena JF, Davila GW. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Apr 11; epub.* An anal pursestring suture is an effective way of reducing fecal contamination of the sterile field when performing vaginal pelvic reconstructive surgery. No wound infections, graft erosions, or healing abnormalities however were noted without the suture.

**Medium-term efficacy of pelvic floor muscle training for female urinary incontinence in daily practice.** *Lamers BH, van der Vaart CH. Int Urogynecol J Pelvic Floor Dysfunct.* 2007;18:301. Pelvic floor muscle training for urinary incontinence is effective for their quality of life in half of the women. If not successful, women seem to benefit significantly from incontinence surgery. This is the result of a study on 355 women treated by specialized physiotherapists, with a mean follow-up of 32 months.

**Deformation of the pelvic floor muscles during a vaginal delivery.** *Parente MP, Jorge RM, Mascarenhas T et al. Int Urogynecol J Pelvic Floor Dysfunct.* 2007 May 24; epub. Since pelvic floor injuries during a vaginal delivery can be considered a significant factor in the development of urinary and fecal incontinence and pelvic organ prolapse, to clarify the mechanisms behind pelvic floor disorders related to a vaginal delivery, a finite element method and a three-dimensional computer model of the pelvic floor and fetus were used. Results for the pelvic floor stretch values obtained during the passage of the fetus head show that the maximum deformation obtained is 0.66 for a vertical displacement of the fetal head of approximately 60 mm.

#### 2 – FUNCTIONAL ANATOMY

**Morphology of the levator ani muscle.** *Li D, Guo M. Dis Colon Rectum. 2007 Aug 16; epub.* Previous studies have suggested that both the levator ani and the puborectalis muscles lift the anus. CT defecography in a sitting position shows that the levator ani is funnel-shaped at rest in the sitting position; it ascends, becoming plate-shaped during squeeze, and it descends, becoming basin-shaped during defecation. There is no muscle to lift the anus during defecation, the puborectalis lifting it during squeeze. The main function of the levator ani is to open the genital hiatus and the anus during defecation, the puborectalis shuts the genital hiatus and anus during squeeze.

Levator co-activation is a significant confounder of pelvic organ descent on Valsalva maneuver. Orno AK, Dietz HP. Ultrasound Obstet Gynecol. 2007;30:346. The Valsalva maneuver is used clinically and on imaging to determine pelvic organ prolapse, but is frequently accompanied by a pelvic floor muscle contraction. Levator co-activation may be a substantial confounder, reducing pelvic organ descent. Without repetition and digital, auditory or visual biofeedback, women may not perform a correct Valsalva maneuver. Biofeedback markedly reduces the likelihood of levator co-activation but does not abolish it completely.

Anal canal anatomy showed by three-dimensional anorectal ultrasonography. *Regadas FS, Murad-Regadas SM, Lima DM et al. Surg Endosc. 2007 May 4; epub.* 3-D anal endosonography enables measurement of the different anatomical structures of the anal canal and demonstrates its asymmetrical configuration. The shorter anterior external anal sphincter and internal anal sphincter associated with a longer gap (distance from the anterior external sphincter to the anorectal junction) can justify the higher incidence of pelvic floor dysfunction in females, especially fecal incontinence and anorectocele with rectal intussusception.

Effects and mechanisms of vaginal electrical stimulation on rectal tone and anal sphincter pressure. Song GQ, Zhu H, Chen JD. Dis Colon Rectum. 2007 Aug 14; epub. Vaginal electrical stimulation with long pulses or trains of long pulses but not trains of short pulses reduces rectal tone and increases anal sphincter pressure in conscious dogs. The inhibitory effect of vaginal electrical stimulation on rectal tone is mediated by the sympathetic pathway. These findings suggest that vaginal electrical stimulation may be a potential therapy for fecal incontinence.

**Rectoanal sensorimotor response in humans during rectal distension.** *De Ocampo S, Remes-Troche JM, Miller MJ, Rao SS. Dis Colon Rectum.* 2007 *Aug 16; epub.* Rectal perception, that facilitates maintenance of continence and defecation, is associated with motor changes in anorectum. Sensory and motor responses of the anorectum during rectal distention were examined, the sensorimotor response first occurring synchronously with the sensation of fullness or more often with the desire to defecate which is associated with a unique, consistent, and reproducible anal contractile response.

**Role of phospholipase A2 in the genesis of basal tone in the internal anal sphincter smooth muscle.** *de Godoy MA, Rattan S. Am J Physiol Gastrointest Liver Physiol. 2007 Aug 23; epub.* Phospholipase A2 plays a critical role in the genesis of tone in the internal anal sphincter and its inhibitors may provide potential therapeutic target for treating anorectal motility disorders.

#### **3 – DIAGNOSTICS**

**Clinical and urodynamic parameters associated with history of urinary tract infections in women.** Athanasiou S, Anstaklis A, Betsi GI et al. Acta Obstet Gynecol Scand. 2007;86:1130. Urodynamic testing does not help in identifying specific urogynecologic mechanisms that could improve medical and/or surgical management or prevent recurrent urinary tract infections.

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#### Pelvic Floor Digest

Effect of anatomic urethral length on the correlation between the Q-tip test and descent at point Aa of the POP-Q system. Larrieux JR, Balgobin S.Int Urogynecol J Pelvic Floor Dysfunct. 2007 Aug 9; epub. The objective of this study is to evaluate the effect of anatomic urethral length on the relationship between descent at point Aa of the pelvic organ prolapse quantification system and the Q-tip straining angle. Urethral length being measured with a urethral profilometer, a substantial correlation was found between descent at point Aa and the straining Q-tip angle, while there was no correlation between the anatomic urethral length and straining Q-tip angle. So urethral length does not affect the straining Q-tip angle, and point Aa is a strong predictor of an abnormal straining Q-tip angle in women with stage I anterior vaginal wall prolapse or greater.

**Segmental colonic transit studies: comparison of a radiological and a scintigraphic method.** *Lundin E, Graf W, Garske U et al. Colorectal Dis. 2007;9:344.* Colonic transit studies are used to diagnose slow transit constipation (STC) and to evaluate segmental colonic transit before segmental or subtotal colectomy. The aim of the study was to compare a single X-ray radio-opaque marker method with a scintigraphic technique (111Indium-DTPA) to assess total and segmental colonic transit in patients with STC. Segmental colonic delay was a common finding. The two methods gave similar results for groups of patients, except in the descending colon. The variation of the results for individuals suggests that a repeated transit test may improve the assessment of total and segmental transit.

**MR colonography.** *Kinner S, Lauenstein TC. Radiol Clin North Am.* 2007;45:377. Combining the advantages of unsurpassed soft tissue contrast and lack of ionizing radiation, MR imaging of the gastrointestinal tract has become increasingly used clinically. Both bowel inflammation and tumor disease of the large bowel can be well visualized by means of MR colonography.

Nurse specialist led flexible sigmoidoscopy in an outpatient setting. Kelly SB, Murphy J, Smith A. Colorectal Dis. 2007 May 17; epub. Objective there has been an increasing demand for diagnostic flexible sigmoidoscopy. In order to improve our diagnostic services, we established a nurse specialist led flexible sigmoidoscopy clinic in 1999. A total of 3956 patients had a flexible sigmoidoscopy performed between 1999 and 2004. Two patients only sustained an iatrogenic rectal perforation. The nurse specialist offers an efficient diagnostic service for patients presenting with colorectal symptoms.

**Digital rectal examination: national survey of undergraduate medical training in Ireland.** *Fitzgerald D, Connolly SS, Kerin MJ. Post-grad Med J.* 2007;83:599. The experience gained in at least one digital rectal examination (DRE) by medical students by the completion of undergraduate training was assessed. No experience was reported in 24%, with mannequin-only experience in a further 20%, 56% performed DRE on at least one patient, but one third reported no confidence in their ability to interpret their findings properly.

#### 4 – PROLAPSES

The natural history of posterior vaginal wall support after abdominal sacrocolpopexy with and without posterior colporrhaphy. Yau JL, Rahn DD, McIntire DD et al. Am J Obstet Gynecol. 2007;196:e45. For abdominal sacrocolpopexy with concomitant posterior colporrhaphy, POP-Q point Ap significantly improved and persisted at 34 months after surgery. Ten months after surgery, descent of POP-Q point Bp returned to preoperative levels and was the same regardless of whether a site-specific posterior colporrhaphy was performed at the time of an abdominal sacrocolpopexy.

**Symptomatic Pelvic Organ Prolapse: prevalence and risk factors in a population-based, racially diverse cohort.** *Rortveit G, Brown JS, Thom DH et al. Obstet Gynecol. 2007;109:1396.* To estimate the prevalence of and identify risk factors associated with symptomatic pelvic organ prolapse and level of distress in racially diverse women aged older than 40 years, the Reproductive Risks for Incontinence Study evaluated a population of 2,001 randomly selected women. Symptomatic prolapse was reported by 6% of women. Almost 50% of these reported moderate or great distress, and in 35% the symptoms affected at least one physical, social or sexual activity. In multivariable logistic regression analysis the risk of prolapse was significantly increased in women with vaginal deliveries compared with nulliparous women. Irritable bowel syndrome, constipation, and self-reported fair or poor health status were strongly associated with prolapse. African-American were significantly less likely to report symptomatic prolapse compared with white women.

**Functional outcome after transperineal rectocele repair with porcine dermal collagen implant.** Smart NJ, Mercer-Jones MA. Dis Colon Rectum. 2007 Apr 9; epub. To assess the safety and efficacy of transperineal rectocele repair with porcine dermal collagen (Permacol (R)) 10 females were followed for 5-16 months with objective assessment for constipation, excessive straining, incomplete evacuation, vaginal bulg-ing, and vaginal digitations (always, usually, occasionally, never) and Medical Outcomes Study Short Form 36 questionnaires. All patients had an improvement in two or more symptoms and 70 percent of patients in three or more symptoms. Improvements in digitations and SF-36 scores were not significant.

A novel technique for rectocele repair in elderly women. Nano M, Ferronato M, Solej M, D'Amico S. Tech Coloproctol. 2007 May 25; epub. The rectal wall was separated from the rectovaginal septum. The vaginal wall was divided in the middle. The first flap was sewn to the second and this onto the first. In 22 elderly women followed-up for 24-84 months the need to digitally assist evacuation disappeared.

**Heterogeneity in anatomic outcome of sacrospinous ligament fixation for prolapse:** a systematic review. *Morgan DM, Rogers MA, Huebner M, Wei JT, Delancey JO. Obstet Gynecol.* 2007;109:1424. To explore why failure rates vary so much between published reports of sacrospinous ligament fixation to correct POP and what the potential sources of heterogeneity may be, Medline was queried for studies between 1966 and 2005 and 187 studies were reviewed. The anterior compartment was the most common site of failure for any given grade. This was most striking when the criterion for failure was grade 1 (40.1% anterior, 11.0% apical, 18.2% posterior) or grade 2 prolapse (21.3% anterior, 7.2% apical, 6.3% posterior). Areas of vaginal support were more equally affected when the criterion for failure was grade 3 prolapse (3.7% anterior, 2.7% apical, 2.3% posterior). Among cohorts using grade 2 prolapse as the criterion for objective failure, the pooled measure of failure to relieve symptoms was 10.3% and to provide patient satisfaction was 13.0%. In conclusion the variation in published failure rates after sacrospinous ligament fixation is, in part, accounted for by differences in how anatomical outcomes are evaluated and which compartment of vaginal support is being considered.

Midline anterior repair alone vs anterior repair plus vaginal paravaginal repair: a comparison of anatomic and quality of life outcomes. Morse AN, O'dell KK, Howard AE. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:245. A retrospective study to compare the anatomic recurrence rates and quality of life outcomes of patients who had undergone either anterior colporrhaphy or anterior colporrhaphy and vaginal paravaginal repair as part of surgery for pelvic organ prolapse did not suggest that adding paravaginal repair is superior in terms of anatomic or quality of life outcomes.

**Mesh-related infections after pelvic organ prolapse repair surgery.** Falagas ME, Velakoulis S, Iavazzo C, Athanasiou S. Eur J Obstet Gynecol Reprod Biol. 2007 Apr 23; epub. Although the use of vaginal meshes has become a new effective method of pelvic organ prolapse surgery clinicians should be aware of the various post-operative complications, including mesh-related infections. The incidence of mesh-related infections and erosion ranges from 0 to 8%, and 0 to 33%, respectively, in the published studies.

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#### Competing Interests: None

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#### Pelvic Floor Digest

**Prolapse repair by vaginal route using a new protected low-weight polypropylene mesh: 1-year functional and anatomical outcome in a prospective multicentre study.** *de Tayrac R, Devoldere G, Renaudie J et al. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:251.* A low-weight polypropylene mesh coated with a hydrophilic absorbable film for vaginal repair of genital prolapse (anterior, posterior and anterior-posterior repair) seems to decrease local morbidity (vaginal erosions 6.3%, de novo dyspareunia 12.8%) while maintaining low recurrence rates (6.8% for cystocele and 2.6% for rectocele). The report is based on the analysis of the first 143 patients of a multicentre study evaluated after at least 10 months follow-up. The improvement of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire were highly significant.

**Changes in the extracellular matrix in the anterior vagina of women with or without prolapse.** *Lin SY, Tee YT, Ng SC et al. Int Urogynecol J Pelvic Floor Dysfunct.* 2007;18:43. To investigate the changes in the connective tissues (collagen type I, III, IV, V, VI, elastin, and glycoproteins) located in the upper portion of the anterior vaginal wall associated with prolapse, in 23 women with prolapse an immunohistochemical study demonstrated that collagen III is significantly less than in a control group with a positive correlations with ageing.

**Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study.** *Deffieux X, de Tayrac R, Huel C et al. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:73.* In 138 women follow-up for 7-60 months cystocele repair was performed according to the technique of tension-free polypropylene mesh. Anatomically, the success rate was 95%. Vaginal erosion was reported in 20% of the patients with no statistically significant difference between Gynemesh and Gynemesh-Soft meshes. Cystocele stage >2 HWS is a protective factor against vaginal erosion. A partial excision of the mesh was necessary in 13/27 symptomatic patients (48%), associated with a vaginal mucosal closure, 2/27 underwent a complete excision. The incidence of de novo dyspareunia was 9% in patients with vaginal erosion.

A prospective, randomised, controlled trial comparing 3 hour and 24 hour postoperative removal of bladder catheter and vaginal pack following vaginal prolapse surgery. *Glavind K, Morup L, Madsen H, Glavind J. Acta Obstet Gynecol Scand.* 2007;86:1122. The aim of this prospective randomised study was to determine whether or not there was a higher incidence of bleeding, reoperation, urinary retention or bacterial count in the urine depending on whether urinary catheter and vaginal pack were removed 3 or 24 h after prolapse surgery. Pack and catheter removal after 3 h is recommended with careful monitoring of the patient's voiding.

**Robot-assisted vs. conventional laparoscopic rectopexy for rectal prolapse:** a comparative study on costs and time. *Heemskerk J, de Hoog DE, van Gemert WG et al. Dis Colon Rectum. 2007 Aug 10; epub.* Robot-assisted laparoscopic rectopexy is a safe and feasible procedure, but results in increased time and higher costs than conventional laparoscopy.

Stapled hemorrhoidopexy and Milligan Morgan hemorrhoidectomy in the cure of fourth-degree hemorrhoids: long-term evaluation and clinical results. *Mattana C, Coco C, Manno A et al. Dis Colon Rectum. 2007 Aug 16; epub.* Long follow-up seems to indicate more favorable results in Milligan-Morgan procedure compared to stapled hemorrhoidopexy (mean follow-up 92 and 54 months respectively) in terms of resumption of symptoms and risk of recurrence.

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# 2008

# TRAINING WORKSHOPS IN ADVANCED PELVIC SURGERY

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Three day workshops are regularly conducted at Sydney Adventist Hospital with both theoretical and practical course content. Temporary registration and hospital accreditation is necessary to enable delegates to scrub into live surgery. Numbers are limited to a maximum of 6 delegates to each workshop.

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For more information contact: **Robyn Tew**, CNS Pelvic Surgery - Centre for Pelvic Reconstructive Surgery Suite 505, San Clinic - 185 Fox Valley Rd - WAHROONGA NSW 2076 - AUSTRALIA Tel: +61 2 94738555 - Fax: +61 2 94738559 E-mail: robynte@yahoo.com.au - http://www.aavis.org/workshops.htm

# Pelvic Floor Digest

#### **5 – RETENTIONS**

**Postoperative urinary retention after primary colorectal cancer resection via laparotomy: a prospective study of 2,355 consecutive patients.** *Changchien CR, Yeh CY, Huang ST. Dis Colon Rectum. 2007 Aug 18; epub.* Risk factors for postoperative urinary retention after colorectal cancer surgery are: male gender, age, lung disease, rectal cancer, longer operation duration, and additional pelvic procedure.

**Causes of failed urethral botulinum toxin A treatment for emptying failure.** *Liao YM, Kuo HC. Urology. 2007 Aug 17; epub.* Urethral injection of BTX-A can reduce urethral resistance in patients with voiding dysfunction. However some patients do not benefit from this treatment. The causes of failed treatment in 23/200 patients were detrusor underactivity with very low abdominal straining pressure in 7, a tight urethral sphincter in 7, bladder neck obstruction in 7, and psychological inhibition of voiding in 2. Transurethral incision of the bladder neck was performed in 7 patients, and all had an improved result.

**Evaluation of constipation by abdominal radiographs correlated with treatment outcome in children with dysfunctional elimination.** *Allen HA, Austin JC, Boyt MA et al. Urology.* 2007;69:966. No correlation between any uroflowmetry parameter and the presence of fecal distention of rectum could be demonstrated, nor a statistical significance between fecal distention of rectum on abdominal radiograph and outcome of wetting symptoms was established.

A novel three-dimensional dynamic anorectal ultrasonography technique (echodefecography) to assess obstructed defectation, a comparison with defecography. *Murad-Regadas SM, Regadas FS, Rodrigues LV et al. Surg Endosc. 2007 Aug 20; epub.* Echodefecography may be used as an alternative method to assess patients with obstructed defectation as it has been shown to detect the same anorectal dysfunctions (anorectocele and rectal intussusception) observed in conventional defecography. It is minimally invasive, well tolerated, inexpensive, avoids exposure to radiation, and clearly demonstrates all the anatomic structures involved with defecation.

#### 6 - INCONTINENCES

Anatomic restoration technique of continence mechanism and preservation of puboprostatic collar: a novel modification to achieve early urinary continence in men undergoing robotic prostatectomy. *Tewari AK, Bigelow K, Rao S. Urology.* 2007;69:726. The complex of puboprostatic ligaments, puboperinealis muscle, and arcus tendineus (acting in unison to provide continence in men and women) can be disrupted during robotic prostatectomy. The preservation of the puboprostatic collar helped to restore early continence in 50 men undergoing robotic prostatectomy for clinically localized prostate cancer. The ligaments were reconnected to the urethrovesical anastomosis, reapproximated the muscles and fixed the distal bladder to the arcus tendineus. The average additional time was only 2 to 5 minutes, and the continence rate was 29% in the first week and 95% in 16 weeks after catheter removal.

**Anal sphincter laceration at vaginal delivery: is this event coded accurately?** *Brubaker L, Bradley CS, Handa VL et al. Obstet Gynecol.* 2007;109:114.

Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women. Farrell SA, Baydock S, Amir B, Fanning C. Am J Obstet Gynecol. 2007;196:474. The Uresta, a new self-positioning women's incontinence pessary, significantly reduces urinary incontinence and is easy for women to use.

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#### Editorial

#### **POLITICS IN THE PELVIS**

All around the world doctors and allied professionals are holding meetings and organizing educational courses that emphasize a multidisciplinary approach to the problems of the pelvic floor. Unfortunately fragmentation and tribalisation of our specialties have led to rival societies forming that aim to capture the attentions of the many interested specialists. Sometimes these societies are created to promote a particular operation or surgical technique. In Australia AAVIS began life as such a society but quickly realized that the only chance of a good future was to accept all interested practitioners and seek out rather than suppress alternative views and criticism of various techniques.

Societies have been formed based on laparoscopic pelvic floor surgery, urodynamic investigations, the Integral Theory and new classifications of pathophysiology. Other groups are heavily associated with one sponsor or supplier. Controversies have arisen with regard to the financing of meetings and educational courses by commercial interests. Even a prestigious scientific group such as the Internatonal Continence Society has become embroiled in internal disputes and political machinations. These conflicts have caused great personal anxiety for those involved and have rarely achieved the political results that were sought by the protagonists.

Recently this Journal has been criticized for being a "publicity machine" for one specialist with strong views because we published an article that he had submitted. Pelviperineology will not suppress the views of surgeons who are "politically incorrect" as long as they are scientifically sound but we will try to present a balanced position by also publishing alternative views. For example, this issue contains two papers which lead to different conclusions with regard to the STARR procedure.

Pelviperineology is a peer reviewed medical journal that is committed to publishing all opinions as we find them. We will consider the technical matters and language issues that could lead to rejection of an article but our main concern is the medical content and the potential interest of an article to our readers. All submitted articles are reviewed by practicing clinicians with a special interest in the area covered by the article under consideration.

Pelviperineology is also a generic term that refers to the multidisciplinary practice of Pelvic Floor Medicine. It is a term that can mean different things to different people and it has the power to release a clinician from the baggage of his narrow medical classification. Most doctors with an interest in the field of pelviperineology will continue to practice as urologists, colorectal surgeons or gynaecologists but some will seek to increase their skills in specific areas. One such society is Le Groupement Européen de Perinéologie (GEP, the European Perineology Group). We welcome the GEP to our journal and in the future each edition will provide a section for the messages and activities of the GEP to be made available to our readers. The GEP is a French language society of clinicians who have developed an interesting system of diagnosis and treatment, especially with regard to pudendal nerve entrapment and associated conditions. This is an area of great interest to many of our readers and we look forward to an ongoing contribution from this group.

THE EDITORS

#### PELVIPERINEOLOGY

#### A multidisciplinary pelvic floor journal

Pelviperineology is published quarterly. It is distributed to clinicians around the world by various pelvic floor societies. In many areas it is provided to the members of the society thanks to sponsorship by the advertisers in this journal.

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The aim of Pelviperineology is to promote an inter-disciplinary approach to the management of pelvic problems and to facilitate medical education in this area. Thanks to the support of our advertisers the journal Pelviperineology is available free of charge on the internet at *www.pelviperineology.org* The Pelvic Floor Digest is also an important part of this strategy. The PFD can be viewed in full at *www.pelvicfloordigest.org* while selected excerpts are printed each month in Pelviperineology.

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#### **Pelvic Floor Digest**

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**Symptoms of anal incontinence and difficult defecation among women with prolapse and a matched control cohort.** *Morgan DM, Delancey JO, Guire KE, Fenner DE. Am J Obstet Gynecol. 2007 Aug 20; epub.* One-third of women with pelvic prolapse have anal incontinence of flatus on "most" or "every" day or difficult defecation with "most" or "every" bowel movement. This study quantifies the risk for these symptoms comparing women with and without prolapse of similar age, body mass index, race, and hysterectomy status. Length of the perineal body, mean parity, and a positive standing cough stress test are associated with greater symptom severity.

A prospective, randomized controlled trial of the use of an anal purse-string suture to decrease contamination during pelvic reconstructive surgery. *Biller DH, Guerette NL, Bena JF, Davila GW. Int Urogynecol J Pelvic Floor Dysfunct. 2007 Apr 11; epub.* An anal pursestring suture is an effective way of reducing fecal contamination of the sterile field when performing vaginal pelvic reconstructive surgery. No wound infections, graft erosions, or healing abnormalities however were noted without the suture.

**Medium-term efficacy of pelvic floor muscle training for female urinary incontinence in daily practice.** *Lamers BH, van der Vaart CH. Int Urogynecol J Pelvic Floor Dysfunct.* 2007;18:301. Pelvic floor muscle training for urinary incontinence is effective for their quality of life in half of the women. If not successful, women seem to benefit significantly from incontinence surgery. This is the result of a study on 355 women treated by specialized physiotherapists, with a mean follow-up of 32 months.

