

# PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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*Official Journal of Australian Association of Vaginal and Incontinence Surgeons,  
Integrated Pelvis Group, Perhimpunan Disfungsi Dasar Panggul Wanita Indonesia*

*Editors*

GIUSEPPE DODI - BRUCE FARNSWORTH



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EVA M. DE CUYPER, MALCOM I. FRAZER



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This section presents a small sample of the *Pelvic Floor Digest*, an online publication ([www.pelvicfloordigest.org](http://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

**Combined surgery in pelvic organ prolapse is safe and effective.** *Riansuwan W, Hull TL, Bast J, Hammel JP. Colorectal Dis. EPUB: 2009-02-12.* Results in the outcome of rectal prolapse surgery in 23 women having combined pelvic organ prolapse (uterine and bladder) surgery with a urologist or urogynecologist (CS) or 71 having abdominal rectal prolapse surgery alone (RP), were similar concerning complications, length of hospital stay, recurrence rate of RP, scores of ASA, CCF incontinence, KESS constipation and SF-36. Therefore surgeons should not hesitate to address all pelvic floor issues during the same operation by working in partnership with the anterior pelvic floor colleagues.

## 2 – FUNCTIONAL ANATOMY

**Do current bladder smooth muscle cell (SMC) isolation procedures result in a homogeneous cell population? Implications for bladder tissue engineering.** *Sharma AK, Donovan JL, Hagerty JA et al. World J Urol. EPUB: 2009-02-24.* Phenotypic analyses demonstrate cell heterogeneity when SMCs are acquired and cultured through conventional methods. Standardized criteria based upon objective experimentation need to be established in order to better characterize cells.

**Effect of age on the enteric nervous system of the human colon.** *Bernard CE, Gibbons SJ, Gomez-Pinilla PJ et al. Neurogastroenterol & Motil. EPUB: 2009-02-18.* The prevalence of constipation increase with age but it is unclear if this is due to confounding factors or age-related structural defects. The number and subtypes of enteric neurons and neuronal volumes in the human colon of different ages was studied in 16 patients (9 male), age 33-99. The number of neurons in the human colon declines with age and this change is not accompanied by changes in total volume of neuronal structures suggesting compensatory changes in the remaining neurons.

## 3 – DIAGNOSTICS

**POP-Q, dynamic MR imaging, and perineal ultrasonography: do they agree in the quantification of female pelvic organ prolapse?** *Broekhuis SR, Kluivers KB, Hendriks JC et al. Int Urogyn J Pelvic Floor Dysf. EPUB: 2009-02-18.* Pelvic organ prolapse staging with the use of POP-Q, dynamic MR imaging, and perineal ultrasonography only correlates in the anterior compartment.

**Nocturia: a non-specific but important symptom of urological disease.** *Schneider T, de la Rosette JJ, Michel MC. JOURNAL: Int J Urol. EPUB: 2009-02-20.* Nocturia is a urinary storage symptom with a major impact on patients' lives and a complex pathophysiology. Some of the possibly underlying non-urological diseases can be life-threatening, implying treatment priorities.

## 4 – PROLAPSES

**Complications from vaginally placed mesh in pelvic reconstructive surgery.** *Blandon RE, Gebhart JB, Trabuco EC, Klingele CJ. Int Urogyn J Pelvic Floor Dysf. EPUB: 2009-02-12.* Complications associated with the use of transvaginal mesh for treatment of pelvic organ prolapse (21 patients) including mesh erosions in 12, dyspareunia in 10, and recurrent prolapse in 9, 16 (76%) were managed surgically. Follow-up among sexually active patients showed 50% with persistent dyspareunia.

**Vascular considerations for stapled haemorrhoidopexy.** *Aigner F, Bonatti H, Peer S et al. Colorectal Dis. EPUB: 2009-02-19.* Modern techniques aim to interrupt arterial blood supply to the hypertrophied piles: stapled haemorrhoidopexy does not reduce arterial inflow in the feeding vessels of the anorectal vascular plexus as assessed by preoperative ultrasound.

## 5 – RETENTIONS

**The association between regional anesthesia and acute postoperative urinary retention in women undergoing outpatient midurethral sling procedures.** *Wohlrab KJ, Erekson EA, Korbly NB et al. Am J Obst Gyn. EPUB: 2009-02-19.* In a study on 131 women following outpatient midurethral slings, regional anesthesia (spinal or combined spinal/epidural) compared to nonregional (general endotracheal, monitored anesthesia care with sedation, or local) was a risk factor for acute postoperative urinary retention (defined as a failed voiding trial prior to discharge).