**Deformation of the pelvic floor muscles during a vaginal delivery.** *Parente MP, Jorge RM, Mascarenhas T et al. Int Urogynecol J Pelvic Floor Dysfunct.* 2007 May 24; epub. Since pelvic floor injuries during a vaginal delivery can be considered a significant factor in the development of urinary and fecal incontinence and pelvic organ prolapse, to clarify the mechanisms behind pelvic floor disorders related to a vaginal delivery, a finite element method and a three-dimensional computer model of the pelvic floor and fetus were used. Results for the pelvic floor stretch values obtained during the passage of the fetus head show that the maximum deformation obtained is 0.66 for a vertical displacement of the fetal head of approximately 60 mm.

#### 2 – FUNCTIONAL ANATOMY

**Morphology of the levator ani muscle.** *Li D, Guo M. Dis Colon Rectum. 2007 Aug 16; epub.* Previous studies have suggested that both the levator ani and the puborectalis muscles lift the anus. CT defecography in a sitting position shows that the levator ani is funnel-shaped at rest in the sitting position; it ascends, becoming plate-shaped during squeeze, and it descends, becoming basin-shaped during defecation. There is no muscle to lift the anus during defecation, the puborectalis lifting it during squeeze. The main function of the levator ani is to open the genital hiatus and the anus during defecation, the puborectalis shuts the genital hiatus and anus during squeeze.

Levator co-activation is a significant confounder of pelvic organ descent on Valsalva maneuver. Orno AK, Dietz HP. Ultrasound Obstet Gynecol. 2007;30:346. The Valsalva maneuver is used clinically and on imaging to determine pelvic organ prolapse, but is frequently accompanied by a pelvic floor muscle contraction. Levator co-activation may be a substantial confounder, reducing pelvic organ descent. Without repetition and digital, auditory or visual biofeedback, women may not perform a correct Valsalva maneuver. Biofeedback markedly reduces the likelihood of levator co-activation but does not abolish it completely.

Anal canal anatomy showed by three-dimensional anorectal ultrasonography. *Regadas FS, Murad-Regadas SM, Lima DM et al. Surg Endosc. 2007 May 4; epub.* 3-D anal endosonography enables measurement of the different anatomical structures of the anal canal and demonstrates its asymmetrical configuration. The shorter anterior external anal sphincter and internal anal sphincter associated with a longer gap (distance from the anterior external sphincter to the anorectal junction) can justify the higher incidence of pelvic floor dysfunction in females, especially fecal incontinence and anorectocele with rectal intussusception.

Effects and mechanisms of vaginal electrical stimulation on rectal tone and anal sphincter pressure. Song GQ, Zhu H, Chen JD. Dis Colon Rectum. 2007 Aug 14; epub. Vaginal electrical stimulation with long pulses or trains of long pulses but not trains of short pulses reduces rectal tone and increases anal sphincter pressure in conscious dogs. The inhibitory effect of vaginal electrical stimulation on rectal tone is mediated by the sympathetic pathway. These findings suggest that vaginal electrical stimulation may be a potential therapy for fecal incontinence.

**Rectoanal sensorimotor response in humans during rectal distension.** *De Ocampo S, Remes-Troche JM, Miller MJ, Rao SS. Dis Colon Rectum.* 2007 *Aug 16; epub.* Rectal perception, that facilitates maintenance of continence and defecation, is associated with motor changes in anorectum. Sensory and motor responses of the anorectum during rectal distention were examined, the sensorimotor response first occurring synchronously with the sensation of fullness or more often with the desire to defecate which is associated with a unique, consistent, and reproducible anal contractile response.

**Role of phospholipase A2 in the genesis of basal tone in the internal anal sphincter smooth muscle.** *de Godoy MA, Rattan S. Am J Physiol Gastrointest Liver Physiol. 2007 Aug 23; epub.* Phospholipase A2 plays a critical role in the genesis of tone in the internal anal sphincter and its inhibitors may provide potential therapeutic target for treating anorectal motility disorders.

#### **3 – DIAGNOSTICS**

**Clinical and urodynamic parameters associated with history of urinary tract infections in women.** Athanasiou S, Anstaklis A, Betsi GI et al. Acta Obstet Gynecol Scand. 2007;86:1130. Urodynamic testing does not help in identifying specific urogynecologic mechanisms that could improve medical and/or surgical management or prevent recurrent urinary tract infections.

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#### Pelvic Floor Digest

Effect of anatomic urethral length on the correlation between the Q-tip test and descent at point Aa of the POP-Q system. Larrieux JR, Balgobin S.Int Urogynecol J Pelvic Floor Dysfunct. 2007 Aug 9; epub. The objective of this study is to evaluate the effect of anatomic urethral length on the relationship between descent at point Aa of the pelvic organ prolapse quantification system and the Q-tip straining angle. Urethral length being measured with a urethral profilometer, a substantial correlation was found between descent at point Aa and the straining Q-tip angle, while there was no correlation between the anatomic urethral length and straining Q-tip angle. So urethral length does not affect the straining Q-tip angle, and point Aa is a strong predictor of an abnormal straining Q-tip angle in women with stage I anterior vaginal wall prolapse or greater.

**Segmental colonic transit studies: comparison of a radiological and a scintigraphic method.** *Lundin E, Graf W, Garske U et al. Colorectal Dis. 2007;9:344.* Colonic transit studies are used to diagnose slow transit constipation (STC) and to evaluate segmental colonic transit before segmental or subtotal colectomy. The aim of the study was to compare a single X-ray radio-opaque marker method with a scintigraphic technique (111Indium-DTPA) to assess total and segmental colonic transit in patients with STC. Segmental colonic delay was a common finding. The two methods gave similar results for groups of patients, except in the descending colon. The variation of the results for individuals suggests that a repeated transit test may improve the assessment of total and segmental transit.

**MR colonography.** *Kinner S, Lauenstein TC. Radiol Clin North Am.* 2007;45:377. Combining the advantages of unsurpassed soft tissue contrast and lack of ionizing radiation, MR imaging of the gastrointestinal tract has become increasingly used clinically. Both bowel inflammation and tumor disease of the large bowel can be well visualized by means of MR colonography.

Nurse specialist led flexible sigmoidoscopy in an outpatient setting. Kelly SB, Murphy J, Smith A. Colorectal Dis. 2007 May 17; epub. Objective there has been an increasing demand for diagnostic flexible sigmoidoscopy. In order to improve our diagnostic services, we established a nurse specialist led flexible sigmoidoscopy clinic in 1999. A total of 3956 patients had a flexible sigmoidoscopy performed between 1999 and 2004. Two patients only sustained an iatrogenic rectal perforation. The nurse specialist offers an efficient diagnostic service for patients presenting with colorectal symptoms.

**Digital rectal examination: national survey of undergraduate medical training in Ireland.** *Fitzgerald D, Connolly SS, Kerin MJ. Post-grad Med J.* 2007;83:599. The experience gained in at least one digital rectal examination (DRE) by medical students by the completion of undergraduate training was assessed. No experience was reported in 24%, with mannequin-only experience in a further 20%, 56% performed DRE on at least one patient, but one third reported no confidence in their ability to interpret their findings properly.

#### 4 – PROLAPSES

The natural history of posterior vaginal wall support after abdominal sacrocolpopexy with and without posterior colporrhaphy. Yau JL, Rahn DD, McIntire DD et al. Am J Obstet Gynecol. 2007;196:e45. For abdominal sacrocolpopexy with concomitant posterior colporrhaphy, POP-Q point Ap significantly improved and persisted at 34 months after surgery. Ten months after surgery, descent of POP-Q point Bp returned to preoperative levels and was the same regardless of whether a site-specific posterior colporrhaphy was performed at the time of an abdominal sacrocolpopexy.

**Symptomatic Pelvic Organ Prolapse: prevalence and risk factors in a population-based, racially diverse cohort.** *Rortveit G, Brown JS, Thom DH et al. Obstet Gynecol.* 2007;109:1396. To estimate the prevalence of and identify risk factors associated with symptomatic pelvic organ prolapse and level of distress in racially diverse women aged older than 40 years, the Reproductive Risks for Incontinence Study evaluated a population of 2,001 randomly selected women. Symptomatic prolapse was reported by 6% of women. Almost 50% of these reported moderate or great distress, and in 35% the symptoms affected at least one physical, social or sexual activity. In multivariable logistic regression analysis the risk of prolapse was significantly increased in women with vaginal deliveries compared with nulliparous women. Irritable bowel syndrome, constipation, and self-reported fair or poor health status were strongly associated with prolapse. African-American were significantly less likely to report symptomatic prolapse compared with white women.

**Functional outcome after transperineal rectocele repair with porcine dermal collagen implant.** *Smart NJ, Mercer-Jones MA. Dis Colon Rectum. 2007 Apr 9; epub.* To assess the safety and efficacy of transperineal rectocele repair with porcine dermal collagen (Permacol (R)) 10 females were followed for 5-16 months with objective assessment for constipation, excessive straining, incomplete evacuation, vaginal bulg-ing, and vaginal digitations (always, usually, occasionally, never) and Medical Outcomes Study Short Form 36 questionnaires. All patients had an improvement in two or more symptoms and 70 percent of patients in three or more symptoms. Improvements in digitations and SF-36 scores were not significant.

A novel technique for rectocele repair in elderly women. Nano M, Ferronato M, Solej M, D'Amico S. Tech Coloproctol. 2007 May 25; epub. The rectal wall was separated from the rectovaginal septum. The vaginal wall was divided in the middle. The first flap was sewn to the second and this onto the first. In 22 elderly women followed-up for 24-84 months the need to digitally assist evacuation disappeared.

**Heterogeneity in anatomic outcome of sacrospinous ligament fixation for prolapse:** a systematic review. *Morgan DM, Rogers MA, Huebner M, Wei JT, Delancey JO. Obstet Gynecol.* 2007;109:1424. To explore why failure rates vary so much between published reports of sacrospinous ligament fixation to correct POP and what the potential sources of heterogeneity may be, Medline was queried for studies between 1966 and 2005 and 187 studies were reviewed. The anterior compartment was the most common site of failure for any given grade. This was most striking when the criterion for failure was grade 1 (40.1% anterior, 11.0% apical, 18.2% posterior) or grade 2 prolapse (21.3% anterior, 7.2% apical, 6.3% posterior). Areas of vaginal support were more equally affected when the criterion for failure was grade 3 prolapse (3.7% anterior, 2.7% apical, 2.3% posterior). Among cohorts using grade 2 prolapse as the criterion for objective failure, the pooled measure of failure to relieve symptoms was 10.3% and to provide patient satisfaction was 13.0%. In conclusion the variation in published failure rates after sacrospinous ligament fixation is, in part, accounted for by differences in how anatomical outcomes are evaluated and which compartment of vaginal support is being considered.

Midline anterior repair alone vs anterior repair plus vaginal paravaginal repair: a comparison of anatomic and quality of life outcomes. Morse AN, O'dell KK, Howard AE. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:245. A retrospective study to compare the anatomic recurrence rates and quality of life outcomes of patients who had undergone either anterior colporrhaphy or anterior colporrhaphy and vaginal paravaginal repair as part of surgery for pelvic organ prolapse did not suggest that adding paravaginal repair is superior in terms of anatomic or quality of life outcomes.

**Mesh-related infections after pelvic organ prolapse repair surgery.** Falagas ME, Velakoulis S, Iavazzo C, Athanasiou S. Eur J Obstet Gynecol Reprod Biol. 2007 Apr 23; epub. Although the use of vaginal meshes has become a new effective method of pelvic organ prolapse surgery clinicians should be aware of the various post-operative complications, including mesh-related infections. The incidence of mesh-related infections and erosion ranges from 0 to 8%, and 0 to 33%, respectively, in the published studies.

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#### Pelvic Floor Digest

**Prolapse repair by vaginal route using a new protected low-weight polypropylene mesh: 1-year functional and anatomical outcome in a prospective multicentre study.** *de Tayrac R, Devoldere G, Renaudie J et al. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:251.* A low-weight polypropylene mesh coated with a hydrophilic absorbable film for vaginal repair of genital prolapse (anterior, posterior and anterior-posterior repair) seems to decrease local morbidity (vaginal erosions 6.3%, de novo dyspareunia 12.8%) while maintaining low recurrence rates (6.8% for cystocele and 2.6% for rectocele). The report is based on the analysis of the first 143 patients of a multicentre study evaluated after at least 10 months follow-up. The improvement of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire were highly significant.

**Changes in the extracellular matrix in the anterior vagina of women with or without prolapse.** *Lin SY, Tee YT, Ng SC et al. Int Urogynecol J Pelvic Floor Dysfunct.* 2007;18:43. To investigate the changes in the connective tissues (collagen type I, III, IV, V, VI, elastin, and glycoproteins) located in the upper portion of the anterior vaginal wall associated with prolapse, in 23 women with prolapse an immunohistochemical study demonstrated that collagen III is significantly less than in a control group with a positive correlations with ageing.

**Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study.** *Deffieux X, de Tayrac R, Huel C et al. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:73.* In 138 women follow-up for 7-60 months cystocele repair was performed according to the technique of tension-free polypropylene mesh. Anatomically, the success rate was 95%. Vaginal erosion was reported in 20% of the patients with no statistically significant difference between Gynemesh and Gynemesh-Soft meshes. Cystocele stage >2 HWS is a protective factor against vaginal erosion. A partial excision of the mesh was necessary in 13/27 symptomatic patients (48%), associated with a vaginal mucosal closure, 2/27 underwent a complete excision. The incidence of de novo dyspareunia was 9% in patients with vaginal erosion.

A prospective, randomised, controlled trial comparing 3 hour and 24 hour postoperative removal of bladder catheter and vaginal pack following vaginal prolapse surgery. *Glavind K, Morup L, Madsen H, Glavind J. Acta Obstet Gynecol Scand.* 2007;86:1122. The aim of this prospective randomised study was to determine whether or not there was a higher incidence of bleeding, reoperation, urinary retention or bacterial count in the urine depending on whether urinary catheter and vaginal pack were removed 3 or 24 h after prolapse surgery. Pack and catheter removal after 3 h is recommended with careful monitoring of the patient's voiding.

**Robot-assisted vs. conventional laparoscopic rectopexy for rectal prolapse:** a comparative study on costs and time. *Heemskerk J, de Hoog DE, van Gemert WG et al. Dis Colon Rectum. 2007 Aug 10; epub.* Robot-assisted laparoscopic rectopexy is a safe and feasible procedure, but results in increased time and higher costs than conventional laparoscopy.

Stapled hemorrhoidopexy and Milligan Morgan hemorrhoidectomy in the cure of fourth-degree hemorrhoids: long-term evaluation and clinical results. *Mattana C, Coco C, Manno A et al. Dis Colon Rectum. 2007 Aug 16; epub.* Long follow-up seems to indicate more favorable results in Milligan-Morgan procedure compared to stapled hemorrhoidopexy (mean follow-up 92 and 54 months respectively) in terms of resumption of symptoms and risk of recurrence.

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# 2008

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# Pelvic Floor Digest

#### **5 – RETENTIONS**

**Postoperative urinary retention after primary colorectal cancer resection via laparotomy: a prospective study of 2,355 consecutive patients.** *Changchien CR, Yeh CY, Huang ST. Dis Colon Rectum. 2007 Aug 18; epub.* Risk factors for postoperative urinary retention after colorectal cancer surgery are: male gender, age, lung disease, rectal cancer, longer operation duration, and additional pelvic procedure.

**Causes of failed urethral botulinum toxin A treatment for emptying failure.** *Liao YM, Kuo HC. Urology. 2007 Aug 17; epub.* Urethral injection of BTX-A can reduce urethral resistance in patients with voiding dysfunction. However some patients do not benefit from this treatment. The causes of failed treatment in 23/200 patients were detrusor underactivity with very low abdominal straining pressure in 7, a tight urethral sphincter in 7, bladder neck obstruction in 7, and psychological inhibition of voiding in 2. Transurethral incision of the bladder neck was performed in 7 patients, and all had an improved result.

**Evaluation of constipation by abdominal radiographs correlated with treatment outcome in children with dysfunctional elimination.** *Allen HA, Austin JC, Boyt MA et al. Urology.* 2007;69:966. No correlation between any uroflowmetry parameter and the presence of fecal distention of rectum could be demonstrated, nor a statistical significance between fecal distention of rectum on abdominal radiograph and outcome of wetting symptoms was established.

A novel three-dimensional dynamic anorectal ultrasonography technique (echodefecography) to assess obstructed defectation, a comparison with defecography. *Murad-Regadas SM, Regadas FS, Rodrigues LV et al. Surg Endosc. 2007 Aug 20; epub.* Echodefecography may be used as an alternative method to assess patients with obstructed defectation as it has been shown to detect the same anorectal dysfunctions (anorectocele and rectal intussusception) observed in conventional defecography. It is minimally invasive, well tolerated, inexpensive, avoids exposure to radiation, and clearly demonstrates all the anatomic structures involved with defecation.

#### 6 - INCONTINENCES

Anatomic restoration technique of continence mechanism and preservation of puboprostatic collar: a novel modification to achieve early urinary continence in men undergoing robotic prostatectomy. *Tewari AK, Bigelow K, Rao S. Urology.* 2007;69:726. The complex of puboprostatic ligaments, puboperinealis muscle, and arcus tendineus (acting in unison to provide continence in men and women) can be disrupted during robotic prostatectomy. The preservation of the puboprostatic collar helped to restore early continence in 50 men undergoing robotic prostatectomy for clinically localized prostate cancer. The ligaments were reconnected to the urethrovesical anastomosis, reapproximated the muscles and fixed the distal bladder to the arcus tendineus. The average additional time was only 2 to 5 minutes, and the continence rate was 29% in the first week and 95% in 16 weeks after catheter removal.

**Anal sphincter laceration at vaginal delivery: is this event coded accurately?** *Brubaker L, Bradley CS, Handa VL et al. Obstet Gynecol.* 2007;109:114.

Effectiveness of a new self-positioning pessary for the management of urinary incontinence in women. Farrell SA, Baydock S, Amir B, Fanning C. Am J Obstet Gynecol. 2007;196:474. The Uresta, a new self-positioning women's incontinence pessary, significantly reduces urinary incontinence and is easy for women to use.

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### **Original article**

# Intravaginal posterior sling procedure (PIVS) for the treatment of uterine descensus and vaginal vault prolapse: retrospective analysis of efficacy, safety, complications and patient satisfaction in 150 cases

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*Abstract:* The safety, efficacy and patient satisfaction of the intra vaginal posterior sling procedure (PIVS) for correction of vaginal vault prolapse or descensus uteri was estimated in 3 Dutch hospitals. A population of 150 patients underwent a PIVS between January 2002 and April 2005 was evaluated retrospectively. Between 4 and 18 months after the operation an inquiry was sent to all to evaluate the results after this middle-long follow-up period. In 87% (131/150) PIVS was combined with other surgical techniques as vaginal hysterectomy, anterior and/or posterior vaginal wall repair. No complications occurred during surgery. Complications post operatively were: cystitis 13, fever 1, hematoma 8. After 8 weeks there was no improvement of prolapse complaints in 16 patients (11%). In 19 (13%) a secondary prolapse was found, mainly cystocele (14 patients). Of the 100 patients with micturition or urinary incontinence problems before the operation, 70 experienced improvement of their presenting complaints. De novo urgency was found in 12 patients (8%). Tape erosion occurred in 4 patients (2.6%) during the follow-up period. Response rate of the questionnaire was 65%. The mean score for patient satisfaction was 4.8 (range 0-5) and the mean score for efficacy 4.6 (range 0-5). PIVS is a safe and effective treatment for vaginal vault prolapse or descensus uteri, with a high score for patient satisfaction during a medium follow-up.

Key words: Vaginal vault prolapse; Posterior intravaginal sling.

#### INTRODUCTION

The posterior intravaginal sling procedure (PIVS) is a surgical technique for the treatment of vaginal wall prolapse or descensus uteri. It was described by Petros in 1997 and is considered to be less invasive when compared to classical surgical procedures.<sup>1</sup> Through two small perianal incisions a tunneler (Tyco IVS Tunneler<sup>™</sup> Device) is guided to the ischial spine on both sides, where the sacrospinous ligament is perforated just medial to the spine to reach the paravaginal space. A polypropylene tape (8 mm wide multifilament polypropylene tape Tyco Health-care, the Netherlands) is pulled through the tunneler. After removal of the tunneler the tape is fixed to the vaginal vault or the posterior side of the cervix. Pulling the tape will now lift the vaginal vault or cervix and create suspension as an artificial neoligament.

The goal of the present retrospective study is to evaluate efficacy and safety of PIVS for the treatment of vaginal wall prolapse or descensus uteri, as well as patient satisfaction.

#### MATERIAL AND METHODS

Three Dutch hospitals participated in the study: Catharina Hospital Eindhoven, Laurentius Hospital Roermond and Maasland Hospital Sittard. All patients who underwent a PIVS procedure between January 2002 and April 2005 were studied retrospectively. The following data were collected:

*a. History:* gynaecological operations, pessary use, pelvic floor physiotherapy, estrogen use, parity, mode of delivery, birthweight of the children, chronic obstructive pulmonary disease.

*b. Complaints:* prolapse, voiding dysfunction, urinary stressor urge incontinence, defecation disorders, dyspareunia.

*c. Physical examination:* age, weight, height. During vaginal examination the position of the cervix or vaginal vault and the presence of cystocele, rectocele and enterocele was graded according to the Baden-Walker halfway classification system for grading prolapse, with patients straining maximally in the dorsal lithotomy position:<sup>2</sup>

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- Grade 0: normal position for each respective site
- Grade I: descent halfway to the hymen.
- GradeII: descent to the hymen
- Grade III: descent halfway past the hymen
- Grade IV: maximum possible descent
  - for each respective site.

*d. Surgical procedure:* duration, blood loss, combination with other surgical techniques (colporrhaphy anterior or posterior, hysterectomy, tension free transvaginal tape for urinary stress incontinence (TVT), use of vaginal pack, urinary catheter, complications.

*e. Hospital stay:* length, time of catheter removal, wound infection, fever (> 38 °C), cystitis, and hematoma.

*f. Outpatient visit after 6 weeks:* effect on pre-existing complaints, new complaints, vaginal assessment according to the Baden-Walker classification, signs of tape erosion.

Subsequently a questionnaire was sent to all involved patients 4-18 months after surgery. In this way the effect on pre-existing complaints was evaluated and the appearance of new complaints, specifically on sensation of prolapse, micturition, incontinence, stool and intercourse. They were asked to judge efficacy and satisfaction from their point of view by scoring both with a figure of 0-5, in which 0 stands for no or a negative effect and 5 for an excellent effect. Those who did not respond were contacted by phone and invited to participate. For evaluation all data were stored in the database program Microsoft Access.

#### RESULTS

A total of 150 patients were included. (Eindhoven 87, Roermond 44, Sittard 19). Median age was 62 years (range 35-86), median BMI 26 kg/m<sup>2</sup> (range 21-34), and median parity 2 (range 0-8). They all had vaginal deliveries except one who had a cesarean section. Birth weights were >3500 grams in 110 cases (55%). Twelve had a history of chronic obstructive pulmonary disease (8%).

Pre-existing complaints were: prolapse 125 (85%), urinary incontinence 79 (urge 43, stress 21, mixed 15, together

#### K. M. Heast - T. H. Hasaart - I. Sanli - E. T. Gondrie - M. G. Bergmans

|                                   | 1                         | 5         | 0 1 1                   |                               | 1 0                               | 1 1   |
|-----------------------------------|---------------------------|-----------|-------------------------|-------------------------------|-----------------------------------|-------|
| descensus cervix/<br>vaginal apex |                           | cystocele | rectocele<br>enterocele | cystocele<br>recto/enterocele | no significant<br>cysto/rectocele | total |
| С                                 | grade 1                   | 0         | 1                       | 2                             | 0                                 | 3     |
| E<br>R                            | grade 2                   | 10        | 19                      | 11                            | 0                                 | 40    |
| V                                 | grade 3                   | 2         | 1                       | 3                             | 0                                 | 6     |
| I<br>X                            | grade 4                   | 2         | 0                       | 0                             | 15                                | 17    |
| vau<br>3 o                        | ılt prolapse grade<br>r 4 | 39        | 33                      | 8                             | 4                                 | 84    |
|                                   |                           |           |                         |                               |                                   |       |

TABLE 1. – Pre-operative assessment of cervical or vaginal vault prolapse, and combinations with anterior and posterior vaginal wall prolapse.

representing 53%), constipation 39 (26%) of whom 5 initiated or assisted defecation with vaginal digitation and dyspareunia 26 (17%).

Before operation 48 used a pessary, 21 had pelvic floor physiotherapy and 51 used vaginal estrogens. Eighty four patients (56%) had a past history of hysterectomy (57 vaginal, 27 abdominal).

The pre-operative findings in physical examination are summarized in table 1. Of the 66 women who still had their uterus, 17 had cervical prolapse below the level of the hymen (26%). Fifteen patients had no significant anterior or posterior vaginal wall prolapse. All 84 women without uterus had a vaginal vault prolapse grade 3 or 4. Only four patients in this group (5%) appeared to have no significant prolapse of the anterior or posterior wall.

The types of operation performed in the study population are summarized in table 2. In 19 patients PIVS was not combined with other surgical procedures. In the majority PIVS was combined with anterior and/or posterior repair, or vaginal hysterectomy.

In the case of an isolated PIVS procedure, operation time was less than 45 minutes. No complications occurred during surgery. At the end of the operation a urinary catheter was placed in all cases and a vaginal pack in 144 cases. Vaginal pack and urinary catheter were removed the following morning. Median hospital stay was 3 days (range 1-12).

Postoperative complications were: fever 1, cystitis 13, and hematoma 8 (two required surgical intervention).

Six weeks after operation the effect of the procedure on

TABLE 2. – Operations performed in the study group in combination with PIVS.

| PIVS alone                              | 19  |
|---|-----|
| with colporraphy anterior               | 21  |
| with colporraphy posterior              | 59  |
| with colporraphy anterior and posterior | 36  |
| with vaginal hysterectomy               | 14  |
| with IVS anterior                       | 1   |
| Total                                   | 150 |

PIVS = posterior intravaginal sling.

 TABLE 3. – Influence of surgical treatment on pelvic floor disorders.

Influence of prolapse surgery Pre Op. Post Op. Complete cure Improved Unchanged Worse Prolapse sensation 83 0 77 3 3 Micturition problems/incontinence 57 26 5 7 19 35 Defaecation problems 22 6 13 0 24 22 6 6 6 Dyspareunia

the presenting symptoms was evaluated. The majority of women experienced disappearance or significant improvement of their pre-existing complaints: prolapse sensation (n = 109/125, 87%), micturition or incontinence problems (n = 70/100, 70%). De novo urgency occurred in 12 cases. Nine patients improved with conservative therapy. Three underwent a subsequent anterior repair.

During the follow-up period of 4 months up to 18 months 19 women developed a prolapse recurrence (13%) of which 13 were of the anterior wall, 2 of the posterior wall, 3 of the vaginal vault and one a combined prolapse. Thirteen needed additional surgical treatment. In one of them no adequate suspension was obtained and the operation was deemed a failure.

Tape erosion was found in 4 women (3%). In 2 cases the tape had to be removed due to local infection. In the other 2 cases cutting of the exposed tape was sufficient to heal the affected area.

The response to the questionnaire was 65% (98/150). The effect on pre-existing complaints is summarized in table 3. A satisfactory effect on prolapse symptoms was found in 93% of patients (77/83). For micturition problems or urinary incontinence it was 54% (31/57), although 7 patients (12%) experienced increase of complaints after surgical treatment. The same pattern was found for dyspareunia. Defecation problems were significant less postoperatively in 63% (22/35) and unchanged in 37%.

Six weeks after the operation 12 women reported de novo urgency. Five of these 12 participated in the questionnaire study and all of them still had urgency complaints to some degree. Five women who had no urgency problems six weeks after operation have developed this complaint subsequently.

All participating women (98) were asked to score satisfaction and effectiveness of the surgical procedure from 0 to 5. The mean score for satisfaction was 4.8 and for efficacy 4.6.

#### DISCUSSION

With PIVS a new surgical technique has been introduced for the treatment of uterine prolapse and vaginal vault prolapse. It is important to determine the safety and effectiveness of such a procedure.

| Literature                  | Cases | Surgical complications | Fever | Hematoma | Cystitis | Tape erosion |
|-----------------------------|-------|------------------------|-------|----------|----------|--------------|
| Biertho et al. <sup>5</sup> | 34    | 0                      | _     | 0        | -        | 1            |
| Everhardt et al.6           | 32    | 0                      | _     | _        | _        | 8            |
| Farnsworth <sup>3</sup>     | 93    | 2                      | 0     | 0        | 5        | 1            |
| Haest et al.                | 150   | 0                      | 1     | 8        | 13       | 4            |
| Meschia et al.4             | 33    | 0                      | -     | _        | -        | 1            |
| Petros <sup>1</sup>         | 75    | 2                      | 0     | 0        | -        | 4            |

TABLE 4. – Complications of surgical treatment of prolapse using PIVS.

In our study there were no operative complications. In table 4 complications are described in the literature of 417 cases of PIVS by 6 authors. The most significant complication was rectal perforation in 4 cases (1%).<sup>1,3-6</sup>

In our study population, 8 patients developed hematoma of the vaginal wall after operation. Two of them were treated surgically.

Postoperative cystitis was found in 8.6% in our study and in 5.4% in the study of Farnsworth.<sup>3</sup> Wagner et al studied the incidence of cystitis after abdominal and vaginal hysterectomy combined with anterior or posterior colporrhaphy.<sup>7</sup> The reported incidence of cystitis as proven by culture was 45%.

We found tape erosion in 4 patients (3%) after a follow-up of 4-18 months. In the literature the reported incidence is 1% (Farnsworth) to 25% (Everhardt).<sup>3,6</sup> Biertho described a tape erosion as early as 2 weeks after operation.<sup>5</sup> Learning curves (tape placed too superficially), variable follow up periods (2 months to 4.5 years) and variable degrees of vaginal wall atrophy, will have contributed to the differences in incidence of tape erosion. Long term results are still unknown.

The incidence of prolapse recurrence after classical prolapse surgery is high. One year after operation Whiteside et al. found, in 389 patients, 58% recurrences grade 2 and 10% recurrences grade 3.8 In our population prolapse recurrence was found in 13%. Petros always combined PIVS with bridge repair of the posterior vaginal wall. In his series (75 patients) he noted recurrence at 1 year of posterior wall prolapse 2% and anterior wall prolapse 8%. Review at 4.5 years showed a failure of 5.2% and 16% respectively.<sup>1</sup> Meschia published a randomized trial in 66 women. He compared two groups of 33 women, each with vaginal vault prolapse of grade 3 or more. One group was treated with sacrospinous fixation of the vaginal vault. The other group had PIVS. Median follow-up was 18 months. Prolapse recurrence was found in 12% of the sacrospinous fixation group and in 12% of the PIVS group (not significant).<sup>4</sup> We conclude that recurrent prolapse seems to be less when classical prolapse surgery is combined with PIVS.

Our study showed symptom improvement as follows: prolapse sensation in 93%, micturition problems or urinary incontinency in 54%, defecation difficulties in 63% and dyspareunia in 50%. These results are in concordance with literature.

Petros defined cure as a reduction of 50% or more in complaints.<sup>1</sup> According to this definition he found a cure rate for prolapse complaints of 91% for PIVS treatment. Farnsworth used the same definition and found a cure rate of 91% for prolapse sensation, 79% for urgency, 82% for nocturia and 78% for pain, using PIVS.<sup>3</sup>

We found de novo urgency in 12 patients (8%), of whom 5 still had complaints at the end of the follow-up period. This complication is not evident in other studies of PIVS. In classical prolapse surgery it is a well recognized complication.

Borstad et al. reported de novo stress incontinence in 22% (16/73) after vaginal repair.<sup>9</sup> In our study we did not identify any cases of de novo stress incontinence after surgery.

Six women (4%) reported dyspareunia, which was not present preoperatively. In all these cases the intravaginal sling procedure was combined with classical vaginal repair of one or more compartments. Other studies on PIVS do not report data on dyspareunia.

Patient satisfaction according to the questionnaire results was very high: the effect of the procedure on pre-existing complaints was rewarded with 4.8 points out of 5 for satisfaction and 4.6 out of 5 for efficacy.

This retrospective study shows that PIVS is a safe and effective treatment modality for uterine and vaginal wall prolapse. Follow-up is needed to assess long term safety.

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# Urinary retention in women with isolated Stage 3 rectocoele

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Abstract: Three unusual cases of women with urethral obstruction in the presence of a 3rd stage rectocoele are reported. Correction or reduction

of the rectocoele resolved urinary obstruction in all patients. *Key words:* Rectocoele; Urethral obstruction: Urinary retention.

#### INTRODUCTION

Uterine prolapse and cystocoele can cause bladder outlet obstruction, due to kinking or compression of urethra <sup>1, 2</sup> while rectocoele can sometimes cause incomplete evacuation of stools.<sup>3</sup> Three cases are presented where an isolated 3<sup>rd</sup> stage rectocoele led to urinary retention. Clinical assessments of prolapse were performed using the Baden-Walker Half Way System (HWS).<sup>4</sup>

#### CASE REPORT

*Case 1.* In January 2003 a 62 years old woman presented with symptoms of incomplete bladder emptying, slow and intermittent stream and a history of recurrent pyelonephritis since 2002. She had previously undergone laparoscopic hysterectomy and bilateral salpingo-oophorectomy in February 2002 because of endometrial adenocarcinoma and then multiple ablations of vulvar lesions due to well differentiated squamous cell carcinoma. This had been followed by bilateral inguinal lymphadenectomy.

On inspection both labia minora and clitoris were missing. The external urethral meatus was hypospadic and completely hidden by a 3<sup>rd</sup> stage (HWS) prolapse of the posterior vaginal wall epithelium (Figs. 1, 2). Uroflowmetry was not obtained but post-voiding residuals of 200-250 ml were documented. Cystocolpodefecography (Fig. 3) and examination by a proctologist confirmed a stage 3 rectocoele together with good anal sphincter function and a tonic pelvic floor. In April 2003 the patient underwent colpoperineoplasty.

Normal micturition was restored and at follow up 51 months after surgery uroflowmetry was normal with no post void residual. The external urethral meatus was now visible and the rectocoele had disappeared.

Case 2. In March 2006 an 83 years old woman presented with urgency, frequency, urge-incontinence and perineal discomfort. She had previously undergone a laparoscopic hysterectomy for fibroids. Urine analysis and urinary cytology were normal. She had a stage 4 rectocoele and a stage 1 anterior colpocele (HWS). Micturition diaries showed 20 voids per day with a mean voided amount of 70 ml. Bladderscan documented 280-300 ml post void residual. The rectocoele was reduced with a ring pessary and a urodynamic assessment was performed. All parameters were normal and the bladder capacity was 400 mL. The patient chose to follow a conservative course with a ring pessary. Twelve months later the ring pessary was still well-tolerated while urinary symptoms had improved significantly. At follow up the urinary diary revealed 8-10 micturitions per day with no more incontinence and no measurable post void residual.

*Case 3*: In April 2006 a 63-year-old woman was admitted into our urology unit for investigation of hypogastric pain and obstructive urinary symptoms which had appeared 10 days before. She reported long term constipation but

the constipation had been worsening in the last few months and was associated with the appearance of genital prolapse. On examination we found bladder overdistension and a 3rd stage rectocoele (HWS) with significant faecal impaction causing direct pressure on the anterior wall of the vagina and urethra.

A urethral catheter was placed, with slow drainage of 1000mls of urine, and the faecal impaction was resolved using digitation and enemas.

A pelvic ultrasound was normal. The rectocoele was reduced using a ring pessary while a programme of regular



Fig. 1. – *Case 1.* – Posterior colpocele evident with the patient straining in the supine position: labia minora and clitoris are absent and the urethral meatus is not visible.



Fig. 2. – *Case 1.* - Straddling and pulling up the labia majora the urethral meatus becomes visible and it is appreciable the obstructive effect on it by the rectocele.

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Fig. 3. – *Case 1.* - Cystocolpodefecography in sitting position during straining; the posterior colpocele is caused by a significant rectocoele.

bowel evacuations was suggested. The patient resumed satisfactory urinary voiding without any post void residual. A year later she is still using a ring pessary without any urinary problems.

#### DISCUSSION AND CONCLUSION

Isolated rectocoele, often asymptomatic, can sometimes lead to rectal symptoms and occasionally can cause urinary symptoms. Only one case of urinary obstruction following rectocoele could be found in the literature.<sup>5</sup>

#### Urinary retention in women with isolated Stage 3 rectocoele

We have reported 3 cases in which a significant (Stage 3 or 4) rectocoele has been associated with urinary retention. Rectocoele exerted a direct pressure to cause obstruction of the urethral meatus in 2 patients, while in third woman urinary obstruction resulted from the pressure of a recto-coele that was distended with impacted faecal material. In all cases surgical repair of the rectocoele or reduction of the urinary retention.

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### **Original article**

# A pilot study: The anal sphincter support procedure for the treatment of anal incontinence

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*Abstract:* Faecal incontinence is a significant and a very debilitating condition. The true prevalence of which is unknown but up to 3% of the general population have stool incontinence which increases with age. Faecal incontinence is much more common in women, increases with parity, and up to 30% have associated urinary incontinence and/or pelvic organ prolapse. Patients who have an identifiable external sphincter defect who fail conservative treatment options are best managed by a primary repair of the defect. This study presents a novel way of supporting the external anal sphincter with a circlage tape prosthesis. Based on the success of tension-free suburethral tapes used to treat stress urinary incontinence a pilot study was devised to assess Anal Sphincter Support System (ASSP) in patients presenting with mild faecal incontinence. Fourteen patients were followed up for a mean period of eighteen months. Outcomes were very encouraging with resolution of symptoms between 70 and 100%. There were no observed complications. This pilot study demonstrates that the ASSP provides a safe and effective method of restoring anal continence and can be used successfully with concomitant procedures which may be necessary for restoration of pelvic floor anatomy and function.

Key words: Faecal incontinence; Anal Sphincter Support Procedure; Hammock hypothesis.

#### INTRODUCTION

Faecal incontinence is rarely due to one single factor. Vaginal childbirth and obstetric trauma are widely accepted as significant causes of faecal and flatal incontinence in women. Approximately 10-15% report symptoms following vaginal delivery culminating in 2-5% of women having faecal incontinence.<sup>1</sup> The most common contributing cause is anal sphincter injury occurring at the time of the second stage of labour. Other significant factors are instrumental delivery, midline episiotomy and prolonged second stage of labour.<sup>2, 3</sup> Also thought to be of significance is traction or entrapment of the pudendal nerve and its branches of the perineal nerve fibres, associated with injury to the levator ani plate (iliococcygeous, pubococcygeous and puborectalis muscles).

Women with symptoms of faecal incontinence following their first pregnancy will deteriorate after their second pregnancy.<sup>4</sup> In one study 26.9% of women had an identifiable occult anal sphincter injury on endoanal ultrasound. With each increase in parity the chance of a new defect increased by 8.5%, while 75-83% of women presenting with faecal incontinence will have an identifiable anal sphincter defect.<sup>5</sup> Follow up of women who underwent primary repair of a third degree vaginal tear has shown that 85% will have persistent structural defects and over 50% of this group will develop faecal incontinence.<sup>6-10</sup>

A wide range of causes may contribute to anorectal dysfunction and anal incontinence.<sup>7</sup> Some iatrogenic causes that may result in injury to the anal sphincter complex include anorectal procedures such as fistulotomy, sphincterotomy and haemorrhoidectomy. Medical etiological factors include psychiatric conditions, chronic constipation, malabsorption syndromes, laxative overuse, diabetes, thyroid disease, gastrointestinal inflammatory conditions, neuropathies and spinal cord disease.

Anatomical distortion associated with chronic straining is commonly known as pelvic floor prolapse syndrome and may also be associated with progressive denervation of the colon, rectum and anus at the pelvic floor, in conjunction with obstructive defaecation and intussusception. Lateral, central and posterior rectal defects including rectal diverticulum may also contribute to anorectal dysfunction with incontinence.

It is difficult to know the true incidence of faecal incontinence due to variations in definitions, age distribution, underreporting due to reluctance to broach the condition, coexistence with other pelvic symptoms such as voiding dysfunction and pelvic organ prolapse.<sup>11</sup> A complex, interactive psychological process is necessary for faecal/flatal continence including rectal motility and compliance with neurophysiology of sensation. Hyposensitivity associated with low resting pressure may indicate internal and external sphincter damage resulting in passive incontinence, whereas hypersensitivity with urge incontinence and the inability to postpone defaecation may be associated with low voluntary squeeze pressure thus indicating external anal sphincter malfunction.

The aim of this study was to explore the possibility that a circumferential mesh support for the anal sphincter would reduce symptoms in patients with faecal or flatal incontinence. This hypothesis arose from consideration of the need for additional anchoring support of the Apogee<sup>™</sup> (American Medical Systems, Inc, Minnetonka, MN, USA) mesh used for the repair of posterior vaginal wall prolapse (rectocele and associated perineal repair). It was found that a percentage of these patients reported a significant improvement in bowel function and in particular a reduction in severity of their previously underreported anal incontinence.<sup>12</sup>

The use of mid urethral slings to treat Stress Urinary Incontinence (SUI) is based on the Hammock Hypothesis of DeLancey.<sup>13</sup> Since the anatomy <sup>14, 15</sup> and pathophysiology of defects arising in the anterior pelvic compartment have been successfully corrected using a mid urethral sling to treat SUI it was postulated that a mesh sling prosthesis placed around the anal sphincter may improve the anal sphincter mechanism of action and address the problem of faecal and flatal incontinence. It was decided to embark on a pilot study of patients with mild faecal incontinence using such a mesh prosthesis and to monitor the outcomes of this group.

#### ANORECTAL ANATOMY

The anal canal extends from the anorectal junction which lies just above the level of the puborectalis sling and sphincters (internal and external) to the anus below. It is surrounded by an external sphincter of voluntary muscle fibres and an internal sphincter of involuntary muscle fibres.<sup>16</sup> Between the two sphincters lies the longitudinal anal muscle of the rectum (LAM) <sup>17</sup> composed of muscle fibres which receive contributions from puborectalis, pubococcygeous

and iliococcygeous.<sup>18</sup> Recently Petros described that the LAM fibres contributed by the levator plate are incorporated into the sphincteric action as described by the integral theory.<sup>19</sup> This is probably important in closure and relaxation of the anal canal and that of the urethra. Individuals show significant variations in detail of the sphincter anatomy.<sup>16</sup>

The external anal sphincter is a voluntary muscle, cylindrical in form being approximately 2 cm deep placed around the anal canal for approximately 5-7 cm. It has three parts. The subcutaneous part is slender and encircles the anal orifice. The superficial part supports the anus in an ovoid circular fashion and extends from the tip of the coccyx and anorectal raphe to the perineal body in the median plane. The deep part encircles the anal canal with some fibres joining the superficial transverse perineal muscle and blends with the puborectalis muscle of the levator ani. The internal sphincter surrounds the superior two thirds of the anal canal and is supported by the levator ani. The inferior two thirds are surrounded by the external sphincter as described above. The longitudinal muscle is comprised of three layers and lies between the internal and external sphincters.<sup>17</sup>

#### PATIENTS AND METHODS

The ASSP was performed on 14 patients between June 2005 and March 2007 with a total follow up time of 20.3 months. Mean follow up time was 18 months. Inclusion criteria for the study were symptoms of mild to moderate faecal soiling and flatal incontinence. Ten patients had a Wexner grading symptom score of 5-8 and four patients had a Wexner grading symptom score of 8-10. Past gynaecological and colorectal surgeries were as follows: Four patients had a past history of vaginal hysterectomy and anterior pelvic organ prolapse repair, six had abdominal hysterectomy (two also Burch colposuspension), four anterior and posterior vaginal repair, two had a haemorrhoidectomy, one an partial sphincterotomy for anal fissure, one an anal stretch procedure. The ages of patients ranged from 45 to 78 years, mean age 64.7 years. Obstetric history: all patients were parous. Five patients were parous 1-3, nine patients 3-5. Two patients had caesarian sections only. Interestingly both these patients had a past history of anorectal surgery. Of the 12 patients who had vaginal births more than 33% had instrumental deliveries. Mean foetal size was 3,700 g, ranging between 4,300 to 2,800 g.

All patients were studied using Magnetic Resonance Imaging (MRI) of the anal sphincter. At imaging 5 patients had evidence of external sphincter defects mainly right, lateral or central. Defects were considered small varying from 2-3 mm. Two patients aged 75 and 78 years had evidence of mild atrophy of the external anal sphincter while 50% of patients had no obvious anal sphincter defects on MRI. All patients were assessed pre and post operatively with resting anorectal pressures and maximal squeeze pressure. Six patients had a concomitant posterior organ prolapse procedure using an Apogee<sup>™</sup> (American Medical Systems, Inc, Minnetonka MN, USA) mesh. Patients were assessed using the POPQ system.<sup>20</sup>

*Operative technique:* All patients had a 24 hour preoperative bowel preparation. Systemic triple antibiotics were given intraoperatively and this combination was continued for 24 hours postoperatively. Clindamycin cream was inserted vaginally as a single dose approximately 1-2 hours preoperatively. The operation was performed in the lithotomy position. Aqueous Betadine antiseptic solution (10% w/v Povidone/Iodine) was used as skin preparation and liberally applied to inner thighs, intravaginally and to the perineal and suprapubic areas. The patient was draped in the



Fig. 1. – Anorectal Anatomy. 1. External anal sphincter. 2. Transverse rectal folds; rectal ampulla. 3. Anal sinuses. 4. Skin. 5. Subcutaneous part of external anal sphincter. 6. Superficial part of external anal sphincter. 7. Deep part of external anal sphincter and pubo rectalis. 8. Semi tendinosus. 9. Gluteous maximus. 10. Ischio rectal fossa. 11. The longitudinal muscle coat. 12. Pubo coccygeous. 13. Obturator internus. 14. Iliococcygeous. 15. Pelvi-rectal space. 16. Para rectal fossa. 17. Internal circular muscle coat/ internal ano rectal sphincter.

usual fashion facilitating good exposure of the operative site with the buttocks extending just below the end of the table. Infiltration of the perianal area and perineal body including the posterior vaginal mucosa was performed using a hydrodissection technique with dilute local anaesthetic. A stab incision of approximately 1 cm using an eleven blade was made 3 cm from the anal verge in the 5 o'clock and 7 o'clock position or a single incision was made at 6 o'clock (Fig. 4, 5).

At the vestibule of the vaginal orifice a transverse incision of approximately 4-5 cm was performed with dissection supramedially and laterally to expose the superior aspect of the perineal body. In the case of an adjuvant posterior prolapse procedure, blunt and minimal sharp tunneling dissection is continued proximally to create a pathway and identify the ischial spine and tendinous arch of the lateral pelvic wall.<sup>21</sup> This dissection is performed bilaterally (Fig. 2, 3).

Gentamycin solution 1 mg per 1cc of saline is used to liberally irrigate the operative site throughout the procedure.



Fig. 2. – Placement of ASSP Monarc<sup>TM</sup> tape. 1. Incision over the perineal body at the hymenal ridge to expose the perineal body. 2. Anal sphincter support prosthesis, Monarc <sup>TM</sup> in situ / surrounding the superficial part of the external anal sphincter. 3. Alternative incision site for placement of the Monarc <sup>TM</sup> tape.

M.E. Haverfield



Fig. 3. – Position of Monarc<sup>™</sup> and Apogee<sup>™</sup> prosthesis when ASSP is performed together with a prolapse repair using the Apogee<sup>™</sup> system. 1. External anal sphincter. 2. Perineal body. 3. Pubo rectalis and pubo vaginalis. 4. Superficial transverse perineal muscle. 5. Anal sphincter support tape (Monarc<sup>™</sup>) in situ. 6. Posterior pelvic compartment support prosthesis (Apogee<sup>™</sup>) in situ.