## 6 – INCONTINENCES

**Initial experience with a short, tension-free vaginal tape (the tension-free vaginal tape Secur system).** *Martan A, Svabik K, Masata J et al. Eur J Obst & Gyn Reprod Biol. EPUB 2009-02-03.* The tension-free vaginal tape Secur System procedure was performed in 85 women with previously untreated stress UI and the safety and efficacy of this new procedure for the treatment of stress urinary incontinence in women was evaluated. There were no perioperative complications, objectively 62% of these patients were completely dry and 25% of patients improved (cough test, POP/UI Sexual Function Questionnaire, ICI Questionnaire-SF). A higher proportion of vaginal wall erosion (7/85) and urgency de novo (5/85) in the learning period group with respect to the routine period group was observed.

## 7 – PAIN

**Phenol neurolysis for relieving intermittent involuntary painful spasm in upper motor neuron syndromes: a pilot study.** *Shafshak TS, Mohamed-Essa A. J Rehabil. EPUB: 2009-02-21.* To assess the efficacy of phenol neurolysis in relieving intermittent attacks of involuntary painful muscle spasm in patients with upper motor neurone syndromes, 19 patients with intermittent involuntary painful muscle spasm of the extensor hallucis longus or psoas major or tensor fascia lata or vastus lateralis were treated using a Teflon-coated stainless-steel injection needle. The frequency and severity of intermittent involuntary painful muscle spasm decreased in all patients for 24 weeks. Analgesic drugs were not required for the intermittent involuntary painful muscle spasm and no serious side-effects were observed.

**Successful treatment of refractory endometriosis-related chronic pelvic pain with aromatase inhibitors in premenopausal patients.** *Verma A, Konje JC. Eur J Obst & Gyn Reprod Biol. EPUB: 2009-02-24.* Aromatase inhibitors (anastrozole or letrozole, for 6 months) have been beneficial in four premenopausal women with chronic pelvic pain secondary to endometriosis refractory to conventional treatment. Fertility was not compromised and side effects have been minimal.

**Can transvaginal sonography predict infiltration depth in patients with deep infiltrating endometriosis of the rectum?** *Hudelist G, Tuttlies F, Rauter G et al. Human Reprod. EPUB: 2009-02-18.* The diagnostic accuracy of transvaginal sonography (TVS) was evaluated for preoperative detection of rectal deep infiltrating endometriosis in 200 patients with related symptoms. TVS appeared to be a highly valuable tool, being also possible to predict infiltration depth based on the distortion of characteristic morphologic features of the rectal wall before laparoscopic radical resection. TVS is less valuable for detection of submucosal/mucosal involvement.

**Genome-based expression profiles as a single standardized microarray platform for the diagnosis of bladder pain syndrome/interstitial cystitis (BPS/IC): an array of 139 genes model.** *Tseng LH, Chen I, Chen MY et al. Int Urogyn J Pelvic Floor Dysf. EPUB: 2009-02-14.* To investigate

*The PFD continues on page 88*

the molecular signatures underlying bladder pain syndrome/interstitial cystitis, cDNA microarray gene expression profiles have been studied. A "139-gene" model was discovered to contain high expressions of bladder epithelium, which feature in BPS/IC. Then complex metabolic reactions including carbohydrate, lipid, cofactors, vitamins, xenobiotics, nucleotide, and amino acid metabolisms have been found to have a strong relationship with bladder smooth muscle contraction through IC status. Finally, the transcriptional regulations of IC-induced bladder smooth muscle contraction status, were including the level of contractile force, tissue homeostasis, energy homeostasis, and the development of nervous system. The study suggested also the mast-cell activation mediated by the high-affinity receptor of Fc epsilon RI triggering allergic inflammation through IC status. All genetic changes are jointly termed "bladder remodelling" and can be a standardized platform for diagnosis and drug discovery for PBS/IC.