The recommended entry site for the Apogee™ (American Medical Systems, Inc, Minnetonka MN, USA) needles is 5-6 cm posterolateral to the anal verge which is 3 cm posterolateral to the incisions used for the ASSP. The posterior compartment mesh repair Apogee™ should be performed before the perianal support procedure. The Apogee™ mesh must be in position and the excess inferior cape trimmed approximately 1cm above the transverse perineal incision before the positioning of the ASSP is performed. The stab incisions are performed as explained above and with the index finger of a double gloved left hand the helical needle of a Monarc™ (American Medical Systems, Inc, Minnetonka MN, USA) prosthesis is inserted into the incision and directed approximately 2-3 cm in depth before rotation of the needle through its natural arc creates a track around the external anal sphincter to emerge laterally through the perineal body enabling visualization of the needle tip at the perineal incision. The same technique is performed on the contra lateral side of the external anal sphincter. With the tips of both needles at the perineal body, the Monarc<sup>TM</sup> sling is attached to both needle tips firmly with an audible click. The mesh is then gently positioned posteriorly through the







track made by the helical needles emerging through the perianal incisions posterior to the anal verge. Gentle traction is used on the mesh contralaterally until it is seen and felt to sit undistorted and without tension over the perineal body. The needles are then detached. The plastic sheaths are removed and the mesh trimmed at the buttock incisions (Fig. 6). All incisions are then closed with 2-0 Vicryl interrupted mattress sutures.

#### RESULTS

All 14 patients were studied over a minimum period of 6 months. Mean average time of follow up was 18 months. During that time there were no perioperative or postoperative complications. In particular there were no cases of mesh erosion or rejection and no cases of rectal perforation or trauma. Four cases had evidence of perianal bruising which resolved spontaneously with the judicious use of ice packs applied to the perianal area for approximately 24 hours. There were no cases of overt haematoma formation, infection or abscess formation. Ten patients whose initial Wexner score <sup>22</sup> was between 5 and 8 were reassessed to have between 90 and 100% improvement in symptoms. The other 4 patients with initial Wexner Score of 8-10 noted an improvement of 70% or better resulting in a Wexner score between 2 and 3.

#### CONCLUSIONS

The purpose of this study was primarily to evaluate the safety and efficacy of the ASSP and its impact on quality of life with respect to anorectal dysfunction and faecal incontinence. The ASSP was found to be a simple procedure with reproducible results and not associated with any significant peri or post operative complications within a mean follow up period of 18 months. In particular there was no evidence of mesh erosion, rejection or anorectal trauma. Subjective improvement of symptoms was noted using the Wexner grading profile and quality of life was maintained in all patients and improved in more than 90%. As a consequence of this pilot study it will be important to consider longer term prospective randomized controlled studies, comparing outcomes of other techniques for treating faecal incontinence with ASSP. The use of ASSP in conjunction with other concomitant procedures for posterior pelvic organ prolapse and dysfunction is efficacious and safe. This study suggests that there is a significant enhancement when used in conjunction with a posterior vaginal mesh procedure using the Apogee<sup>TM</sup>. Further studies in mesh design and in particular a wider dimension in the mesh prosthesis may be desirable. Further research into the role of pelvic floor imaging will increase our knowledge into the pathogenesis and management of functional pelvic floor disorders.<sup>23</sup> There is also a need for standardized terminology and diagnostic criteria for defaecatory dysfunction and for a comprehensive classification of site specific anatomical variations of the posterior pelvic compartment. This will also need to be addressed from a multidisciplinary perspective as recently proposed by Farnsworth and Dodi.24

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#### Competing Interests: None

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#### Pelvic Floor Digest

**Prolapse repair by vaginal route using a new protected low-weight polypropylene mesh: 1-year functional and anatomical outcome in a prospective multicentre study.** *de Tayrac R, Devoldere G, Renaudie J et al. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:251.* A low-weight polypropylene mesh coated with a hydrophilic absorbable film for vaginal repair of genital prolapse (anterior, posterior and anterior-posterior repair) seems to decrease local morbidity (vaginal erosions 6.3%, de novo dyspareunia 12.8%) while maintaining low recurrence rates (6.8% for cystocele and 2.6% for rectocele). The report is based on the analysis of the first 143 patients of a multicentre study evaluated after at least 10 months follow-up. The improvement of Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire were highly significant.

**Changes in the extracellular matrix in the anterior vagina of women with or without prolapse.** *Lin SY, Tee YT, Ng SC et al. Int Urogynecol J Pelvic Floor Dysfunct.* 2007;18:43. To investigate the changes in the connective tissues (collagen type I, III, IV, V, VI, elastin, and glycoproteins) located in the upper portion of the anterior vaginal wall associated with prolapse, in 23 women with prolapse an immunohistochemical study demonstrated that collagen III is significantly less than in a control group with a positive correlations with ageing.

**Vaginal mesh erosion after transvaginal repair of cystocele using Gynemesh or Gynemesh-Soft in 138 women: a comparative study.** *Deffieux X, de Tayrac R, Huel C et al. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:73.* In 138 women follow-up for 7-60 months cystocele repair was performed according to the technique of tension-free polypropylene mesh. Anatomically, the success rate was 95%. Vaginal erosion was reported in 20% of the patients with no statistically significant difference between Gynemesh and Gynemesh-Soft meshes. Cystocele stage >2 HWS is a protective factor against vaginal erosion. A partial excision of the mesh was necessary in 13/27 symptomatic patients (48%), associated with a vaginal mucosal closure, 2/27 underwent a complete excision. The incidence of de novo dyspareunia was 9% in patients with vaginal erosion.

A prospective, randomised, controlled trial comparing 3 hour and 24 hour postoperative removal of bladder catheter and vaginal pack following vaginal prolapse surgery. *Glavind K, Morup L, Madsen H, Glavind J. Acta Obstet Gynecol Scand.* 2007;86:1122. The aim of this prospective randomised study was to determine whether or not there was a higher incidence of bleeding, reoperation, urinary retention or bacterial count in the urine depending on whether urinary catheter and vaginal pack were removed 3 or 24 h after prolapse surgery. Pack and catheter removal after 3 h is recommended with careful monitoring of the patient's voiding.

**Robot-assisted vs. conventional laparoscopic rectopexy for rectal prolapse:** a comparative study on costs and time. *Heemskerk J, de Hoog DE, van Gemert WG et al. Dis Colon Rectum. 2007 Aug 10; epub.* Robot-assisted laparoscopic rectopexy is a safe and feasible procedure, but results in increased time and higher costs than conventional laparoscopy.

Stapled hemorrhoidopexy and Milligan Morgan hemorrhoidectomy in the cure of fourth-degree hemorrhoids: long-term evaluation and clinical results. *Mattana C, Coco C, Manno A et al. Dis Colon Rectum. 2007 Aug 16; epub.* Long follow-up seems to indicate more favorable results in Milligan-Morgan procedure compared to stapled hemorrhoidopexy (mean follow-up 92 and 54 months respectively) in terms of resumption of symptoms and risk of recurrence.

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#### **Review article**

# Colonic manometry and sacral nerve stimulation in patients with severe constipation

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*Abstract:* The current treatment options that are available for patients with severe chronic constipation are unsatisfactory. Long-term high dose laxative therapy produces significant morbidity in some, with ongoing bloating and abdominal pain. In refractory cases subtotal colectomy has become increasingly popular. However this is a major abdominal procedure with all the normal associated risks. Less invasive procedures for the treatment of constipation are being sought. However, improved therapies can only stem from a better understanding of the phenomena underlying severe constipation. Colonic propagating pressure wave sequences (PSs) are responsible for discrete movements of content and are vital for normal defaecation. Deficiencies in PS frequency, amplitude and extent of propagation are all implicated in severe defaecatory dysfunction. Mechanisms that can normalise these aberrant motor patterns may help rectify the problem. Recently the novel therapy of sacral nerve stimulation (SNS) has been utilized for the treatment of severe constipation. The results from a limited number of studies are encouraging, with improved stool frequency commonly reported. However, little is known of the effects of SNS upon colonic motor patterns. Colonic manometry provides the ideal test-bed to examine this phenomenon. Additionally colonic manometry can be used as a measurement tool to evaluate a range of stimulus parameters and determine those that give the optimal colonic response.

Key words: Constipation; Colonic manometry; Sacral nerve stimulation.

#### CONSTIPATION, EPIDEMIOLOGY AND HEALTH CARE BURDEN

Constipation, a common cause of morbidity, is estimated to affect between 15 and 27% of the western world.<sup>1</sup> The prevalence increases to 30-40% of people aged over 65.<sup>2</sup> Direct and indirect costs and resource utilisation are substantial. Chronic constipation in the US accounts for 13.7 million days of restricted activity and 3.4 million days of bed disability.<sup>3</sup> The diagnosis and management of constipation leads to 5.7 million physician visits and 0.6 million hospitalisations per year, accounting for total costs of \$US235M (2006 value).<sup>4</sup> Drug costs are high with \$US368M per yr (1985 value) being spent on over the counter remedies <sup>5</sup> and an additional \$US22M per year spent on prescription drugs.<sup>6</sup>

For many constipated patients laxative use will sufficiently alleviate their symptoms. However, for patients in whom laxatives do not restore normal bowel habit increased abdominal pain and bloating can result. Some patients, particularly those with obstructed defaecation can undergo a trial of biofeedback therapy, which can demonstrate significant improvement in quality of life and stool frequency.<sup>7, 8</sup> However, the long-term efficacy (>1yr) in patients with severe slow transit constipation is poor.9, 10 Overall at least 36% of those presenting to the clinic subsequently fail non-surgical therapies (diet, bulking agents, laxatives, biofeedback).<sup>11</sup> These patients can be extremely debilitated with physiological functioning, mental health, general health and bodily pain all scoring poorly on quality of life questionnaires in comparison to health.<sup>12</sup> For such cases subtotal colectomy becomes an option. However as this is a major abdominal procedure it comes with all of the normal associated risks. In addition patients can develop post-operative small and large bowel complications such as intractable diarrhoea, small bowel obstruction, faecal incontinence and recurrent constipation.13,14

# COLONIC PROPULSIVE MOTOR PATTERNS IN HEALTH AND PATIENTS WITH CONSTIPATION

The cause of severe constipation remains undetermined; however abnormal colonic motor patterns are implicated. In health studies utilising combined colonic manometry and scintigraphy have shown that colonic propagating sequences

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(PS) and high amplitude propagating sequences (HAPS) are temporally associated with discrete movement of colonic content.<sup>15-17</sup> Studies in health also demonstrate that defaecation is preceded by a series of PSs and HAPSs in which the site of origin of each PS approaching stool expulsion moves in an orad direction (Fig. 1).<sup>18</sup> These data indicate that defaecation is a complex process incorporating the entire colon. Indeed in health motor activity in the proximal colon is an essential component of defaecation. Our own studies have also demonstrated that this pre-defaecatory colonic response is absent in patients with obstructed defaecation.<sup>19</sup>

It is recognised that both HAPSs and long-extent PSs are deficient or absent in severe slow transit constipation <sup>20-22</sup> although the neural apparatus necessary for the generation of these motor patterns appears to be intact because intraluminal irritant laxatives can trigger them.<sup>16, 23</sup> This observation suggests that extrinsic or intrinsic factors capable of modulating the propulsive characteristics of PSs are likely to contribute to the pathogenesis of constipation.

The actual mechanisms involved in the induction of these propulsive pressure waves are only partially understood.



Fig. 1. – The pre-defaecatory array of propagating sequences (PS). Note that with each PS approaching stool expulsion the site of origin of the PS shifts in an orad direction.

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| Reference No.               | No. of<br>patients | Constipation<br>Type # | Intervention<br>Technique | Study<br>Design      | Outcome<br>Measure                       | Response    |
|-----------------------------|--------------------|------------------------|---------------------------|----------------------|--|-------------|
| Ganio et al. <sup>38</sup>  | 12                 | OD                     | PNE                       | Uncontrolled         | Successfull Evacuation<br>StoolFrequency | 66%*<br>25% |
| Malouf et al.39             | 8                  | STC                    | PNE                       | Uncontrolled         | Stool Frequency                          | 25%         |
| Kenefick et al.40           | 4                  | STC                    | PNE<br>&<br>Parmanant     | Uncontrolled         | Stool Frequency                          | 100%        |
|                             |                    |                        | remanent                  |                      | Stoor Frequency                          | 1370        |
| Kenefick et al.41           | 2                  | STC                    | Permanent                 | RCT                  | Stool Frequency                          | 100%        |
| Dinning et al <sup>46</sup> | 8 STC              | DNE                    | Uncontrolled              | Coloc motor response | 100%*                                    |             |
| Diming et al.               |                    | 510                    | TIL                       | Oncontrolled         | Stool Frequency                          | 75%*        |
| OD 01.4                     | 1.6                | OTC 01                 |                           |                      |  | * D . 0.05  |

TABLE 1. – Sacral nerve stimulation in patients with constipation.

# OD = Obstructed defaecation; STC = Slow Transit Constipation

The enteric nervous system provides the direct neuronal control of colonic motility, modulated through the sympathetic, parasympathetic and extrinsic afferent pathways. The vagal nerves provide parasympathetic innervation to the caecum, ascending colon and most of the transverse colon, whilst parasympathetic fibres from the second to the fourth sacral sections of the spinal cord innervate the distal part of the transverse colon, the descending colon and the rectosigmoid colon. Therefore intuitively, stimulation of pelvic nerves would be expected to have a motor response confined to the distal colon and ano-rectum. Yet evidence exists to suggest that stimulation of pelvic nerves is capable of inducing pan-colonic motor patterns. For example rectal chemical stimulation in the healthy human colon induces proximal colonic PSs presumably through long recto-colonic afferent pathways.<sup>24</sup> This pathway appears to be blocked in at least one form of constipation.2

It is possible that this attenuated pathway can be re-established through electrical stimulation of pelvic nerves. Indirect evidence supporting this hypothesis can be extrapolated from a case study in which a young female with severe constipation, received direct electrical stimulation to the anal canal and demonstrated significantly increased stool frequency.<sup>26</sup> As defaecation in health is preceded by proximal colonic pressure waves and that patient demonstrated improved stool frequency, we could make the reasonable assumption that the electrical stimulation of the anal canal helped to re-establish pre-defaecatory, pan-colonic pressure waves. Similar results were also obtained in patients with severe constipation and spinal cord injury. Here direct high voltage stimulation to the sacrum induced spontaneous stool evacuation.<sup>27-30</sup> While high voltage stimulation can not be applied to patients with an intact spinal cord, applying direct low-voltage stimulation to the sacral nerves can achieve comparable results. For example a high proportion of patients undergoing sacral nerve stimulation treatment for urinary or faecal incontinence reported an incidental increase in stool frequency.<sup>31,32</sup> Finally data recorded in vivo from a canine colon suggested that electrical stimulation of sacral nerves can generated a similar colonic pre-defaecatory PS response to that observed during spontaneous defaecation.<sup>33</sup> Taken collectively we can form the hypothesis that electrical stimulation of the pelvic floor nerves may be capable of inducing proximal colonic propulsive pressure waves in severe constipation, which in turn may improve constipa-

tion symptoms. This hypothesis prompted our lab to examine both the symptomatic and colonic response of the novel therapy sacral nerve stimulation (SNS) in a severely constipated cohort of patients.

#### SACRAL NERVE STIMULATION IN CONSTIPATION

The techniques of sacral nerve stimulation (SNS) and its use in patient's with urinary and fecal incontinence has been documented in several recent reviews.<sup>34-37</sup> Briefly, SNS is a minimally invasive surgical technique that allows for direct electrical stimulation of the sacral nerves S2-S4 via an electrode placed through the sacral foramen. Of the three sacral roots used S3, which contains afferent sensory, efferent autonomic motor nerves and voluntary somatic nerves, provides the most satisfactory clinical response.<sup>37</sup> The SNS technique involves two stages. The first, commonly termed



Time (min)

Fig. 2. – Iso-contour map of antegrade colonic motility in a patient with severe slow transit constipation, pre- and post sacral nerve stimulation. Each individual ridge represents an individual propagating sequence (PS) at the time the PS was initiated. The start of each ridge indicates the site of origin of the PS and the length of the ridge the extent of propagation of the propagating sequence. The shades of grey within each ridge represent the amplitude of each individual propagating pressure wave. The map highlights the dramatic increase in the frequency, amplitude and extent of propagation of PSs during sacral nerve stimulation.

the peripheral nerve evaluation (PNE), is conducted over two to three weeks and involves a temporary wire, with a single electrode, being introduced to the sacral root and connected to an external stimulator. Patients that respond favorably to the PNE move on to the second stage where a pulse generator (Interstim<sup>®</sup>) connected to a tined lead with 4 electrodes, is implanted permanently.<sup>37</sup>

In comparison to SNS use in urinary and faecal incontinence, investigation of the effects of SNS in patients with constipation is still in its infancy. Only 4 previous studies had been published each with a small sample size ( $\leq 12$ ).<sup>38.41</sup> (Table 1). The patients chosen to participate in these studies were carefully selected with all having long standing symptoms of constipation (unrelated to pelvic surgery) that had failed to respond to non-surgical therapy.<sup>38.41</sup> In such patients the data suggests that SNS can improve stool frequency and reduce the percentage of time patients suffer from bloating and pain. Importantly these studies also report very few adverse events. However, it should be stressed that the majority of these data are derived from the short-term PNE phase (Table 1).

While SNS appears to influence stool frequency in constipated subjects the in vivo effects of SNS upon colonic motor function remained unknown. The only available data in humans had come from previous studies of patients with faecal incontinence, from which SNS had been shown to alter ano-rectal motor function.<sup>32, 42-45</sup> In our own study of SNS in severe constipation we used our validated technique of pan-colonic manometry to simultaneously record colonic motor patterns during periods of SNS.46 The data obtained from this study indicates that SNS appears to induce both proximal and distal colonic motor patterns. Furthermore we observed an increase in the frequency of long extent PSs and the frequency of HAPSs (Fig. 2). As mentioned above these particular motor patterns are linked to both colonic transit and defaecation in health. During the 3-week PNE phase 75% of the patients reported improvement in stool frequency (Table 1).

The mechanism of action of SNS in relation to initiating pan-colonic motor patterns remains unknown. It is likely that efferent neural pathways are activated but it is almost certain that afferent pathways are also activated. The rapidity of the colonic response to SNS<sup>46</sup> is certainly compatible with a neural pathway.

# THE FUTURE OF SACRAL NERVE STIMULATION IN PATIENTS WITH SEVERE CONSTIPATION.

The reported positive outcome in carefully selected patients, coupled with minimal adverse side effects suggests that SNS is a reasonable option for patients who are faced with surgical procedures such as a colectomy in order to relieve their constipation symptoms. In addition SNS, at least in treating faecal incontinence, has been shown to be highly cost effective in comparison to other surgical intervention.<sup>47</sup> However, further work is still required. As yet only one randomized control trial has assessed the effects of SNS in costipated patients and that study had a sample size of two.<sup>40</sup> Cleary data derived from adequately powered radomised control trials and long-term follow-up in patients with permanent implantation are still required. As is data determining which patients may benefit form SNS treatment.

In addition while a colonic response to SNS in constipation has been shown, the stimulation parameters necessary to optimise this colonic response remain unclear. Assessing the merits of various combinations of parameters (i.e. alteration to pulse width, frequency and amplitude) can be time consuming if the yardstick is a clinical response which can take weeks or even months to develop.<sup>41</sup> Measurement of the immediate colonic contractile responses in the laboratory setting may prove to be a direct and powerful means of evaluating a wide range of stimulus parameters in order to help define the optimal ones.

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### **Original article**

# Reducing mesh exposure in Posterior Intra-Vaginal Slingplasty (PIVS) for vaginal apex suspension

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Abstract: OBJECTIVES. Urogynecologists are constantly looking for simple, safe and effective ways to cure vaginal apex supportive defects. A novel surgical technique, Posterior Intra-vaginal Slingplasty (PIVS), was described recently to concomitantly achieve a high therapeutic efficiency with a low complication rate. Mesh exposure was reported to complicate up to 16% of the operations. This study evaluates surgical steps aimed to mesh exposure reduction in PIVS-operated patients. STUDY DESIGN. A total of 140 patients with vaginal apex prolapse were subjected to the PIVS operation in a daycare set-up by one of two surgeons: In the first surgeon's patients group (N=66) the surgical vaginal incisions were made as small as feasible, the para-rectal dissection was performed at the infra-fascial level, and the mucosal edges were not trimmed. These surgical procedures, assumed to have some anti-mesh exposure value, were not performed in the second group of patients (N=74), who were operated by a different surgeon. Preoperative demographics, operative details and postoperative follow-up data were prospectively collected for all patients. RESULTS. The demographics in both PIVS patient's groups were similar. A statistically non-significant improvement regarding the mesh exposure rate was observed in the patient's group where the three anti-mesh-exposure surgical steps had been applied. CONCLUSIONS. Reduction of vaginal mesh exposure rate following PIVS might be achieved by performing three simple antiexposure surgical steps. However, more and long-term data is required for being able to draw solid conclusions concerning the superiority of the discussed operative techniques.

Key words: Mesh exposure; Vaginal apical defect; Posterior Intra-Vaginal Slingplasty.

#### INTRODUCTION

Pelvic organ prolapse is very common, and to some degree normal, especially among older women. Yet, up to 30% of all females suffer from pelvic floor relaxation advanced to a level, which has a negative impact upon their quality of life.1 The affected women frequently require manual assistance to urinate and to defecate, and report urinary and fecal frequency, urgency and urge incontinence, as well as sex function-related symptoms.<sup>24</sup> The lifetime risk to undergo prolapse surgery is one in eleven, and up to 30% of those who underwent surgery will have repeat prolapse surgery.<sup>5-</sup> There are two primary routes of access in reconstructive pelvic surgery: the abdominal (either by laparotomy or laparoscopy 9-10) and the vaginal approach. 11-12 Vaginal sacrospinal fixation and abdominal sacrocolpopexy have remained the "gold-standard" for repair of vaginal apical suspension defects. Yet, being less invasive, the vaginal approach offers a safer option for the anatomical correction of this suspension defect.13-21

Though the best approach for restoration of vaginal apical support among the commonly utilized abdominal and vaginal routes remains controversial, the uterosacral ligament vault suspension is the most anatomical among the repairs. Hence, it is most unlikely that the uterosacral ligament support for the vaginal apical prolapse will create a predisposition to future anterior or posterior vaginal vault defects or compromise vaginal function.22 Given that vaginal vault herniation is the result of separation of the pubocervical fascia from the recto-vaginal and paracolpion fascia, resulting in an apical enterocele, it should be corrected by meticulous herniorraphy including reattachment of the vaginal vault to the uterosacral ligaments.<sup>23</sup>

These considerations encouraged Petros to design an innovative procedure for the correction of the apical vaginal support defect, through replacement of the uterovaginal ligament encoding with a synthetic sling, positioned at the levator plate level space via vaginal approach to the pararectal area, performed in a daycare setting.<sup>23-25</sup> Mesh exposure has been described to complicate the postoperative course of these and similar procedures in up to 16% of the patients, necessitating additional operations.<sup>26-29</sup> The current study

was conducted to evaluate the feasibility of reducing the vaginal mesh exposure rate by three simple surgical procedures: infra-fascial dissection, minimization of incisions and non-trimming of the vaginal incision edges. These procedural steps are intended at precluding mucosal mal-healing and hence to prevent vaginal mesh exposure.