**Treatment of endometriosis of uterosacral ligament and rectum through the vagina: description of a modified technique.** Camara O, Herrmann J, Egbe A et al. *Human Reprod. EPUB: 2009-02-19*. The optimum way to diagnose endometriosis is by direct visualization of the implants. Four patients with a uterosacral ligament and rectal endometriosis, average tumour diameter 3.5 cm, complaining of rectal bleeding and lower abdominal pain in relation to their menstrual cycle were successfully treated with combined laparoscopic-transvaginal resection.

## 8 – FISTULAE

**A retrospective review of chronic anal fistulae treated by anal fistulae plug.** El-Gazzaz G, Zutshi M, Hull T. *Colorectal Dis. EPUB: 2009-02-18*. The efficacy of the anal fistulae plug (Cook Surgisis) for the management of complex anal fistulae was reviewed in 49 patients treated between 2005-2007. The fistulae etiology was cryptoglandular in 61% and Crohn's disease in 39%. The median follow up 221.5 days (range 44-684). The overall success rate was 8/32 patients (25%). Two of the 22 Crohn's (9.1%) and 9/26 (34.6%) cryptoglandular fistulae healed, failure being due to sepsis in 87% and plug dislodgement in 13%. Anal fistulae plug is then associated with a lower success rate than previously reported and septic complications are the main reason for failure.

## 9 – BEHAVIOUR, PSYCHOLOGY, SEXOLOGY

**Violence against women and the risk of foetal and early childhood growth impairment. A cohort study in rural Bangladesh.** Asling-Monemi K, Naved RT, Persson LA. *Arch Dis Child. EPUB: 2009-02-20*. Physical, sexual and emotional violence, and level of controlling behaviour in family against women is associated with increased risk impaired size at birth and early childhood growth, adding to the multitude of proven and plausible health consequences caused by this problem.

**Stress, workload, sexual well-being and quality of life among physician residents in training.** Sangi-Haghpeykar H, Ambani DS, Carson SA. *Int J Clin Pract. EPUB: 2009-02-19*. To assess the impact of stress and workload on sexual health and quality of life of the medical residents in training, in 339 male and female residents from 11 specialties level of stress, sexual health and QOL were measured using validated questionnaires. Overall, 49% of the female and 11% of male residents had sexual dysfunction, and 47% and 34% respectively indicated being very to mostly dissatisfied with their sexual life. Both the frequency of sexual activity and quality of relationship with partner having decreased during residency compared with the time immediately prior to residency. Long hours of work (> 70 h per week) impacted sexual health less profoundly than did stress.

## 10 – MISCELLANEOUS

**Endoscopic closure of the natural orifice transluminal endoscopic surgery (NOTES) access site to the peritoneal cavity by means of transmural resorbable sutures: an animal survival study.** von Renteln D, Eickhoff A et al. *Endoscopy. EPUB: 2009-02-14*. Endoscopic closure of the transgastric access site is still a critical area of active research and development into NOTES. Endoscopic gastrostomy closure by means of resorbable sutures was performed in 10 female domestic pigs in an animal survival study. Mean suturing time was 26 minutes (range 14 - 35 minutes). One case of gallbladder perforation occurred during peritoneoscopy and the pig was sacrificed due to peritonitis.

**Impact of marital status in patients undergoing radical cystectomy for bladder cancer.** Pruthi RS, Lentz AC, Sand M et al. *World J Urol. EPUB: 2009-02-17*. Married vs. unmarried individuals have improved health status and longer life expectancies in a variety of benign and malignant disease states, including prostate, breast, head/neck, and lung cancers. Also in patients undergoing cystectomy, married individuals appear to have improved pre-operative laboratory variables, shorter hospitalization, and improved pathological outcomes. These findings may support the evidence that married persons present earlier than unmarried individuals, and this may help explain the improved survival outcomes.

**Acupuncture for menopausal hot flashes: a qualitative study about patient experiences.** Alraek T, Malterud K. *J altern complem med. EPUB: 2009-02-17*. A randomized controlled trial investigated the effect of 10 acupuncture treatments on menopausal hot flashes in 127 women. Many reported a reduction in frequency and intensity of hot flashes by night and day, improved sleep pattern, feeling in a good mood, several were uncertain whether any changes had occurred, and a few women reported feeling worse. Further analysis is needed.