#### PATIENTS AND METHODS

Patients suffering from an advanced vaginal apical supportive defect, diagnosed clinically according to the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POPQ) standard scoring system, were referred for a PIVS (Tyco healthcare) operation. Between 1/2003 and 6/2005, 140 PIVS procedures were performed according to Petros by two surgeons in daycare set-ups, after an informed consent form had been signed.<sup>24-26</sup> All patients were given one gram Monocef (Cefonicid, Beecham Healthcare) intravenously, one hour prior to surgery. Prior to the commencement of surgery, all patients were subjected to prophylactic antiseptic iodine vaginal wash. The mode of anesthesia depended upon the patient's request. Patients presenting with additional significant features of pelvic floor relaxation had anterior and posterior colporrhaphy, concomitant with the apical supportive surgery. Patients with uterine prolapse were asked to elect either vaginal hysterectomy or preservation of the uterus, while the uterine cervix was amputated if it dilated over more than half of the vaginal length.30 The first patient's (study) group was subjected to three anti-mesh-exposure surgical procedures: 1) The initial incision at the posterior vaginal wall was minimized, ending more than 2 cm from the tape anchoring point at the vaginal apex. 2) The medial-to-lateral dissection developing the para-rectal space was made under the fascia rather then the traditional supra-fascial method of dissection. 3) The vaginal wall free edges were not trimmed prior to incision closure as usually is done with colporrhaphy. These 3 additional surgical procedures were not performed in the second (control) group of patients. Intra-operative and post-operative complications were prospectively recorded. The patients were interviewed in the first and sixth postoperative month

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| Feature                                   | Study group (N=66) | Control group (N=74) | Statistical significance |
|---|--------------------|----------------------|--------------------------|
| Age (Yrs): Av., (SD <sup>1</sup> .)       | 62.5(8.9)          | 58.3(13.8)           | $NS^2$                   |
| Parity: Av., (SD)                         | 3.0(1.5)           | 4.1(2.3)             | NS                       |
| Chronic illness <sup>3</sup> : N (%)      | 34(51.5%)          | 30                   | NS                       |
| Previous hysterectomy: N (%)              | 37(56%)            | 19(25.7%)            | NS                       |
| Previous anti-incontinence surgery: N (%) | 1(1.5%)            | 0                    | NS                       |
| Pre-operative BOA4: N (%)                 | 20 (30.0%)         | 70 (94.0 %)          | P=0.022                  |

<sup>1</sup>Standard Deviation; <sup>2</sup>Not significant; <sup>3</sup>D.M., Bronchial Asthma, Hypertension, etc.; <sup>4</sup>Bladder overactivity.

and yearly thereafter, with 6 to 24 months follow-up. Subjective data was prospectively recorded regarding urinal and fecal urgency, frequency, stress and urge incontinence, sexual function impairments, voiding habits and pelvic pain and bulging. Objective findings, including verification of urine and feces leakage, relaxation and prolapse of pelvic floor and organs, were also prospectively collected through a physical pelvic examination according to the ICS standards terminology. All statistical analyses were performed with SPSS 10.1.4 (SPSS Inc, Chicago, IL). Student's T test was used for the quantitative variants analysis, while Fisher's exact test and the Chi-square test were applied for the categorical variants. All statistical tests were evaluated at the 0.05 significance level.

#### RESULTS

One hundred and forty patients diagnosed with vaginal vault prolapse stage 3 or 4 according to the POPQ standard scoring system (D point 1 cm or more beyond the hymeneal ring) were enrolled into this study. All demographic and personal details are tabulated in Table 1. Fifty-eight (41.4%) patients were 0.5 to 25 years post hysterectomy (26 by abdominal and 32 by vaginal approach), 10 (7.1%) had undergone previous pelvic floor reconstructive surgery and 7 (5.0%) had undergone previous anti-incontinence surgery. One hundred thirty-seven (97.9%) of the patients presenting with significant features of pelvic floor relaxation underwent successful anterior and posterior colporrhaphy. Forty-four (31.4%) among those underwent vaginal hysterectomy and nine (6.4%) underwent cervical amputation concomitantly with PIVS. Thirty-five (25.0%) underwent anti-incontinence surgery (either TVT or TVT-Obturator) in addition to PIVS (Table 2). The only statistically significant difference in pre-operative details between the study and control patients groups found related to bladder over-activity, 30% versus 94%, respectively.

The patients were operated on by one of two surgeons: one performed the three anti-mesh-exposure surgical steps in the study group (N=66); these were omitted by the second surgeon who operated on the control group (N=74). When comparing the study and control patient groups, no significant differences regarding operative details or intra-operative complications were recorded with the exception of the mode of anesthesia, general or regional: 78% and 22% respectively for the study group, compared to 28% and 72% respectively for the control group. Two study group patients and four control group patients suffered early post-operative hematoma within the para-rectal fossa. These patients were treated orally with prophylactic broad-spectrum antibiotics and recovered spontaneously without need for infusion of blood products or bleeding control procedures.

Three (2.1%) patients, two of the study group and one of the control group, presented with operative failure, as the D point was found to be over 1 cm beyond the hymeneal ring. Four patients (2.9%) had a significant postoperative vaginal wall defect: three (of the control group) had cystocele and one (of the study group) had rectocele beyond the hymeneal ring, necessitating further corrective procedures. According to the POPQ measurements of the post-operative procedures, the cystocele, rectocele and vaginal vault prolapse corrections were satisfying in 93.9% of the study group patients and 95.9% of the control group patients (Table 3). One patient of the control group, who developed post-operative unilateral gluteal skin infection, was treated by surgical removal of the affected hemi-tape; the vaginal apex remained well suspended. Thirteen patients, four of the study group and nine of the control group, had vaginal mesh exposure. Ten of these patients underwent segmental tape resection at the outpatient clinic and three remained without treatment. Two patients (1.4%), one of each patient group, had complete spontaneous tape expulsion while the vaginal apex remained well suspended. One control group patient suffered post-operative fever of unknown origin,

| Statistical signif | ïcance Number(%)     | of patients per    | Feature                   |
|--------------------|----------------------|--------------------|---------------------------|
|                    | Control group (N=74) | Study group (N=66) |                           |
|                    |                      |                    | Anesthesia                |
| P=0.000            | 21(28%)              | 52(78%)            | General                   |
| P=0.000            | 53(72%)              | 14(22%)            | Regional                  |
|                    |                      |                    | Additive surgery          |
| NS*                | 73(98.6%)            | 64(97.0%)          | Colporrhaphy              |
| NS                 | 19(25.7%)            | 25(37.9%)          | Vaginal hysterectomy      |
| NS                 | 16(21.6%)            | 19(28.8%)          | Anti-incontinence surgery |
| NS                 | 7(9.5%)              | 2(3.0%)            | Cervical amputation       |

which recovered with oral antibiotics. All patients desiring sexual intercourse were able to do so, dyspareunia was not reported, and no de-novo post-operative urinary incontinence was recorded.

#### DISCUSSION

Pelvic organ prolapse (POP) may occur in up to 50% of parous women. It may cause a variety of urinary, bowel and sexual symptoms,<sup>1-4</sup> and is reported to necessitate surgical correction in 11% of the female population.<sup>4</sup> Previous hysterectomy, vaginal rather than abdominal, aggravates the risk for further vaginal prolapse. This probably is due to surgical damage as well as to pre-existing weakness of the pelvic floor.7 Neither simple colporrhaphy, with or without plication of the uterosacral ligaments, nor sacrospinous and sacral colpopexies, seem to be the preferred procedures for repairing vaginal prolapse. Some authors observed that these procedures are associated with an up to 58% recurrence rate in terms of objective POPQ scoring and prolapse related subjective symptoms,<sup>6</sup> while others reported a recurrent surgery rate for pelvic floor reconstruction of 30%.7-8 The use of mesh for fixing the vaginal apex to achieve sacral anchorage frequently resulted in vaginal mesh erosion and protrusion, complicating colposacral fixation.<sup>15-1</sup>

Sacro-spinous colpopexy, thought to be less invasive and safer than the abdominal route,<sup>11</sup> was reported to be complicated by post-operative dyspareunia, buttock pain, urinary and fecal incontinence, cystocele and rectocele formation,<sup>17</sup> altered defecation and constipation, bladder injuries, urinary retention and infections.<sup>14</sup> Laparoscopic sacral colpopexy necessitates meticulous and proper prior training <sup>9-10</sup> and, therefore, was unpopular.

Against this background, Petros was encouraged to develop the novel 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.24-26 Magnetic resonance imaging showed that significant improvements in the restoration of the vaginal configuration were achieved in patients who underwent PIVS.<sup>21</sup> The operative results in the current series of patients are in agreement with previously reported data regarding the safety and efficacy of the PIVS method for vaginal apex support.<sup>24-26</sup> 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. In the current series of patients, the restoration of the uterosacral ligaments support along with uterine preservation was performed in 38 (27.1%) of the women according to their personal preferences. One of the repeatedly reported PIVS complications is post-operative vaginal mesh exposure.<sup>29-33</sup> This study was aimed at evaluating the introduction of three preventative surgical measures, namely infra-fascial undermining, minimization of the incision and non-trimming. The study and control group showed statistically significant differences regarding preoperative bladder over-activity (30% versus 94% respectively) and regarding the mode of anesthesia, being general or regional: 78% and 22% respectively in the study group versus 28% and 72% respectively in the control group. According to the POPQ measurements on the post-operative patients, the cystocele, rectocele and vaginal vault prolapse corrections were satisfactory in 133 (95%) of the patients, 93.9% in the study group and 95.9% in the control group. Bladder over-activity symptoms, preoperatively troublesome for 30% of the study group patients and for

94% of the control group patients were reduced post-operatively to 6.0% and 6.7% respectively. An explanation for this finding was offered earlier by Petros, suggesting that the well supported bladder tends to fire less neurological electrical activity than the poorly supported one.<sup>26</sup> The two patients groups are similar, except for the bladder over-activity and the mode of anesthesia. Those differences should not bias the study conclusions regarding the value of the three preventive steps to avoid tape protrusion, performed with the study group patients, but not with those in the control group. This included minimization of the incision at the posterior vaginal wall, making the para-rectal space dissection below the fascial level rather than the traditional supra-fascial method and not trimming the vaginal wall free edges. These steps, which seemingly improve mesh covering and mucosal healing, and might bring about some reduction of the tape exposure rate, do not seem to interfere with the well-proven efficacy and safety of the PIVS operation. The fact that the difference between the study and control group exposure rates (6.0%) and 12.2% respectively) was not statistically significant might be attributed to the rather relatively small patient groups. It was retrospectively calculated that, for the above-reported exposure percentages, a sample size of 280 women per group would be required to prove a significant difference in mesh exposure rate between the two patient groups at a power of  $\hat{80\%}$  (alpha=5%).

Implementation of the above mentioned anti-exposure surgical procedures might ameliorate the patient's satisfaction and reduce the need for reparations after PIVS. This should be proved by additional studies before being adopted as proven preventive measures for vaginally implanted mesh exposure.

#### CONCLUSIONS

Three simple surgical steps, which are safe, effective and easy-to-perform procedures, might reduce mesh exposure after Posterior Intra-vaginal Slingplasty. If supported by additional and long-term data, this might be adopted for other vaginal mesh implants to cure pelvic floor supportive defects, to avoid one of the rather frequent complications of these operations.

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#### Pelvic Floor Digest

**Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial.** *Porena M, Costantini E, Frea B et al. Eur Urol. 2007 Apr 27; epub.* Seventy three women were randomised to TVT and 75 to TOT: both procedures appear safe and effective with minimal complications at mean follow-up of 31 months.

**Long-term results of perianal silicone injection for faecal incontinence.** *Maeda Y, Vaizey CJ, Kamm MA. Colorectal Dis.* 2007; 9:357. This study is the first to determine the efficacy of silicone biomaterial (PTQ) injection in the long term for passive incontinence, in 6 patients followed up at 61 months: 1 patient had undergone a colostomy, in the score little was changed, but there was a substantial improvement in physical and social function on the SF-36 scores.

**Biofeedback for fecal incontinence: short-term outcomes of 513 consecutive patients and predictors of successful treatment.** *Byrne CM, Solomon MJ, Young JM et al. Dis Colon Rectum. 2007;50:417.* Little is known about factors that may be associated with biofeedback effective-ness. This retrospective study on 513 patients assessed short-term outcomes, predictors of patients who completed treatment, and predictors of treatment success. More than 70 percent of patients demonstrated improved short-term outcomes. Treatment success was more likely in those who completed six training sessions, were female, older, or had more severe incontinence.

#### 7 – PAIN

**Urethral pain syndrome and its management.** *Kaur H, Arunkalaivanan AS. Obstet Gynecol Surv. 2007;62:348.* Persistent or recurrent episodic urethral pain usually on voiding with daytime frequency and nocturia, in the absence of proven infection or other obvious pathology is a condition of uncertain etiology. Treatment includes antibiotics, alpha-blockers, acupuncture, laser therapy and psychological support.

Chronic prostatitis/chronic pelvic pain syndrome and male interstitial cystitis: enigmas and opportunities. Forrest JB, Nickel JC, Moldwin RM. Urology. 2007;69(4 Suppl):S60.

Successful management of interstitial cystitis in clinical practice. Forrest JB, Dell JR. Urology. 2007;69(4 Suppl):S82.

**The emerging presence of interstitial cystitis in gynecologic patients with chronic pelvic pain.** *Stanford EJ, Dell JR, Parsons CL. Urology.* 2007;69(4 *Suppl*):S53. It is important to consider the bladder as a generator of symptoms early in the evaluation of the gynecologic patient with chronic pelvic pain. New tools have been developed to aid the gynecologist in ruling out interstitial cystitis in these patients, including a new IC symptom questionnaire and the Potassium Sensitivity Test (PST).

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# TVT-SECUR: 100 teaching operations with a novel anti-incontinence procedure

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*Abstract:* AIM. To evaluate the technical aspects and training process of the TVT-SECUR – a novel minimally invasive anti-incontinence operative procedure. METHODS. With this prospective, observational and consecutive patient series, the TVT-SECUR operation was taught by one trainer to experienced pelvic floor surgeons on 100 patients with urodynamically proven stress urinary incontinence. Peri-operative data was prospectively collected. RESULTS. The surgical aspects of these 100 patient's parameters were evaluated. No voiding difficulties, significant pain, or any other patient inconvenience was observed post-operatively. The early therapeutic failure rate for the TVT-SECUR procedure was 9.0%. Four patients had vaginal wall penetration with the inserters, requiring withdrawal and re-insertion as well as vaginal wall repair. Three other patients needed trimming of a vaginaly extruded tape segment, done in the office with satisfactory results. Five patients had un-intended tape removal at the time of inserter removal, necessitating the usage of a second TVT-SECUR. No signs for bowel, bladder, or urethral injuries, intra-operative bleeding or post-operative infections were evident. Conclusions. Use of the TVT-SECUR, a novel mid-urethral sling, seems to be a safe anti-incontinence procedure. Operative complications associated with the TVT, such as bladder outlet obstruction seem to be reduced with the TVT-SECUR.

Key words: TVT-SECUR; Urinary Stress Incontinence; Training.

#### INTRODUCTION

The Tension-free Vaginal Tape (TVT) procedure is a wellestablished surgical procedure for the treatment of female stress urinary incontinence. The operation, described by Ulmsten in 1996, which is based on a mid-urethral Prolene tape support, is accepted worldwide as an easy-to-learn, effective and safe surgical technique.<sup>1-5</sup> Some typical TVT operative complications of concern to the operating surgeons include: bladder penetration, urinary outlet obstruction, potential bowel penetration, intra-operative bleeding and post-operative infections.<sup>2, 3, 5-9</sup> Against this background, Jean de Leval was encouraged to design a novel mid urethral sling in the form of an "inside-out" trans-obturator TVT-like procedure. In such, the TVT needle bypasses the retropubic area, which is in intimate proximity with the bladder, bowel and blood vessels, by making the needle route pass through the relatively safe medial compartment of the obturator fossa area, remote from the pelvic viscera and vessels.10 The TVT-Obturator was shown to be a safe and easily performed minimally invasive anti-incontinence procedure.11-12

The novel TVT-SECUR was designed to overcome two of the peri-operative complications reported with use of TVT-Obturator: thigh pain and bladder outlet obstruction.<sup>11-12</sup> This was addressed by tailoring the tape to be only 8 cm long and anchoring the tape edges into the internal obturator muscle, rather than passing it through the obturator foramen, muscles and membrane. The initial pull-out force of the tape and further tissue ingrowth were studied in the sheep model, revealing satisfactory figures.<sup>13</sup> The aim of the current analysis was to evaluate the operative data collected with early training in the first 100 novel, minimally invasive anti-incontinence procedures.

#### METHODS

Patients suffering from urinary stress incontinence with no intrinsic sphincteric deficiency, based on subjective complaints and objective clinical signs and confirmed with urodynamic diagnosis including cystometry, uroflowmetry and stress test, were prospectively and consecutively referred for corrective surgery from 25/9/2006 to 25/12/2006. One hundred TVT -SECUR training procedures were performed

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after receiving profound consultation and explanation of the informed consent, highlighting the novelty of the procedure, the lack of experience and the training issues. This operative series of Hammock approach was done at 13 hospitals with one single trainer having previous experience with 35 TVT-SECUR operations. All patients were given one gram of Monocef (Cefonicid, Beecham Healthcare) intravenously, one hour prior to surgery and were subjected to an iodine antiseptic prophylactic vaginal wash prior to commencement of the operation. The mode of anesthesia depended on patient request. No Foley catheter was placed and no diagnostic cystoscopy was performed. Pelvic floor relaxation was recorded in accordance with the ICS pelvic organ prolapse quantification system (POPQ).14 Patients presenting with significant pelvic organ prolapse had colporrhaphies (anterior and posterior) with or without implantation of vaginal mesh (Pro-Lift<sup>TM</sup>, Gynecare, Summerville, NJ) implantation for pelvic floor concomitant with the anti-incontinence surgery. Hysterectomies were not performed with this series. Operative bleeding was managed with hemostatic suture placement via vaginal approach.15 Intra-operative and early post-operative complications within this patient series were recorded. Patients were interviewed and subjected to pelvic examination at the ends of the first and second post-operative months. The clinical findings regarding urine and feces leakage and prolapse were also collected according to the ICS standards terminology.14 Therapeutic failure was defined as persistent urinary stress incontinence, that affected her quality of life, reported by patient and clinically confirmed. Minimal residual leakage, not deteriorating the patient's quality of life, was mentioned but not regarded as therapeutic failure.

#### RESULTS

Patient's pre-operative, operative and post-operative details have been tabulated in Tables 1 and 2, respectively. According to the POPQ system,<sup>14</sup> 48 patients (48.0%) had an advanced cystocele (Aa/Ba>+1), 19 (19.0%) had an advanced rectocele (Ap/Bp>+1), 2 (2.0%) had uterine prolapse (C>+1) and 5 (5.0%) had vaginal vault prolapse (C>+1). All patients had the TVT-SECUR as primary anti-incontinence operation. Fifty one patients (51.0%) underwent concomitant operative procedures in addition to the TVT-SECUR: 48 patients



M. Neuman

TABLE 1. – Pre-operative details (No. = 100).

| Cystocele (Aa/Ba>+1)*          | 48 Pts (48.0%) |
|--------------------------------|----------------|
| Rectocele (Ap/Bp>+1)*          | 19 Pts (19.0%) |
| Uterine prolapse (C>+1)*       | 2 Pts (2.0%)   |
| Vaginal vault prolapse (C>+1)* | 5 Pts (5.0%)   |

(\*) In accordance with the POP-Q system.

(48.0%) had anterior and 19 (19.0%) had posterior colporrhaphies, Eleven patients (11.0%) had anterior ProLift, 2 (2.0%) had posterior ProLift and 5 (5.0%) had total ProLift<sup>TM</sup> operation (Gynecare) for the support of the vaginal walls and apex. No hysterectomies where performed with this patient's series. The 82 trainees where experienced pelvic floor staff surgeons, 28 (34.1%) of them where Urologists and 54 (65.9%) Gynecologists, each performed one or two operations. The mode of anesthesia was subject to patient's request, resulting in general in 52 (52.0%) operations, regional in 11 operations and local in 37 (37%) operations. No anesthetic mode appeared to be superior in terms of facilitating the procedure or the recovery.

The TVT-SECUR patients were followed up for period of 2 to 5 months. Therapeutic failure, meaning sustained urinary stress incontinence, was diagnosed in 7 out of the first 35 patients (20.0%). Seven (20.0%) other patients reported residuals non-significant post operative leakage, not influencing quality of life and hence not regarded as therapeutic failures. Acknowledging these figures, the mesh tension was subsequently minimally increased with the last 65 patients and a further two failure patients (3%) were observed. In total 9 patients (9%) failed. No clinical signs for operative bleeding, bladder or intestinal penetration, post-operative infection, bladder over activity or outlet obstruction were observed. Four patients (4.0) had vaginal wall penetration with the inserters, requiring withdrawal and re-insertion as well as vaginal wall repair. This was avoided later by making the preliminary sub-mucosal tunnel as wide as 12 mm to permit the device to slip in smoothly. With such, no further vaginal penetrations were noted. Three other patients (3.0%) presented with vaginal tape extrusion, this was easily resected in office and no morbid sequela was recorded. After incorporating suburethral dissection to the procedural steps and allowing the tape to sink away from the vaginal mucosa - no more mesh extrusion occurred. Five patients had un-intended tape removal at the time of inserter removal,

 TABLE 2. - Operative and post-operative patient's details (No. = 100).
 100

| Anesthesia: general /regional/local (Pts)   | 52(52.0%)/11(11.0%)/37(37.0) |
|---|------------------------------|
| Concomitant corrective operations (Pts)   |                              |
| Colporrhaphy: Anterior / Posterior  | 48 (48.0%) / 19 (19.0%)      |
| Vaginal Mesh:   |                              |
| ProLift - anterior/posterior/total  | 11 (11.0%) / 2 (2.0%)/5(5.0) |
| Un-intended tape removal (Pts)  | 5 (5.0%)                     |
| Vaginal wall penetration (Pts)  | 4 (4.0%)                     |
| Post-operative vaginal tape protrusion (Pts)  | 3 (3.0%)                     |
| Post operative para-vesical hematoma (Pts)  | 1 (1.0%)                     |
| Early therapeutic failure (Pts)   | 9 (9.0%)                     |
| Residual non significant urinary leakage (Pts)  | 7 (7.0%)                     |
| Clinical signs for post-operative bleeding, blac<br>penetration, bowel and/or urethral injury, p<br>operative outlet obstruction or infection (Pt | dder<br>ost-<br>s) 0 (0.0%)  |

| 1 | 22 |  |
|---|----|--|
| 1 | LL |  |

necessitating the usage of a second TVT-SECUR. This was addressed by proper inserter separation from the tape prior to its withdrawal, and with such, no further unintended tape displacements were recorded. One patient had to be taken back to theater for evacuation of an early post operative para-vesical hematoma of 50 ml. Hematocrit level was not altered and neither blood transfusion nor bleeding control measures were required. All the above mentioned complications, other than the one case of hemorrhage and one case of vaginal tape extrusion, occurred with the first 42 patients.

#### DISCUSSION

The TVT procedure has become very popular ever since it was first described by Ulmsten in 1996. Common complications in previously performed surgeries for the treatment of stress urinary incontinence, such as intra-operative blood loss, pelvic and abdominal organ injury, post-operative de novo detrusor instability, dyspareunia and urethral erosion, are rare in the TVT era.<sup>1-5</sup> Prospective randomized multicenter studies, comparing TVT to the former gold standard Burch colposuspension, demonstrated similar therapeutic impact for both. However, TVT was associated with a higher intra-operative complication rate while colposuspension was associated with a higher post-operative complication rate and a longer recovery period.<sup>16-17</sup> The previously reported TVTrelated complications included bladder penetration, intraoperative bleeding, post-operative infection and vessel and bowel injuries.<sup>1-3, 5-8</sup> Since surgical procedures are more likely to cure stress urinary incontinence rather than non-surgical procedures,<sup>18</sup> de Leval adapted the TVT-Obturator procedure to avoid the aforementioned complications. His novel type of surgery enables mid urethral support for the treatment of female urinary stress incontinence, while not encroaching on the bladder, the femoral blood vessels, or the bowel. This is achieved by exploiting the obturator fossa as a route for the Prolene tape, replacing the retropubic space. The reported data regarding efficacy of the TVT-Obturator in terms of cure as well as intra-operative and early post-operative complication rates is encouraging.<sup>11-12</sup> Bladder penetration, previously reported in relation to "outside-in" trans-obturator designed mid urethral tape procedures,<sup>19-20</sup> has not been described in association with an "inside-out" trans-obturator procedure. Though bladder perforation could not be ruled out as diagnostic cystoscopy is not routinely performed, the absence of any indicative signs provides additional support to the idea that the TVT-Obturator does not cause bladder penetration. Therapeutic failure, intra-operative bleeding, post-operative infection and voiding difficulties also seem to occur less with the TVT-Obturator than previously reported for TVT.<sup>2, 3, 5, 8</sup> 11-12, 15-17 However, the TVT-Obturator is not free of operative

complications: thigh-pain is reported to interfere with patient satisfaction, operative infections and post-operative bladder outlet obstruction still occur as well as occasional operative hemorrhage.

The TVT-SECUR was designed to minimize the operative procedure as much as possible in order to reduce those undesired complications.<sup>21</sup> This new device is composed of an 8 cm long laser cut polypropylene mesh and is introduced to the internal obturator muscle (Hammock position) by a metallic inserter, while no exit skin cuts are needed. This approach imitates the sub-mid-urethral support provided with the TVT-obturator, yet imitating the TVT is possible as well, by introducing the TVT-SECUR arms retropubically rather than to the obturator area. This "U" position approach necessitates urethral catheterization as well as diagnostic cystoscopy for recognition of possible bladder penetration. As the main possible advantage of the TVT-SECUR is minimalisation of the procedure and its side-effects, the simpler "hamTVT-SECUR: 100 teaching operations with a novel anti-incontinence procedure

mock" approach was elected for this patient's series. The 100 teaching operations reported herein served for training TVT-SECUR to experienced pelvic floor surgeons. It was obvious that the first trainee's tended to use their previous knowledge and experience gained with the former mid-urethral slings to the performance of this newly developed surgical device. Given that the new laser cut tape and novel inserters are different than the former equipment, one could understand the trainer's early learning curve difficulties. Laser cutting of the Secur tape is thought to greatly diminish the fraying previously seen with the mechanically cut tape. The elasticity of the laser cut mesh is, however, the same as the mechanically cut mesh within the physiologic range of forces applied to a mid-urethral tape. However, it does not "rope out" and remains flat under the urethra. The extra tension applied to the TVT and TVT-Obturator tapes during removal of the covering plastic sleeves, does not occur with the TVT-SECUR. Hence, some extra tension needs to be applied to the TVT-SECUR compared to the TVT in order to achieve the desired therapeutic result. Even doing so, no clinical signs for postoperative bladder outlet obstruction were observed. To accommodate the flatter, wider tape under the urethra that laser cutting produced, further mucosal undermining was done in order to permit the tape to sink deeper, away from the vaginal mucosa. The inserters, being more than twice as wide as TVT and TVT-Obturator needles, necessitate wider tunnels; 12 mm at least, in order to permit smooth passage of the tape and inserter and avoid gathering of vaginal skin which might lead to vaginal wall penetration. The tunnel depth should not go beyond the bone edge to avoid damaging the tissue meant to hold the coated tape edge; otherwise the initial pull out force might be impaired. The unique locking mechanism, attaching the tape to the inserter, should be unlocked properly and detached gently, to avoid unwanted tape removal with withdrawal of the inserter. Doing these simple surgical steps the author was able to lead the trainees toward successful completion of the operation.

In summary, the TVT-SECUR procedure appears to be potentially easier to perform and relatively trouble-free for both surgeons and patients and might not require urethral catheterization or diagnostic cystoscopy during surgery. Paying respect to the above mentioned procedural specific surgical steps might shorten the TVT-SECUR learning curve. The novel TVT-SECUR's actual place among TVT and TVT-related procedures can only be determined with randomized prospective longitudinal comparisons.

#### CONCLUSIONS

The data presented here supports the notion that the TVT-SECUR, a novel mid-urethral sling operation for the treatment of female stress urinary incontinence, seems to be safe and easy to perform. Intra-operative diagnostic cystoscopy and bladder catheterization might not be mandatory for an experienced surgeon when using the Hammock approach. The TVT-SECUR procedure might be associated with fewer complications, both intra-operatively and post-operatively, than previously reported for the TVT and TVT-related procedures. One should respect the above mentioned special features of this novel procedure to ensure simplicity, safety and security. Randomized comparative controlled trials and long-term follow-ups are still required to clarify the relative places of the different mid-urethral tape anti-incontinence techniques.

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### **Clinical audit**

# Personal evolution of surgical technique using mesh for severe prolapse - a prospective audit of outcomes in 172 cases

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*Abstract:* A series of patients who underwent surgery for POPQ Stage 3 or 4 prolapse between 1999 and 2006 using multifilament polypropylene sling, autologous vaginal grafts or monofilament polypropylene mesh are presented. The change of mesh from Surgipro to Gynemesh resulted in a reduction of mesh erosion from 44 to 9%. Ongoing audit of results has brought about alterations in surgical technique and utilization of technologies.

Key words: Prolapse; Surgery; Mesh; Audit.

#### INTRODUCTION

This paper is a clinical audit of the pelvic reconstructive surgery of a consultant gynaecologist since commencement of private specialist practice in 1995. Initial techniques for management of utero-vaginal prolapse were vaginal hysterectomy<sup>1</sup> anterior and posterior repair<sup>2</sup> and sacrospinous colpopexy.3 These techniques frequently failed to adequately deal with major degrees of prolapse (POPQ Ordinal Stages 3 & 4). Either the apex of the prolapse failed to be adequately reattached (failure of Level 1 supports) or, over weeks to months, the vaginal epithelium sagged and collapsed to create a recurrent prolapse (failure of level 2 supports). A chance meeting with Professor Peter Petros in 1999 lead to training in the use of the IVS Tunneller (Tyco, USA) to produce neo-ligaments in the anterior and the Posterior IVS operations, and the adoption of the Bridge Repair technique where the recycling of vascularised islands of vaginal epithelium provided new Level 2 and 3 supports. Subsequently, a standardised technique using mesh in conjunction with the Posterior IVS was developed and this clinical audit relates to the outcomes of this technique.

#### METHODS

A prospective audit of clinical outcomes enabled ongoing evaluation of surgical results and modification of surgical technique. All cases involved women with POPQ Ordinal Stage 3 or 4 prolapse who were treated with mesh. Cure of prolapse was defined as achievement of POPQ ordinal stage 0 or 1. Improvement of prolapse was defined as achievement of POPQ ordinal stage 2. Failure of prolapse repair was defined as either unchanged physical findings post operatively. From 1999 to 2001 a standardised operative dissection technique was used. This technique remained unaltered for the entire study period. The only changes which occurred during the study period were in the use of different mesh prostheses.

#### OPERATIVE PROCEDURE

Pararectal and paravesical spaces were opened trans vaginally using sharp dissection after development with hydrodissection using dilute 30-50 mls of Bupivicaine and adrenaline (Astra).

1. A full thickness midline anterior vaginal wall incision was made down to the bladder. The vagina was dissected free from the bladder on each side, utilizing Gyrus bipolar forceps, laterally to the subpubic arch. The paravesical space on each side was entered at the level of the bladder neck by holding the tips of Metzenbaum scissors against the subpubic arch and advancing them through the urogenital diaphragm with a "push-open" technique. Entry to this space was confirmed by the appearance of perivesical fat. The space was developed by inserting the index finger and sweeping away (in an anterior to posterior direction) any fibrous attachments of the bladder to the obturator fascia.

A full thickness midline posterior vaginal incision was made down to the rectum. The vagina was dissected from the rectum along the full length from perineal body to uterus, utilizing Gyrus bipolar forceps. The avascular plane of perirectal fat was utilized to dissect down to the ischial spines. The peritoneum was elevated from the levator ani using Navratil retractors, thus exposing the sacrospinous ligament and freeing the rectum of any lateral attachments.

2. Identify visually the sacrospinous ligaments and the Arcus Tendineus Fascia Pelvis (ATFP).

3. Develop neo-uterosacral ligaments – using prostheses. Posterior Intravaginal Sling – using the technique previously described by Farnsworth.<sup>4</sup>

4. Develop neo vesico & rectovaginal fascia – securing repair tissue to the ATFP & levator ani.

a. Bridge repairs – as described by Farnsworth.<sup>5</sup>

b. Polypropylene Mesh – Mesh was placed anteriorly in the paravesical and cervico-vaginal spaces and sutured to the ATFP and uterus using Maxon (Tyco Healthcare, USA) sutures. Mesh was placed posteriorly in the pararectal and rectovaginal spaces and sutured to the sacrospinous ligaments and the perineal body using Maxon sutures. The vagina was closed with continuous Vicryl (Johnson & Johnson, USA) sutures.

c. Prolift Mesh – in the last year of the study, isolated pieces of mesh were replaced with Prolift Mesh (Johnson & Johnson, USA). This was inserted into the anterior and posterior spaces previously developed by the above mentioned dissection and was secured by utilizing transobturator wings perforating the obturator fascia and the posterior wings perforating the sacrospinous ligaments.

#### RESULTS

#### Posterior IVS and Bridge Repairs

During 1999-2000 a Posterior IVS tape as a "level one" support and isolated islands of vaginal epithelium as level 2 supports. These islands were sutured to the ATFP and levator ani. Table 1 shows the result obtained. In short, one third of patients were cured, one third improved and one third failed. The tape problems were those of infection and erosion through the overlying vagina. On analysing the failures, they appeared to occur because of poor longevity of the level 2 supports.

#### Posterior IVS + Surgipro Mesh (Tyco Healthcare, USA)

In order to improve the quality of Level 2 supports, Surgipro Mesh (Tyco Healthcare, USA) was substituted for Personal evolution of surgical technique using mesh for severe prolapse - a prospective audit of outcomes in 172 cases

TABLE 1. - PIVS + Bridge.

| All           | 35 |
|---------------|----|
| Cure          | 13 |
| Improve       | 13 |
| Fail          | 9  |
| Tape Problems | 5  |

#### $\label{eq:TABLE 2.} TABLE \ 2. - PIVS + Surgipro \ mesh.$

| All          | 45 |
|--------------|----|
| Cure         | 39 |
| Improve      | 4  |
| Fail         | 2  |
| Mesh erosion | 20 |

Vaginal epithelial bridge repairs. Table 2 summarises the experience.

This resulted in a dramatic improvement in cure rate. The two failures which occurred were due to Level 1 support failures in woman who had undergone a previous hysterectomy. Disturbingly, mesh erosions occurred in half the patients. These produced a foul smelling blood stained discharge. All patients so affected, requested treatment. This problem was resolved by surgically removing the exposed part of the mesh. Interestingly, there didn't appear to be any worsening of prolapse repair results following partial mesh excision.

#### Posterior IVS + Gynemesh (Gynecare, USA)

In 2004, Johnson & Johnson began marketing in Australia a new macroporous mesh specifically designed for vaginal repairs – Gynemesh. The expectation was that because of its monofilament, macroporous design, that there should be a reduction in infection related extrusions of this mesh. Table 3 summarises experience with this mesh.

| TABLE 3. $- PIVS + Gyneme$ |
|----------------------------|
|----------------------------|

| All     | 45 |
|---------|----|
| Cure    | 40 |
| Improve | 5  |
| Fail    | 0  |
| Erosion | 4  |
|         |    |

The same excellent anatomical results achieved with the Surgipro mesh (Tyco Healthcare, USA) were repeated with Gynemesh (Johnson & Johnson, USA) and there was a dramatic reduction in the number of mesh erosions. Moreover, these erosions were frequently asymptomatic.

#### Prolift Mesh

In June 2005 the Prolift kit (Ethicon Women's Health and Urology, USA) for vaginal repair became available. This kit consisted of a unique preformed piece of Gynemesh with six extensions for placement through pelvic ligaments and purpose built instrumentation. This combined the insertion of Gynemesh, an equivalent to the posterior IVS procedure and a novel way of fixing the anterior wall mesh in position – fixation by perforation of the obturator fascia with lateral extensions of the mesh. During the time of this review the Johnson & Johnson approved technique was followed in which a

| TABLE | 4  | -Prc | olit | 4  |
|-------|----|------|------|----|
| TADLE | т. | -100 | 111  | ι. |

| All                   | 47 |
|-----------------------|----|
| Total Reconstruction  | 29 |
| Anterior              | 8  |
| Posterior             | 7  |
| Abdo/Vag              | 2  |
| Abandoned             | 1  |
| TVT-O                 | 10 |
| Fascial Sling         | 2  |
| Hysterectomy          | 2  |
| Anal sphincter repair | 1  |
|                       |    |

trocar is used to perforate the sacrospinous ligament with the mesh extension analogous to the Posterior IVS procedure.

Table 4 summarises the number and types of procedures and additional procedures performed on patients whose operations occurred between August 2005 and April 2006. All patients had been followed for a minimum of 3 months.

One procedure was abandoned following inadvertent cystotomy during the anterior dissection. In two combined abdomino-vaginal procedures the mesh was inserted transvaginally and then the abdomen was opened and the mesh was attached to the sacral periosteum. Both patients had previous POPQ Ordinal stage 4 prolapse and both had technical failure of an earlier transvaginal mesh procedure. Two hysterectomies were performed for patients who had both Grade 3 prolapse and dysfunctional uterine bleeding. An anal sphincter repair was performed on a patient with a grade 4 prolapse and faecal incontinence secondary to an incompletely repaired external anal sphincter tear.

Table 5 summarises the results of Prolift repairs.

TABLE 5.

| Cure    | 43 |
|---------|----|
| Improve | 2  |
| Fail    | 0  |

One patient was lost to follow up. Two cases of improvement occurred in women with grade 4 prolapse and a previous hysterectomy – the lack of cure was due to less than ideal repair of the apical prolapse. In retrospect, this is possibly due to loosening of the apical portion of the mesh graft prior to complete healing. This might have been prevented by securing the apical portion of the graft to the sacrospinous ligament with permanent sutures.

Table 6 describes the complications experienced in the Prolift repairs.

TABLE 6.

| Mesh erosion           | 7 |
|------------------------|---|
| Urinary Retention      | 1 |
| Deep Venous Thrombosis | 1 |

Of the seven erosions, only 2 patients requested active treatment by excision of the exposed mesh.

#### DISCUSSION

Over a six year period there has been a constant refinement of surgical technique in the management of POPQ Stage 3 and 4 prolapse. This constant refinement has been

#### P. Paris-Browne

directed by a prospective review of the results of treatment and identifying weaknesses in technique and technology.

Using autologous grafts for level 2 supports quickly proved to lack any longevity. However, as soon as polypropylene meshes were introduced for this purpose, there was an obvious and major improvement in durability and quality of the anatomical repair. The downside of this technology has been the occurrence of mesh erosion. This was worst with a multifilament mesh, Surgipro Tyco Healthcare, USA) and least with a macroporous monofilament polypropylene mesh, Gynemesh & Prolift (Ethicon Women's Health and Urology, USA). The vagina is a relatively thin walled structure making it a less suitable site for mesh enhancement than the anterior abdominal wall.

Second generation polypropylene meshes such as Prolift (Ethicon Women's Health and Urology, USA) and Apogee/ Perigee (American Medical Systems, USA) use a transobturator passage of the mesh with integrated mesh extensions and purpose built instrumentation. This has improved the quality of repair of the anterior vaginal wall and better recreates the anterior sulci of the vagina compared to the previous technique of suturing the mesh to the ATFP.

The posterior IVS and procedures derived from it at are best used as level 2 supports<sup>4</sup> and level one support should be provided using an independent suspension, such as a permanent suture from the apex of the mesh to the sacrospinous ligaments. This has since been introduced into surgical technique following analysis of these audit results.

#### CONCLUSIONS

Experience with a standardized dissection technique for surgical treatment of utero-vaginal prolapse has shown that the Posterior IVS procedure is ineffective as a focal apical support and that the use of autologous vaginal grafts were ineffective for vaginal wall fascial support (De Lancey Level 2). The use of polypropylene mesh has been shown to provide a highly effective Level 2 support.

Mesh extrusion remains a diminished but continuing problem in spite of the use of monofilament, macroporous meshes. Transobturator suspension of the anterior arm of Prolift mesh has been shown to be highly effective in supporting the anterior vaginal wall.

Ongoing use of a prospective audit has made it possible to easily assess the effectiveness of one surgeon's techniques and the rate of success of new technologies as they become available.

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#### Financial Interests: none

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# Pelvic Floor Digest continued from page 120

**Neural pain after uterosacral ligament vaginal suspension.** Lowenstein L, Dooley Y, Kenton K, Mueller E, Brubaker L. Int Urogynecol J Pelvic Floor Dysfunct. 2007;18:109. This case report describes the possibility of neural compromise after transvaginal uterosacral ligament suspension. Two women presented shortly after surgery with a unilateral, shooting groin pain with radiation along the ipsilateral lumbosacral nerve distribution. Surgical removal of the permanent stitch and physical therapy provided prompt and near-complete relief.

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### **Original article**

# Stapler-assisted trans-anal surgery for the treatment of outlet obstruction syndrome

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Abstract: Outlet obstruction syndrome (OOS) is related to anatomic alterations, such as rectocele, enterocele and distal intussusception which may be associated with functional disorders, such as paradoxical puborectalis contraction. Patients unresponsive to conservative treatment are eligible for surgical correction of the specific anatomic defect. Recently, new techniques of stapler-assisted trans-anal surgery have been proposed as an alternative to traditional trans-anal operations. This prospective study was undertaken with the aim of assessing the efficacy and postoperative morbidity of two trans-anal stapled techniques (stapled trans-anal prolapsectomy or stapled trans-anal rectal resection, STARR) which were selectively performed in patients with OOS, based on the specific clinical, manometric and defecographic findings. From January 2004 to December 2006, 31 female patients (median age = 58.2 years: range = 27-77 years) underwent surgery at the Division of General Surgery, Colo-Rectal Disease Unit of San Martino Hospital in Genoa. Patients had preoperative colonoscopy, anorectal manometry, defecography, and a complete standardized questionnaire was completed preoperatively and at every six-month follow-up visit aimed at assessing the obstructed defecation score (ODS), the degree of symptoms (Gravity Disease Score = GDS), as well as the quality of life (PAC-QoL), and the satisfaction index by means of a visual analogue scale (VAS: 0-10). A complete re-assessment was performed after one year, including anorectal manometry and defecography. Six patients underwent stapled trans-anal prolapsectomy and 25 underwent STARR (double-STARR in seven, and single anterior STARR in 18 patients). All patients had a regular postoperative course. They had follow-up visits for a median period of 12 months (range: 4-27 months); 23 patients completed clinical and instrumental follow-up at one year, with a significant improvement of post-operative scores of outlet obstruction; moreover, 3 of them (13%) judged their final clinical outcome as excellent, and 18 (80%) as good or moderate. As regards anorectal manometry, pre- and postoperative resting and squeeze pressures were not different thus excluding any postoperative damage to the anal sphincter; conversely, an improvement of rectal sensation was observed in 15 patients (79%) as suggested by the decrease of rectal sensitivity threshold volumes (P = 0.01) and maximum tolerable volume (P < 0.01); moreover, in 7 out of 19 patients (36.8%) the balloon expulsion test became positive. With regard to postoperative defecography, normal findings were observed in 11 patients (61,2%) with a significant reduction of rectocele (P < 0.001); persistent abnormal findings were observed in 7 patients (38,8%). The accurate preoperative assessment and the selective trans-anal correction of rectocele and/or intussusception determined a significant improvement of outlet obstruction scores coupled with a normalization of defecographic and manometric findings, which was most relevant in patients undergoing STARR, without any serious postoperative complication.

Key words: Outlet obstruction syndrome; Obstructed defecation; Rectocele.

#### INTRODUCTION

Outlet Obstruction Syndrome (OOS) mainly affects adult female patients (80-90%) presenting with difficulty in rectal emptying with painful efforts, prolonged time spent in the bathroom, insertion of fingers into vagina and/or the anal canal, laxative and/or enema abuse, and occasional bleeding. From the anatomic standpoint, various defects are detectable, such as rectocele, enterocele and internal mucosal prolapse with or without distal intussusception. Functional alterations may coexist, such as paradoxical puborectalis contraction or spastic external sphincter contraction which are likely to respond to biofeedback traning.1-4 Patients unresponsive to conservative treatment (1.5 l/day of water, high-fiber diet, biofeedback training) are eligible to surgical correction of the specific anatomic defect (i.e., vaginal or perineal levatorplasty, laparotomic or laparoscopic rectopexies, resection-rectopexy, Delorme's transrectal excision).5-11 Actually, surgical correction has achieved satisfactory results in 58% to 90% of patients in the short-middle term clinical follow-up, with favourable response in less than 50% in extended follow-up (6-7 years).<sup>12-14</sup> Recently, thanks to the development of stapler-assisted trans-anal surgery (such as stapled hemorrhoidopexy), new procedures have been proposed as an alternative to traditional trans-anal techniques for the treatment of OOS, which proved effective at least in short-term follow-up with a low postoperative complication rate.15-16

This prospective study was performed in consecutive patients with OOS with the aim of assessing the efficacy and postoperative morbidity of two trans-anal stapled techniques (stapled trans-anal prolapsectomy and stapled trans-anal rectal resection, STARR) which were selectively performed based on the specific clinical, manometric and defecographic findings: stapled prolapsectomy was performed when the main anatomic defect was represented by internal mucosal prolapse and/or recto-anal intussusception while STARR was undertaken in patients whose rectocele was the most remarkable finding.

#### PATIENTS AND METHODS

From January 2004 to December 2006, 31 consecutive female patients with OOS (median age = 58.2 years: range = 27-77 years) were recruited with informed consent in this prospective clinical study which was performed at the Division of General Surgery, Colo-Rectal Disease Unit of San Martino Hospital in Genoa. Patients had preoperative colonoscopy, anorectal manometry and defecography. When colonic inertia was suspected, colonic transit time study using radiopaque markers was performed in order to detect slow colonic transit. A complete standardized questionnaire was completed preoperatively and at every six-month follow-up visit in order to assess obstructed defecation score (ODS), degree of symptoms (Gravity Disease Score = GDS), as well as the quality of life (PAC-QoL), and the satisfaction index by means of a visual analogue scale (VAS: 0-10).<sup>17-18</sup> Intra- and postoperative complications (such as: bleeding, haematoma, intractable pain, local infection, recto-vaginal fistula, anastomotic stenosis, urinary tract infection or retention, outlet obstruction symptoms, urge to defecate, incontinence to flatus) were recorded. Clinical follow-up was

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performed every six months, and a complete re-assessment was undertaken after one year, including anorectal manometry and defecography. Moreover, a qualitative self-assessment was determined considering the clinical outcome as *excellent* when patients were symptom-free; *good* when they had 1-2 episodes/month of use of laxatives without digital assistance, use of enema, or bleeding; *moderate* when they had more than 2 episodes/month of laxative use, and *poor* when their symptoms were unchanged as compared to the preoperative period. As regards statistical evaluation, all analyses were performed using SPSS for Windows (SPSS Inc., Chicago, IL) statistical software; t-test for paired data was used to compare the scores of questionnaires, and Fisher exact test to compare pre- and post-operative manometric and defecographic findings.

Anorectal manometry: With the patient lying in the left lateral position and the hips flexed 90 degrees, a manometric probe, consisting of a silastic tube with an external diameter of 3 mm and bearing six open-ended-tip transducers with continuous water perfusion (Medtronic) was inserted into the anus. The transducers were in the anal canal, and an inflatable latex balloon was mounted on a polyvinyl tube at 5 cm from the anal verge. The transducers were connected via amplifiers to a multichannels computerized unit (PC Poligram VIII - Synectics Medical - USA) showing pressure/time curves in real-time. The main parameters which were assessed included: length of the anal canal, maximal anal resting pressure (MARP), maximal anal squeezing pressure (MASP), rectal sensitivity threshold volume (RSTV), objective recto-anal inhibitory reflex (RAIR), and maximum tolerable volume (MTV); moreover, the balloonexpulsion test was performed at the end of the manometric study.19

Defecography: Dynamic radiologic rectal evacuations were performed as described by Andromanakos et al.20 Three hours before the exam the patient was given hydrosoluble contrast by mouth in order to check the small bowel and exclude the co-existence of enterocele. The rectum and vagina were filled with different barium contrast medium. Radiographs were taken in the lateral projection at rest, during and after straining until the complete evacuation of the contrast; anterior-posterior projections were acquired in selected cases in order to exclude any lateralization of the anatomic defect. Defecography was used to document the extent of rectoanal intussusception according to Wexner's classification ( $1^{st}$  degree: < 10 mm infolding on the rectal wall; 2<sup>nd</sup> degree: > 10 mm infolding extending into the anal canal) and the size (in mm) and shape of rectocele according to Marti's classification (Type I: digitiform rectocele; Type 2: big sacculation with anterior rectal mucosal prolapse; Type 3: rectocele associated with intussusception and/or prolapse of the rectum).<sup>21-22</sup>

*Surgical Techniques:* Preoperatively a cleansing enema was given, and the patient received a routine antibiotic prophylaxis (single shot cefotaxime 2 g and metronidazole 500 mg intravenously) immediately after the induction of anaesthesia. The operation was always performed under spinal anaesthesia with the patient in lithotomic position.