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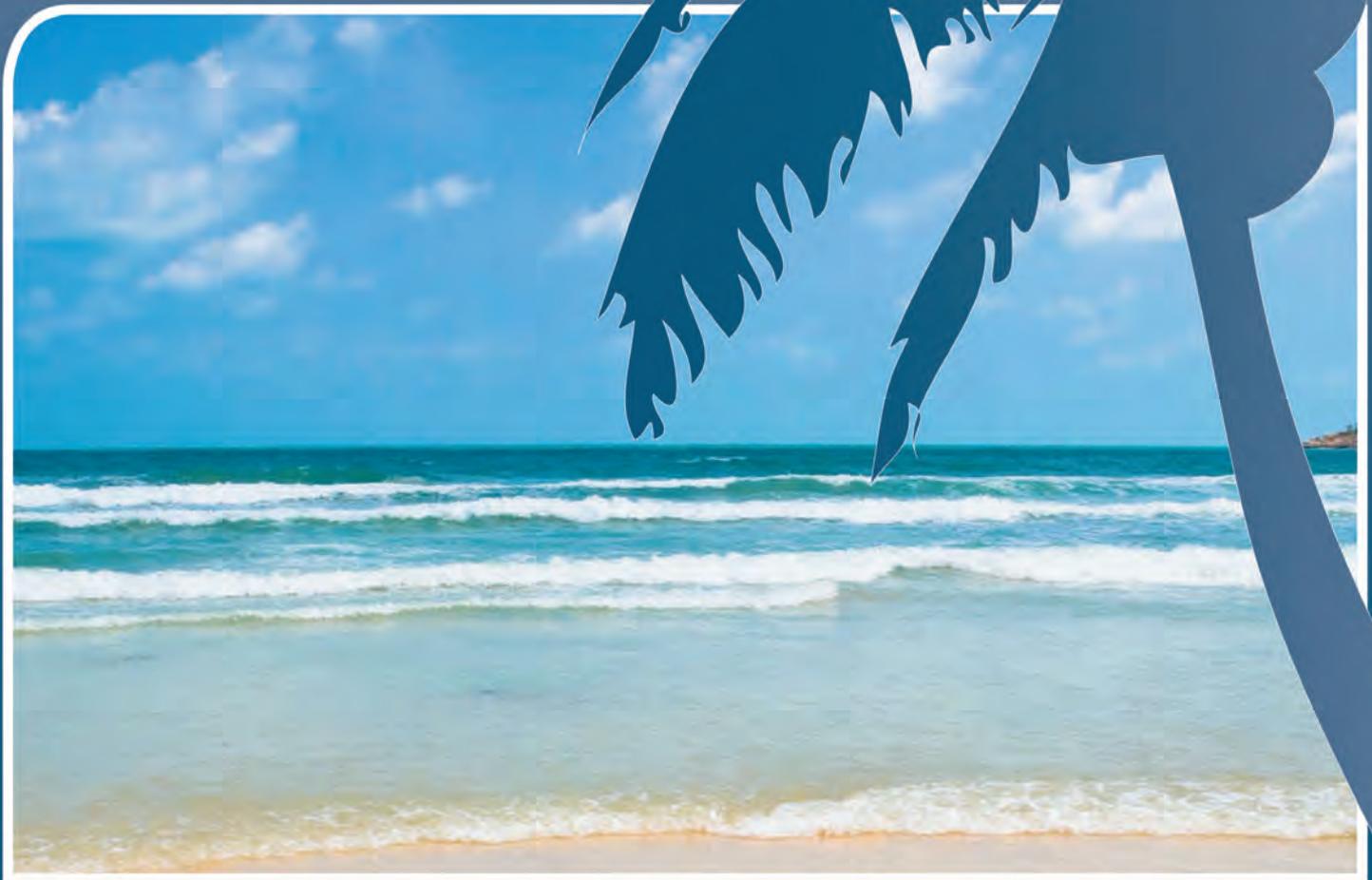
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# International Pelviperineology Conference



**Noosa Sheraton Resort and Spa July 30 – August 1 2009**  
**Noosa, Sunshine Coast, Australia**

*ABSTRACTS*

## AVOIDING & MANAGING MESH COMPLICATIONS OF SURGERY

### THE USE OF BIOLOGICAL MATERIALS TO AVOID COMPLICATIONS

Richard Reid

Newcastle University and University of New England, Australia

The use of prosthetic materials and trocar driven kits in prolapse repair has risen sharply, despite a paucity of safety and efficacy data. Much of this impetus has been driven by marketing claims, not prudent practice. There is an abundance of short term clinical series which over-emphasize anatomic outcome but under-emphasize the morbidity potential of these devices. There is an urgent need for a return to critical analysis and common sense. While the concept of evidence based medicine is laudable, it equally important to recognize that surgery is a craft. The effect of implanting a given biomaterial is largely determined by its biochemical properties. Before looking for statistical guidance, gynecologists should first ensure that their mesh usage does not violate these basic biochemical rules and that their decision making remains in accord with established surgical principles.