Stapled Trans-Anal Prolapsectomy: According to the technique described by Longo for the treatment of hemorrhoids,<sup>15</sup> the anal verge was gently dilated with one and then two fingers, and the lubricated dilator with obturator (CAD) of the PPH-03<sup>TM</sup> kit (Ethicon Endo-Surgery, Inc., Pratica di Mare - Rome, Italy) was introduced and left in place for 60 seconds. Four radial stitches were applied to the perineal skin and knotted in order to hold the CAD in place. After removing the obturator, the operative anoscope was introduced within the CAD, and one purse-string including mucosa and submucosa was prepared with Prolene 2-0 (Ethicon, Somerville, NY, USA) 2.0 cm above the dentate line. The PPH-3 circular stapler was opened and its head was placed above the purse-string which was knotted and the ends of the sutures were brought through the specific holes of the stapler. Keeping the end of the sutures in traction, the stapler was closed, fired, and then gently withdrawn thus performing prolapse resection with rectopexy. The haemostasis was accurately controlled by supplementary haemostatic sutures of the anastomotic ring with Vicryl 3-0 (Ethicon, Somerville, NY, USA). After 5-10 minutes of careful observation to check for bleeding, a piece of gauze was positioned into the anorectal canal for 4 to 6 hours, and the CAD was removed.

Stapled Trans-Anal Rectal Resection (STARR): The preliminary operative phases were similar although a different kit was used (PPH-01<sup>™</sup>; Ethicon Endo-Surgery, Inc., Pratica di Mare - Rome, Italy). The posterior rectal wall was protected by a retractor, inserted in the lower hole on the CAD 33 and pushed along the anal canal and lower rectal ampulla. The anoscope (PSA 33) was introduced into the CAD 33 and two half (180°; from 9 to 3 hours) purse-strings with Prolene 2-0 (Ethicon, Somerville, NY, USA), including prolapsed rectal wall with mucosa, submucosa and rectal muscle wall, were inserted 2 cm above the dentate line, 1-2 cm apart, to include the top of rectocele. Should the anterior rectocele only be resected, the two purse-strings were a little wider, from 8 to 4 hours instead of 9 to 3 hours. The PPH-1 circular stapler was opened and its head was placed above the purse-strings which were knotted and the ends of the sutures were brought through the specific holes of the stapler. Before firing the stapler, the posterior vaginal wall was carefully checked with fingers and a vaginal valve was introduced to prevent mucosa entrapment. Keeping the end of the sutures in traction, the stapler was closed, fired, and then withdrawn. A minimal mucosal bridge with a staple connecting the two edges of the anterior anastomosis was sometimes found and cut by scissors. The haemostasis of the anterior stapled line was completed with haemostatic stitches using Vicryl 3-0 (Ethicon, Somerville, NY, USA). The procedure was repeated in the posterior rectal wall, with the retractor inserted into the upper hole of the dilator. Two half (180°) purse-strings with Prolene 2-0 were prepared in the posterior rectal wall above the dentate line including mucosa, submucosa and rectal wall, to reduce the posterior intussusception. Subsequent surgical manoeuvres were similar to the previous phase and, after careful inspection for bleeding, the operation was concluded by positioning a piece of gauze into the anorectal canal for 4 to 6 hours, and the CAD is removed. All removed tissue was always carefully checked and sent for definitive histologic assessment.

#### RESULTS

Six patients underwent stapled trans-anal prolapsectomy and 25 underwent STARR (double-STARR in seven, and single anterior STARR in 18 patients). All but one patient, who developed a peripheric neuropathy of the sciatic nerve, had a regular postoperative course. They had follow-up visits for a median period of 12 months (range: 4-27 months); 23 patients completed clinical and instrumental follow-up at one year, and a significant improvement of the main scores of outlet obstruction was observed (Tab. 1). Moreover, three of them (13%) judged their final clinical outcome as excellent, 16 patients (69.5%) as good, two patients (8.6%) as moderate, with only two patients (8.6%) having poor results (Tab. 2).

| Items                            | Preoperative  | 12 months     | P value |
|----------------------------------|---------------|---------------|---------|
| Frequency                        | 1.09 (0.259)  | 0.35 (0.135)  | 0.001   |
| Straining (intensity)            | 1.78 (0.108)  | 0.35 (0.119)  | 0.000   |
| Straining (time)                 | 1.83 (0.081)  | 0.48 (0.124)  | 0.000   |
| Sense of rectal fullness         | 2.83 (0.120)  | 0.74 (0.237)  | 0.000   |
| Rectal pain                      | 2.13 (0.269)  | 0.26 (0.180)  | 0.000   |
| Reduction of daily activity      | 1.83 (0.469)  | 0.26 (0.191)  | 0.001   |
| Use of laxatives                 | 3.87 (0.678)  | 1.96 (0.567)  | 0.002   |
| Use of enema                     | 2.74 (0.654)  | 0.48 (0.326)  | 0.001   |
| Manual assistance                | 1.65 (0.493)  | 0.30 (0.183)  | 0.006   |
| Failure                          | 3.09 (0.301)  | 0.74 (0.229)  | 0.000   |
| Feeling of incomplete evacuation | 3.83 (0.174)  | 1.00 (0.295)  | 0.000   |
| Painful evacuation effort        | 0.91 (0.288)  | 0.22 (0.177)  | 0.010   |
| Daily urge for defecation        | 0.22 (0.125)  | 0.09 (0.87)   | n.s.    |
| Rectal bleeding                  | 1.30 (0.277)  | 0.22 (0.108)  | 0.002   |
| Continence Grading Scale         | 0.30 (0.183)  | 0.17 (0.136)  | n.s.    |
| PAC-QOL (unsatisfactory index)   | 50.13 (4.352) | 13.22 (2.973) | 0.000   |
| PAC-QOL (satisfactory index)     | 0.83 (0.306)  | 10.13 (1.118) | 0.000   |
| VAS satisfactory index           | 3.52 (0.444)  | 7.39 (0.396)  | 0.000   |

TABLE 1. – Preoperative and Postoperative scores in 31 patients operated for Outlet Obstruction.

Values are expressed as means with standard errors.

As regards anorectal manometry, pre- and postoperative resting and squeezing pressures were not different thus excluding any postoperative damage to the anal sphincter; conversely, an improvement of rectal sensation was observed in 15 out of 19 patients (79%) as suggested by the decrease of rectal sensitivity threshold volumes (P = 0.01) and maximum tolerable volume (P < 0.01); moreover, in 7 out of 19 patients (36.8%) the balloon expulsion test became positive. In postoperative defecography normal findings were observed in 11 out of 18 patients (61.2%) while persistent abnormalities were observed in 7 patients (38.8%) (n = 3, second degree rectocele; n = 1, internal mucosal prolapse; n = 3, second degree rectocele with internal mucosal prolapse). As compared to preoperative defecographic findings, anterior rectocele was significantly reduced from 96 percent to 12 percent of patients (P < 0.001) while intussusception was reduced, although not significantly, from 48 percent to 20 percent.

The assessment of post-operative defecographic findings stratified by type of surgery showed that residual rectocele and intussusception were more frequent after stapled transanal prolapsectomy than after STARR (both anterior or double). Patients in the former group had residual rectocele and intussusception in two out of four cases (50%) while those undergoing single anterior STARR had residual intussusception in two out of ten patients (20%), and those

TABLE 2. – Subjective evaluation of the outcome of surgery of 25 patients at one-year follow-up.

| Subjective evaluation of the outcome of surgery | n. pts | %     |
|---|--------|-------|
| Excellent                                       | 3      | 13.0% |
| Good  | 16     | 69.5% |
| Moderate  | 2      | 8.69% |
| Poor  | 2      | 8.69% |
| F001  | 2      | 8.095 |

undergoing double STARR had residual rectocele and intussusception in one out of four patients (25%). As regards post-operative manometric assessment, the improvement of rectal sensation was more frequently achieved by STARR than by stapled prolapsectomy, as suggested by persistently increased rectal sensitivity threshold volumes and maximum tolerable volumes in 33 percent of patients undergoing stapled prolapsectomy (1 out of 3) as compared to 9 percent of patients undergoing single anterior STARR (1 out of 11) and complete normalization of manometric parameters in all five patients undergoing double STARR.

#### DISCUSSION

Outlet Obstruction Syndrome (OOS) is a clinically relevant and emerging problem which mainly affects adult female patients (80-90%) referring with difficulty in rectal emptying with painful efforts, long time spent in bathroom, insertion of fingers into vagina and/or the anal canal, laxative and/or enema abuse, and occasional bleeding. This syndrome should not be confused with constipation related to colonic inertia or associated with irritable bowel syndrome, as they are characterized by a slow transit time of radio-opaque markers.1 The pathophysiology of OOS is still far to be clearly understood because anatomic defects, such as rectocele, enterocele, internal mucosal prolapse with or without distal intussusception. may be associated with functional alterations, such as paradoxical puborectalis contraction or spastic external sphincter contraction.<sup>1-4</sup> Noteworthy, none of these alterations is regarded as pathognomonic because: 1) an anterior rectocele has been shown in 20 to 81 percent of asymtomatic females or with constipation; 2) only 23 to 70 percent of unselected patients with a rectocele have symptoms related to obstructed defecation; 3) clinical outcome after surgery is not strictly related to the complete repair of rectocele, and 4) notwithstanding rectocele repair, 30% al 72% of patients have still persistent difficulty with defecation.<sup>12</sup> The same considerations may be true for internal intussusception, a frequent find-

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ing on defecography observed in 13 to 50 percent of control patients and in 28 to 50 percent of patients with OOS. $^{23-27}$ 

Preoperative evaluation of patients with OOS should include a detailed clinical history by means of validated questionnaires, such as the Constipation Scoring System and the Continence Grading System, to allow a postoperative assessment of the effectiveness of treatment, and diagnostic investigations (defecography, anorectal manometry) to define the specific anatomic and functional abnormalities; colonoscopy should exclude concomitant colo-rectal disease.<sup>16-18</sup>

Patients should usually undergo preliminary conservative treatment (1.5 l/day of water, high-fiber diet, use of bulk laxatives); when paradoxical puborectalis contraction or descending perineum is confirmed, biofeedback training is valuable because in 30 to 38 percent of patients a prolonged clinical improvement has been reported.28-31 Unresponsive patients are eligible to different surgical options for the repair of the specific anatomic defect, proven the absence of primarily colonic constipation.32 Moreover, patients with impaired sphincter function should be excluded due to the high risk of inducing definitive postoperative incontinence; actually, postoperative anorectal manometry in patients treated by means of traditional trans-anal surgery demonstrated a significant reduction of maximum anal resting and squeezing pressures (P = 0.043) which may be related to anal stretching by the retractor, with damage of the anal sphincter complex, although a partial recovery was observed within two years after surgery.<sup>33-35</sup>

Different surgical options have been proposed, such as: vaginal or perineal levatorplasty, open or laparoscopic rectopexies, resection-rectopexy, and Delorme's transrectal excision.<sup>5-11</sup> Some surgeons and urogynecologists are in favour of traditional transperineal anterior repair of rectal wall with levatorplasty, while rectocele with concomitant cystocele is best repaired by transvaginal anterior levatoplasty with posterior colporraphy; postoperative dyspareunia is frequently reported, with a negligible improvement of obstructed defecation symptoms.<sup>36-39</sup> The abdominal approach seems the best for the high type rectocele, as it makes possible combined treatment of rectal and urogynecologic alterations, and is also indicated in case of rectocele associated with enterocele, especially in young women.40 For low lying rectocele which is usually associated with OOS, the transanal repair is employed by colorectal surgeons and it seems to be more effective than traditional transperineal or vaginal operation in obstructed defecation symptoms improvement.

Open and closed procedures have been proposed. The principles of open methods are: to resect superabundant layer of rectocele and anterior rectal wall prolapse: to restore solidity of the anterior rectal wall by means of submucosa and muscularis plication and by contemporary fibrosis induced from submucosa surgical trauma; a longitudinal plication by transverse suture of the rectal wall in the dissection area has been proposed by Khubchandani et al.41 and Sullivan et al.42 while transversal plication by longitudinal suture has been suggested by Sarles.43 The most common closed technique for trans-anal rectocele repair (i.e., obliterative suture) has been proposed by Block et al.44 As regards the outcome of patients, the improvement of obstructed defecation ranges from 62 to 84 percent with closed Block technique, up to 78 to 92 percent with open techniques by Sarles, Sullivan e Khubchandani.<sup>45</sup> However, postoperative complications are rather frequent, as suggested by an Italian multicentric study: postoperative bleeding (7.8%), dehiscence of endorectal suture (5%), distal rectal stenosis (2%), recto-vaginal fistula (1.4%) and acute urinary retention (3.5%).46

Recently, thanks to the development of stapler-assisted trans-anal surgery (such as, the stapled hemorrhoidopexy proposed by Longo<sup>15</sup>), new procedures have been proposed as an alternative to traditional trans-anal techniques for the treatment of OOS, which proved effective at least in short-term follow-up with a low postoperative complication rate.<sup>16</sup> The STARR procedure is performed using two circular staplers (PPH-01<sup>TM</sup>), the first to anteriorly reduce the intus-susception and the anterior rectocele, thus correcting the anterior rectal wall muscle defect, and the second to posteriorly correct the intussusception.

In the present experience, trans-anal prolapsectomy and STARR were adapted to the clinical and anatomic and functional findings in the specific patient, the former being performed when the most relevant defect was represented by internal mucosal prolapse and/or recto-anal intussusception while single anterior STARR (limited to anterior rectal wall, from 8 to 4 hours) was undertaken in patients whose anterior rectocele was the most remarkable finding, and double STARR in patients with anterior and posterior rectocele. Actually, trans-anal prolapsectomy allowed only a partial correction of the anatomic defect, with a high rate of recurrent rectocele and intussusception detected at defecography coupled with a less than optimal normalization of manometric findings. Conversely, both anterior and double STARR could achieve a persistent correction of rectocele and intussusception coupled with normalization of manometric parameters.

As regards post-operative complications, no serious bleeding, recto-vaginal fistula or local infection did occur; this low morbidity rate seems to be related to the careful haemostasis of the anastomotic ring, and to the proper use of retractor and vaginal valve in order to avoid any entrapment of adjacent viscera, mostly associated enterocele or the posterior wall of vagina. Moreover, no significant reduction of maximal anal resting pressure and maximal anal squeezing pressure was observed as compared to traditional trans-anal surgery, which can be related both to the reduced operative time (20 to 25 minutes) and minimal anal divulsion produced by the use of CAD 33 (36 mm) as compared to Park's rectal retractor which has been associated with transient sphincteric impairment.<sup>33-35</sup>

#### CONCLUSIONS

The results of this prospective clinical study suggest that: 1) more than 90% of patients had a satisfactory surgical result of OOS with stapler-assisted trans-anal surgery, coupled with a negligible postoperative morbidity;

2) the clinical resolution of symptoms was associated with an improvement of functional parameters in over 80% of patients, with normal defecographic findings in more than 60% of patients;

3) although the symptoms of OOS were significantly improved with either operations, trans-anal prolapsectomy allowed only a partial correction of the anatomic defect, with a high rate of recurrent rectocele and intussusception detected at defecography as well as less than optimal normalization of manometric findings, while STARR achieved a persistent correction of rectocele and intussusception coupled with normalization of manometric parameters.

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# Persistent dyschezia after double stapled transanal rectal resection for outlet obstruction: four case reports

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*Abstract:* Sometimes dyschezia may be due to rectocele and/or recto-anal intussusception. Stapled transanal rectal resection (STARR) is a surgical option for dyschezia caused by rectocele and/or recto-anal intussusception. We reported four cases of patients evaluated for persistent symptoms of impaired defecation after STARR. Goals of the study were to identify the causes of failure, to outline an effective rehabilitative treatment program and to evaluate the post-rehabilitation results. Four females (mean age:  $48.5 \pm 3.3$  years old), who had a previous STARR and who were symptomatic for dyschezia, underwent clinical evaluation, defecography, and anorectal manometry. A rehabilitative treatment was successively planned on the basis of the diagnostic instrumental data. A post-rehabilitative clinical evaluation was performed and the instrumental data of patients were compared with those of the healthy women (mean age 54 years, range 43-67) with normal bowel habits. Clinical evaluation, defecographic X-rays, and anorectal manometry made diagnosis of outlet obstruction, supported by pelvic floor dyssynergia was also preoperatively present in all patients. An appropriate cycle of rehabilitation was outlined for each patient. After the rehabilitation the patients were clinically evaluated and Agachan constipation score lowered in all 4 cases. The persistent dyschezia after STARR was caused by pelvic floor dyssynergia, which was present pre-operatively. Rehabilitation was a useful therapeutic option in these patients.

Key words: Obstructed defecation; Chronic constipation; Rehabilitation; Biofeedback.

#### INTRODUCTION

Dyschezia, which presents with symptoms of outlet obstruction and difficult defecation including straining, feeling of incomplete evacuation after defecation, and manual manoeuvres to facilitate defecation,<sup>1</sup> is sometimes due to an intussusception extending into the anal canal (i.e. recto-anal intussusception) and/or to anterior rectocele. After failed first line medical and/or rehabilitative therapy, both diseases may be treated with surgical repair, but there is little agreement on the best approach. A recent technique, the double stapled trans-anal rectal resection (STARR), has been proposed for obstructed defecation due to recto-anal intussusception and rectocele.<sup>2</sup> The first stapler is used anteriorly, to correct rectocele and reduce intussusception, the second stapler is fired posteriorly, to complete the resection of intussusception.

In this study we present four cases of failed treatment, i.e. post-operative persistent difficulty in defecation following STARR. The aims of the study were to identify the causes of failure, outline an effective rehabilitative treatment program and evaluate post-rehabilitation results.

#### METHODS

Between June 2003 and January 2007, 4 females (mean age:  $48.5 \pm 3.3$  years old), suffering from obstructed defecation that was not cured by conservative therapy, underwent a STARR in different surgical units. Some months after surgery, these patients came to the Surgical Clinic of the University of Florence (Italy) for persistent difficulty in defecation. All four patients were routinely studied for obstructed defecation by means of clinical evaluation, anorectal manometry, and defecography. The diagnostic tools suggested a rehabilitative program, which was performed in accordance to the pathophysiological profile of each patient. In order to attain the goals of the study, defecographic and manometric data were compared to the normal values of 10 healthy women (age range 43-67 years; mean age 54 years) with normal bowel habits and who were never seen by a doctor for intestinal problems. The patients were clinically re-evaluated after the rehabilitation.

In accordance with the ethical guidelines of our University, all four of the participants gave a written consent to use their clinical data with full knowledge of the procedures to be undertaken.

#### Clinical evaluation

A clinical questionnaire, concerning births, previous pelvic or anorectal surgery, concomitant diseases and bowel habits was administered to all the patients. A four weeks diary was used to evaluate the obstructed defecation<sup>3</sup> and the Agachan score gave objective evaluation of chronic constipation.<sup>4</sup>

A clinical examination was performed focusing on perineum, anus, rectum, and vagina. In particular, perineal descent, size and extension of rectocele, presence of genital prolapse by means of Pelvic Organ Prolapse Quantification (POPQ) examination,<sup>5</sup> were noted.

#### Defecography

The radiological assessment was carried out at rest, during contraction, and during expulsion of the barium in according to the methods suggested by the Italian Working Team.6 All the X-rays showed latero-lateral views. Radiological measurements included the anorectal angle (measured and expressed in degrees between the longitudinal axis of the anal canal and the tangential line to the posterior rectal wall) and pelvic floor descent (defined as the vertical distance between the pubococcygeal line and the anorectal junction). The latter was expressed in mm. A qualitative evaluation was made by noting the barium trapping, recto anal intussusception and the persistence of the puborectal indentation during evacuation. A rectocele was also identified as a herniation of the anterior wall of the rectum into the vagina; the size was measured in mm and was defined as the distance between the tip of the rectocele and the longitudinal axis of the anal canal.

#### Anorectal manometry

Anorectal manometry was carried out according to the previously described technique.<sup>7</sup> Anal resting pressure (ARP) was carried out four times with the stationary pull-through technique and recorded in mmHg. Computerized analysis identified the maximal anal pressure (Pmax) and the mean pressure (Pm) of the anal canal. The maximal voluntary contraction (MVC) was evaluated by asking the subject to voluntarily contract the anal sphincter as long as he could. The computer quantified the amplitude in mmHg. Straining test was performed and anal relaxation (AR) during attempted defecation was evaluated by asking the subject to voluntarily strain and relax the anal sphincters. A relaxation value >75% from the basal line was considered normal. The rectoanal inhibitory reflex (RAIR) was elicited four times in the proximal sphincter by inflating a balloon (40 ml of air) in the rectum. Forty ml of air is considered the normal value necessary to induce complete relaxation. RAIR was noted for its presence.

The conscious distension volume threshold was identified as the first perceived transient sensation [conscious rectal sensitivity threshold (CRST)]. Values were expressed in ml. The maximal tolerated volume (MTV), also expressed in ml, was considered an expression of the rectal reservoir capacity. Compliance of the rectum (expression of the ratio mmHg/ml of inflated air) was measured by means of the pressure/volume curve.

#### Rehabilitation

The data of computerized anorectal manometry, carried out in all of the patients prior to the rehabilitation cycle. were used to guide rehabilitation. Signs of pelvic floor dyssynergia suggested the use of pelviperineal kinesitherapy and biofeedback, according to bimodal rehabilitation programme.<sup>8</sup> Impaired (≤ 20 ml) or delayed (> 80 ml) CRST (normal values:  $40.0 \pm 10.0$  ml) were treated using volumetric rehabilitation.9 Impaired MTV (< 130 ml or > 240 ml; normal values:  $20\hat{1}.3 \pm 19.4$  ml) and impaired compliance of the rectum (ratio mmHg/ml > 0.5) were considered manometric signs for rehabilitative treatment using volumetric rehabilitation.9 Electrostimulation was used as the preliminary step for biofeedback and kinesitherapy when the patients needed to better feel the anoperineal plane.9 The sequence of rehabilitative program was adjusted according to the manometric reports of each patient. Therefore, it was aimed at the mechanisms of impaired defecation. This model resulted in individualized cycles of rehabilitation that were specifically designed for each subject.

TABLE 1. – Clinical evaluation in outpatient unit.

#### CASES REPORTS

The clinical evaluation and diagnostic data of all the four women are reported in tables 1-4.

Case 1. - A.R. - Female - 48 years old. One childbirth with episiotomy. I grade uterine prolapse. In 1998, the patient underwent a Sarles operation for a rectocele, but difficult evacuation continued. A later defecography (2001) showed a descending perineum with an anterior rectocele (Ø 4 cm), recto-anal intussusception (13 mm) and the persistence of puborectal indentation at evacuation. The patient received no further anorectal manometry or other functional evaluations of her bowel habits. Nevertheless, in June 2003, the woman underwent STARR for dyschezia and outlet obstruction. Unfortunately, symptoms of difficult evacuation did not disappear even if defecatory frequency was higher than before surgery (8 times/week versus 3 times/week) and fecal soiling began. In November 2003, the patient came to our outpatient unit. She had a high residual fiber diet and good intake of water (> 1.5 l/die). The details of the clinical evaluation are reported in table 1. The patient underwent defecography and anorectal manometry: the instrumental data are reported in tables 2 and 3. Defecography showed a descending perineum with persistent puborectalis indentation during evacuation: no rectocele nor rectal invagination were noted, but barium trapping was 50%. Anorectal manometry showed a reduced ARP and a low amplitude of MVC. Impaired AR was noted at attempted defecation. Rectal capacity (MTV: 110 ml) and compliance  $(\Delta p / \Delta v > 0.6)$  were impaired.

Due to the pathophysiological profile of her bowel dysfunction conservative rehabilitation therapy was recommended and commenced. The sequence was electrostimulation, to better perceive the anoperineal plane, volumetric rehabilitation, to restore the rectal capacity and impaired compliance and pelviperineal kinesitherapy and biofeedback, to coordinate pelvic floor activity during defecation and restore sphincteric endurance. Rehabilitative therapy was very useful. Difficult defecation disappeared and the patient had no further episodes of fecal soiling. The clinical goals were obtained (table 4).

Case 2. – M.L. - Female - 49 years old. Two childbirths (1980 and 1983) with II grade perineal tears. In 1985, sacral trauma and fracture of the coccyx. Previous surgery in 1996 (Milligan-Morgan hemorrhoidectomy) and 2000 (right ovariectomy). Dyschezia began at a young age, worsened after each childbirth and fracture of the coccyx. In June 2003, a defecography was performed. Rectocele ( $\emptyset$  3.3 cm) and recto-anal intussusception (rectoanal infold-

|        | Age | Births | Previous<br>surgery                    | Perineal<br>descent | Rectocele | Genital prolapse<br>POPQ | Agachan<br>score |
|--------|-----|--------|--|---------------------|-----------|--------------------------|------------------|
| Case 1 | 48  | 1      | Sarles operation                       | Present             | _         | Stage I                  | 16               |
| Case 2 | 49  | 2      | Haemorrhoidectomy<br>Right ovariectomy | -                   | -         | _                        | 20               |
| Case 3 | 51  | _      | Haemorrhoidectomy                      |                     |           |                          |                  |
|        | -   | _      | _                                      | 18                  |           |                          |                  |
| Case 4 | 46  | 1      | _                                      | Present             | Present   | Stage II                 | 18               |

TABLE 2. – Defecography.

|                                     |            | Case 1  | Case 2  | Case 3  | Case 4  | Controls    |
|-------------------------------------|------------|---------|---------|---------|---------|-------------|
|                                     | resting    | 96      | 91      | 96      | 100     | 94 ± 3      |
| Anorectar angle (degrees)           | evacuation | 100     | 95      | 92      | 102     | $110 \pm 3$ |
| Pelvic floor descent (mm)           | resting    | 59      | 22      | 16      | 52      | 17 ± 7      |
|                                     | evacuation | 96      | 20      | 19      | 89      | $25 \pm 2$  |
| Rectocele size (mm)                 |            | 0       | 0       | 0       | 15      | 0           |
| Barium trapping (% retained volume) |            | 50%     | 40%     | 50%     | 40%     | 10%         |
| Recto-anal intussusception          |            | absent  | absent  | present | absent  | 0           |
| Puborectalis indentation            |            | present | present | present | present | 0           |
|                                     |            |         |         |         |         |             |

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|                     | Case 1  | Case 2  | Case 3  | Case 4  | Controls         |
|---------------------|---------|---------|---------|---------|------------------|
| Pmax (mmHg)         | 54.6    | 74.0    | 84.9    | 63.4    | $78.01 \pm 10.2$ |
| Pm (mmHg)           | 25.9    | 42.7    | 47.8    | 31.3    | $41.8 \pm 6.6$   |
| MVC (mmHg)          | 99.6    | 114.4   | 136.8   | 95.9    | 124.1 ± 13.7     |
| Anal relaxation (%) | 37%     | absent  | absent  | absent  | >75%             |
| RAIR                | present | present | present | present | present          |
| CRST (ml)           | 40      | 50      | < 20    | 40      | $40.0\pm10.0$    |
| MTV (ml)            | 110     | 190     | 80      | 200     | 201.3 ± 19.4     |

ing: 12 mm) combined with paradoxical puborectalis contraction at fecal evacuation were diagnosed. In November 2003 the patient, after a failed rehabilitative cycle with biofeedback, underwent a STARR. The dyschezia however persisted and in March 2004 the patient came to our outpatient unit. The clinical evaluation is reported in table 1. The patient had low intakes of vegetal fiber and water (< 1 l/die). Stool frequency was 1-2 times/week and the stools were dry and hard. A diagnostic work up was made. A colonoscopy showed a "melanosis coli" due to laxative abuse. Colonic transit time was impaired in the recto-anal region with persistence of 75% of the radiopaque markers after 5 days. Defecographic and manometric data are reported in tables 2 and 3. Defecography confirmed the presence of puborectalis indentation at evacuation; neither recto-anal intussusception nor a rectocele were found. Anal endosonography showed a small hypoechoic area (width 27°, length 1.4 cm) in the anterior wall of the external anal sphincter. Anorectal manometry reported anal contraction during attempted defecation. The conclusive diagnosis, based on defecographic and manometric reports, was pelvic floor dyssynergia.<sup>10</sup> Preliminarily, a high residual fiber diet and hydration (> 1.5 l/die) were prescribed. A successive cycle of pelvic floor rehabilitation was performed: bimodal rehabilitation, including pelviperineal kinesitherapy and biofeedback, was used.8 At the end of the therapeutic program, bowel function was normal (Tab. 4). Stool frequency was daily, and there were no longer any symptoms of difficult defecation.

Case 3. - C.V. - Female - 51 years old. Nulliparous. Previous Milligan-Morgan hemorrhoidectomy (1994). Dyschezia began 5 years ago, and worsened until digital evacuation was found to provide relief. In December 2003, a defecographic evaluation showed impaired emptying of the rectum with increased puborectalis indentation at evacuation, rectocele (Ø 3.8 cm) and recto-anal intussusception (recto-anal infolding: 16 mm). The patient had no further functional evaluation and in June 2004 underwent STARR after unsuccessful rehabilitative therapy with biofeedback. A few days after surgery, the 5-6 bowel movements/day were already characterized by urgency and symptoms of incomplete rectal emptying requiring digitation. During the next months, this defecation behavior continued and for this reason, in October 2004, the patient came to our outpatient unit. The frequency of bowel movements was high (5-8/day) but excreta were few for each stool, sometimes with digital evacuation. Preliminary endoscopic evaluation was negative for organic lesions of the colon and rectum. A new defecography was performed and radiological pictures showed an increased puborectalis indentation at evacuation combined with a recto-anal intussusception (Tab. 2). Anorectal manometry showed anal contractions during attempted defecation and impaired values for rectal sensation (CRST < 20 ml), rectal capacity (MTV= 80 ml) and rectal compliance  $(\Delta p/\Delta v > 0.5)$  (table 3). On the basis of the pathophysiological data (impairment of functional rectal properties and the presence of pelvic floor dyssynergia), a rehabilitative program was

TABLE 4. – Agachan score.

|        | Pre-rehabilitation cycle | Post-rehabilitation cycle |
|--------|--------------------------|---------------------------|
| Case 1 | 16                       | 3                         |
| Case 2 | 20                       | 3                         |
| Case 3 | 18                       | 6                         |
| Case 4 | 18                       | 5                         |
|        |                          |                           |

outlined. Volumetric rehabilitation, used to restore normal rectal volumes of sensation, capacity and compliance, was the first step of the rehabilitative program. Bimodal rehabilitation (i.e. pelviperineal kinesitherapy and biofeedback) was the second rehabilitative step. At the end of the rehabilitation cycle the patient was better: the number of bowel movements was about twice a day, but some degree of urgency persisted (Tab. 4). Rectal emptying was complete and digital evacuation was no longer necessary.

Case 4. – P.G. - Female - 46 years old. One childbirth. Uterine prolapse (II grade). From the time the patient was in her twenties, chronic constipation was treated with laxatives. In 2002, a gastroenterological evaluation diagnosed "descending perineum syndrome: rectocele", suggesting rehabilitative therapy. The patient, however, received no treatment. Symptoms of difficult defecation worsened over time until digital evacuation was practiced and in July 2004 a new defecography was performed. The radiological report confirmed the abnormal and mobile descending pelvic floor with the persistence of puborectalis indentation at evacuation and the appearance of a rectocele (Ø 3.4 cm). Anorectal manometry pointed out low ARP and absent sphincter relaxation at attempted defecation.

A rehabilitation program with biofeedback proved unsuccessful and in February 2006 the patient underwent STARR. After surgery, bowel evacuation occurred daily, but the symptoms of dyschezia persisted, sometimes with post-defecatory fecal soiling. In January 2007, the patient was evaluated in our outpatient unit (Tab. 1). The diagnostic work up included defecography, anorectal manometry and neurophysiological tests (external anal sphincter electromyography, latency of pudendo-anal reflex, evoked sensory/motor potentials). The instrumental data are reported in tables 2 and 3. Pre and post operative defecography studies were similar but the rectocele was smaller (Ø 1.5 cm). Anorectal manometry confirmed the low ARP (Pm: 31.3 mmHg) and the absence of anal relaxation at straining. Neurophysiological tests excluded pudendal neuropathy. The patient was treated using bimodal rehabilitation which led to improved bowel function, requiring the use of a micro-enema once/week (Tab. 3).

#### DISCUSSION

Outlet obstruction is a complex disorder. A wide variety of non-specific symptoms are present and there is an overlap among the clinical profiles of functional (pelvic floor dyssynergia) and organic (rectocele and rectal intussusception) diseases.<sup>11</sup> Moreover, anatomic abnormalities, when present, are involved with functional disorders, such as pelvic floor dyssynergia, in the pathophysiology of this syndrome. Therefore, it follows that the surgical treatment of rectocele and/or recto-anal intussusception, after failed conservative treatment, is debatable. When to operate and which type of surgical technique to use are the two important questions, and both are without a decisive answer.<sup>12</sup> Three years ago, an Italian group published the results of a prospective multicenter trial on the new procedure, STARR, for outlet obstruction.13 The level of evidence was II-2:14 This was not a randomized clinical trial and there was no control group. The results were encouraging, but some symptoms of dyschezia persisted in a group of patients. For example, the feeling of incomplete evacuation was present in 18.9% of the patients at a 12 month follow-up. In spite of the low evidence-based evaluation,15 implementation of the technique has become widespread in Italy. Over a relatively short period of time (November 2003-January 2007), we evaluated four women affected by persistent dyschezia after STARR. Our case reports help to better understand the surgical failures. All four patients had pre-operative pelvic floor dyssynergia, combined in different ways with rectocele and recto-anal intussusception. These instrumental data could have been used as exclusion criteria for STARR<sup>13</sup> but surgeons intervened following "failed biofeedback". Surgery solved some pre-operative signs of obstructed defecation. In fact, post-operative evaluation showed a resolution of morphologic lesions (rectocele and/or rectoanal intussusception), but clinically there were unchanged symptoms of impaired defecation. A recent paper<sup>16</sup> underlined the symptomatic failure in 58.3% patients treated by STARR for obstructed defecation where the failure was due to pelvic floor dyssynergia. In our patients there was a similar pathophysiological pathway and it can be reasonably supposed that their pre-operative "failed biofeedback" could be due to a poorly performed pre-operative rehabilitation programme, since dyssynergic patients who do not respond to bimodal rehabilitation are very few.8 We don't know if STARR was useful or not but, surely, a more complex rehabilitative programme would have been more helpful. Two patients required multimodal rehabilitation for the physiopathological complexity of the obstructed defecation.

In conclusion, this report advocates caution when considering surgery for patients affected by obstructed defecation with pelvic floor dyssynergia and emphasizes the importance of an effective rehabilitation program in the treatment of this condition.

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# Pelvic Floor Digest

**Repeat transanal advancement flap repair: impact on the overall healing rate of high transsphincteric fistulas and on fecal continence.** *Mitalas LE, Gosselink MP, Zimmerman DD, Schouten WR. Dis Colon Rectum. 2007 Aug 14; epub.* Repeat transanal advancement flap repair increases the overall healing rate of high transsphincteric fistulas from 67 percent after one attempt to 90 percent after two attempts without a deteriorating effect on fecal continence (87 patients, median follow-up 15 months range 2-50).

#### 9 - BEHAVIOUR, PSYCHOLOGY, SEXOLOGY

**Male sexual dysfunction after pelvic fracture.** *Metze M, Tiemann AH, Josten C. J Trauma. 2007;63:394.* Major pelvic trauma may impair sexual function in men. The results demonstrate an objective measurement of erectile dysfunction by the International Index of Erectile Function as well as an extended spectrum of complaints (ejaculatory dysfunction, sensory loss in genital region, and pain during sexual activity). Patients that need further medical evaluation must be identified.

**Sexual function in adult patients with spina bifida and its impact on quality of life.** *Lassmann J, Garibay Gonzalez F et al. J Urol.* 2007 *Aug 15; epub.* 

**Should we avoid stapled hemorrhoidopexy in males and females who practice receptive anal sex?** *Mlakar B. Dis Colon Rectum.* 2007 *Aug 9; epub.* 

#### **10 – MISCELLANEOUS**

**Modified posterior sagittal transanorectal approach in repair of urogenital sinus anomalies.** *Pratap A, Agrawal CS, Kumar A et al. Urology. 2007 Aug 2; epub.* The modified posterior sagittal transanorectal approach is a safe and effective technique in the treatment of urogenital sinus anomalies and can be performed without the need for a protective colostomy.

#### Letter to the Editor

# Professor PETER PETROS MB BS (Syd) D Med Sc (Uppsala) DS (UWA) MD (Syd) FRCOG (Lond) FRANZCOG CU

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## Re Posterior IVS for vault suspension: A re-evaluation

#### by BRUCE FARNSWORTH

Dr Farnsworth is to be complimented on an excellent historical summation. He has played a central role in simplifying the teaching of this technique. I endorse his comments on method and sterile technique, and would add, it is absolutely necessary to create a fascial layer below the tape. Approximation of suburethral or rectovaginal fascia will give a better symptomatic result, and vastly reduce tape rejections. Any direct contact with the tape on the incision will initiate the action of lytic enzymes, and may explain the high rejection rate reported by some surgeons.

I present some comments below which I hope will stimulate further debate.

# 1. THE CONTENTION THAT THE OPERATION IS A LEVEL 2 REPAIR.

The tape is inserted through the uterosacral ligaments. As the uterosacral ligaments attach to the posterior part of the cervix, the operation is by definition, a level 1 repair. The penetration point for the muscles is 1cm medial and posterior to the ischial spine.

The accompanying xray studies demonstrate that the ischial spine is above the cervix in the resting position, figure 1, and well above the cervix during straining, figure 2.

#### 2. SUGGESTIONS BY OTHERS THAT THE TAPE SHOULD PENETRATE THE SACROSPINOUS LIGAMENT

I agree entirely with Dr Farnsworth, that the tape should not penetrate the sacrospinous ligament. This new trend has, I believe, 3 major flaws. Firstly, there would be increased risk of causing major haemorrhage by damage to the venous plexus below the sacrospinous ligament (SSL).<sup>2</sup> Secondly, a rigid attachment is created between vagina and SSL. This would inhibit the backward/downward stretching of vagina and bladder base by the levator muscles, evident on comparing figures 1 & 2. This movement restores support to the bladder base stretch receptors, a pre-requisite for the reported clinical cure of urgency, frequency and nocturia.<sup>3</sup> There is anecdotal evidence from surgeons in the field that the 80% cure rate reported for such symptoms <sup>3</sup> has halved with the use of large mesh systems which attach to the sacrospinous ligament.

However, his advice that "A separate apical attachment using independent permanent nonabsorbable sutures can be placed on the posterior and medial end of the sacrospinous ligament on each side", is, I believe, a sacrospinous fixation (SSF) in all but name, something the "PIVS" or "infracoccygeal sacropexy"<sup>4</sup> was specifically designed to avoid.

Any excess stretching of the vagina during surgical attachment to the SSL would bring back the post-operative pain associated with sacrospinous fixation (SSF). Any sacrospinous fixation risks the vascular complications described by Nichols. A penetration point of the tunneller 1cm medial and behind the ischial spine is safer, allows greater muscle stretching of the organs, figure 2, and is potentially a less painful procedure than PIVS with a SSF component.

#### 3. OTHER ISSUES

Speaking from an experience of >4000 IVS cases, I make the following observations. It is important to distinguish between "infection" and foreign body reaction. Both are inflammatory reactions, and both may present as purulent reactions. Patients with tape "rejections" are invariably afebrile. The presenting symptom is usually a painless purulent



Fig. 1. – Xray of a nulliparous patient, resting sitting position. Note that the cervix I situated just below the level of the ischial spine. X marks the penetration point of the tunneller just medial and behind the ischial spine (IS). SSL=sacrospinous ligament; LP=levator plate; V=vagina; R=rectum; PB=perineal body; B=bladder. The tape and line of SSL have been superimposed on the original xray.

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Fig. 2. – Xray of a nulliparous patient, straining. Same patient as figure 1. The tape and line of SSL have been superimposed on the original xray. Note the natural movement of the cervix and vagina activated by the posterior muscle forces. Whereas a tape allows such movements, fixation on SSL is far more rigid, and would inhibit them.

discharge. With my patients, I took bacterial swabs from every tape rejection observed, and rarely was a significant bacterial growth returned. Histology showed macrophages and giant cells, the cardinal diagnostic sign of a foreign body reaction. Partial rejection was dealt with simply by excision of a loop, total rejection simply by pulling on the tape, *as an office procedure*. Such tape rejection, in a small percentage of patients, is a small penalty to pay for vastly reducing morbidity, mortality, urinary retention, and hospital stay. A foreign body reaction depends on the quantum of foreign material inserted. A large mesh used in conjunction, will greatly increase the foreign body reaction rate. The IVS multifilament tape was used in 1999 because it was the only non-stretch tape available at the time. Even when rejected, it is much easier to remove than a monofilament tape. Unlike the monofilament TVT tape, there is no known report of a urethral fistula.

Used alone, my rejection rate was 1% for the midurethral sling, and 2% for the PIVS. The explanation for the high rates of rejection experienced by Dr Farnsworth may well lie in the combination of PIVS tape with large mesh or biological mesh. Mixed use does not seem so well tolerated.

The PIVS operation was never designed to repair the middle zone of the vagina, which has an entirely different fascial/ligamentous support system. Repair of the posterior zone will inevitably divert the intraabdominal forces to a subclinically damaged middle zone, causing cystocoele. This occurred in 16% of patients.<sup>4</sup>

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#### **Response to the letter from Professor Petros**

I thank Professor Petros for his letter to the editor. Whilst the anatomic points made by Professor Petros are correct the reality is that the Posterior IVS does not achieve a true Level 1 apical attachment. In order to provide a true apical attachment the IVS tape would need to pull the apex of the vagina up and back towards the insertion point of the uterosacral ligament over the medial end of the sacrospinous ligament, whereas the Posterior IVS tape passes down from where it attaches to the vaginal apex through the levator plate and into the ischiorectal fossa. It secures the vault to the levator muscle below the apex of the vagina. This is acknowledged by Jelovsek et al. when they performed cadaver studies on the anatomy of the Posterior IVS and commented that the "posterior IVS procedure appears to give support to the mid posterior vaginal wall rather than the vaginal apex".<sup>1</sup> They classified the procedure as a Level 2 support procedure rather than a Level 1 operation.

In order for the IVS tape to truly replicate the uterosacral ligament it would have to pass from one insertion point of the ligament to the other. Umek et al.<sup>2</sup> have shown that in 82% of patients the proximal attachment of the uterosacral ligament overlies the sacrospinous ligament and coccygeus muscle complex. My own clinical experience with posterior compartment reconstruction supports this finding and I have found an advantage in placing an independent apical support at this point.<sup>3</sup> The more posterior and medial the attachment

the better the anatomical restoration. When combined with an independent apical attachment the Posterior IVS is an excellent Level 2 support and is critical in ensuring adequate vaginal length and a normal vaginal orientation as it pulls the posterior fornix of the vagina downwards and backwards into the pit of the sacrum.

Professor Petros describes how creating a rigid attachment between the vagina and sacrospinous ligament reduces functionality. I agree that use of a high density mesh in conjunction with a posterior IVS leads to excessive fibrosis and reduces the cure rate for urinary urgency and other functional symptoms. This finding was reported in an abstract presented to the ICS.<sup>4</sup>

Professor Petros has come to the conclusion that an anatomically lower placed tension free attachment using the posterior IVS is preferable to an immovable tensioned attachment of the vagina to the sacrospinous ligament. However, the technique that I advocate does not rely on such a fixation, rather it is also a tension free Level 1 non absorbable suture attachment using quite a long suture bridge which extends from the proximal, medial end of the sacrospinous ligament to the cervix on each side (Fig. 1). The higher posterior apical attachment is more effective in recreating Level 1 and complements the important role of the Posterior IVS at Level 2 described above (Figs. 2, 3).

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Fig. 1. – The uterosacral ligaments (USL) extend from the coccyx to the cervix. The USL shares a common origin adjacent to the cervix with the sacrospinous ligament (SSL) which extends from the lower sacrum and coccyx to the ischial spine (IS). A suture bridge from position A to position B accurately recreates theUSL while a tape from position B to X or X1 does not. The traditional point of attachment of the Posterior IVS to the pelvic side wall is at position X below and medial to IS. Some surgeons advocate attachment of the Posterior IVS to the SSL itself at position X1. Position X1 is also the usual point of a attachment when performing a sacrospinous hitch procedure. A more physiological attachment of the vaginal apex can be achieved when the sacrospinous hitch is made to position A.



Fig. 2. – Lateral view of the position of a posterior IVS sling which extends from the cervix (position 1) to the point of insertion through the levator muscle (position 2) and then down into the ischiorectal fossa (3) to exit the skin of the buttocks. This does not replicate the true attachment of the uterosacral ligaments at position 2a.

Finally, the argument that Professor Petros uses to defend the multifilament tape is unlikely to sway the large number of pelvic surgeons who now only use monofilament tapes and no longer see tape related problems. We need to move forward as the battle to defend the multifilament tape is lost. Surgeons have continued to report mesh erosion, rejection and extrusion with the multifilament IVS tape up to ten years after the original implantation. These problems are not seen with the new monofilament IVS tape.



Fig. 3. – Superior ("birds eye") view of pelvic support ligaments. The Cervix (C) is the key support of the vaginal apex and uterus with ligamentous attachments to the pelvis (a: uterosacral ligaments, b: cardinal ligaments and c: arcus tendineous fascia pelvis. The uterosacral ligaments (USL) help support the rectum (R) which passes between them. The USL and SSL share a common insertion adjacent to the coccyx and lower sacrum at position A which is the best position for apical support. The Posterior IVS is attached to the levator plate at position B.

There is no doubt that the Posterior IVS has proven to be a landmark innovative procedure and Professor Petros has been responsible for a paradigm shift in our understanding of pelvic dysfunction. As the years go by we will all modify our clinical practice in response to our own experiences and the experiences we share with colleagues and each surgeon will individually determine the role of this procedure in his or her future surgical practice.

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# perineology

## LATEST NEWS FROM THE GROUPEMENT EUROPEEN DE PERINEOLOGIE

# EDITORIAL: PERINEOLOGY OR PELVIPERINEOLOGY: THE SAME GOAL BUT DIFFERENT APPROACHES

The name *perineology* was used for the first time in 1990 by Giuseppe Dodi. This colo-proctological surgeon used the name in an editorial of the journal Rivista Italiana di Colon-proctologia to speak about a new speciality dedicated to the management of all the functional pelvic floor disorders.<sup>1</sup>

Independently, a group of French and Belgian physicians and physiotherapists created the Groupement Européen de Périnéologie (GEP) and developed the concept of perineology, wrote a book about the subject<sup>2</sup> and published the definition of perineology<sup>2-6</sup> developing the subject well beyond Dodi's original vision.

According to this group, perineology can be described as:

- an interdisciplinary (only one specialist dealing with the patient), three axis (gynaecological, urological and coloproctological) and holistic approach to the patient
- dealing only with the functional problems of the perineum
- using "defect specific" treatments (restoration ad integrum)
- avoiding side effects on each of the three axis (primum non nocere)

Because of the strong limits of the concept (avoiding certain surgical procedures, only one specialist dealing with the patient...) and of a more "from the top" (endopelvic) vision of the pelvic floor, some physicians in France and Italy are more comfortable with the term pelviperineology. Pelviperineology includes all the aspects of the management of the pelvic floor without any restriction and refers to a more multidisciplinary approach.

Whilst perineology and pelviperineology are both using a global approach to obtain better patient outcomes, there may be differences in how this goal is achieved but confrontation of ideas is the only way to progress. It will be our pleasure to present a "GEP's corner" in the journal to review regularly some aspects of perineology and to introduce the concept to those of you who may be interested in learning more about this exciting and evolving area of medicine.

Jacques Beco *(Liège, Belgium)* Jack Mouchel *(Le Mans, France)* 

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### **UPCOMING MEETINGS**

# 6<sup>TH</sup> ANNUAL MEETING OF THE MEDITERRANEAN PELVIC FLOOR SOCIETY CAIRO, EGYPT APRIL 3-5 2008 - www.mspfd.org

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