Implantation of a biomaterial evokes one of two possible host responses, depending on the biochemical make up and structural organization of the implant.

– Alloplastic biomaterials (eg, polypropylene) and denatured xenografts (eg, Pelvicol®) evoke a 'transplant rejection' immune response, orchestrated by an M1 macrophage infiltration. From this point forwards, the sequence of events is entirely predictable. There is invariably an initial foreign body giant cell inflammation, followed by late fibrosis at the host-implant interface. The resulting scar formation can be beneficial or morbid, depending on such local factors as tissue mobility and security of mesh fixation.

– In contrast, if an acellular mammalian connective tissue is prepared such that collagen structure remains architecturally normal and component matrix molecules remain viable (eg, Surgisis®), the xenograft will evoke a 'transplant acceptance' immune response, orchestrated by an M<sub>2</sub> macrophage infiltration. Under these circumstances, the implanted collagen scaffold will first be repopulated by host fibroblasts and angioblasts, and then remodeled into a new layer of strong human connective tissue. Default response now becomes one of tissue induction, rather than scar formation. Repairs with second generation biomaterials are just as permanent as with polypropylene, because constructively remodeled tissue is self-renewable under the control of collagen homeostatic mechanisms. Research has identified 'biodegradability' as the key factor in ensuring a constructive remodeling (rather than a scarring) response.

Preservation of an architecturally normal collagen structure and still viable matrix molecules creates a "biodegradable scaffold with an ingrained information highway".

There is a striking discordance in how information on extracellular matrix grafting has been received amongst engineers and scientists, as compared to surgeons. The development of tissue inductive therapeutic scaffolds has created a paradigm shift in Biomaterials Science; it has also attracted substantial investment from Industry. In contrast, 20 years of ingenious preclinical evaluation has passed virtually unnoticed in clinical circles. Prolapse surgeons have persisted in the use of unduly morbid polypropylene devices or cross-linked xenografts, articles from the do not achieve circulation amongst clinicians. There is an urgent need for surgeons to assimilate the knowledge attained through the preclinical experiments reported in the scientific literature.

1. Reid RI. A comparative analysis of biomaterials currently used in pelvic reconstructive surgery. In: Von Theobald P, Zimmerman CW, Davila W, eds. *Vaginal Prolapse Surgery: New Techniques*. Springer-Verlag, Guildford, U.K. 2009 (In Press).

### MESH? PESSARIES REVISITED...

David Molloy

Brisbane, Queensland - Australia

The use of various meshes in the repair of pelvic floor defects has blossomed over the past 15 years. There is clear evidence that some meshes have a definitive part to play in such repairs. However concerns have been raised that not all mesh products have been sufficiently tested to provide a strong evidence base for their use. There is a lack of randomized trials and products on the market

change regularly. Mesh is a long term prosthesis and as such does have potential longer term consequences and complications so establishing an evidence base is important. The skill base in the use of meshes needs ongoing encouragement and education

### AVOIDING THIGH PAIN IN TRANSOBTURATOR SLINGS

Menahem Neuman

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**Introduction:** The trans-obturator mid Urethral supportive sling were designed by Emanuel Delorm, the TOT (outside-in, 2001) and then by Jane de-Leval, the TVT Obturator (inside-out, 2003) to cure female urinary stress incontinence. This was thought to preserve the high therapeutic rate of the previously reported classic (retro-pubic) TVT (Ulmsten & Petros, 1996), and reduce the potential iatrogenic hazard for pelvic viscera and vessels. Bladder penetration and operative hemorrhage were reduced as anticipated, yet a trans-obturator related complication rose, the post-operative thigh pain. This obturator neuralgia was attributed to specific tissue damage caused by the device needle and tape passage through the obturator muscles. Acknowledging the need to avoid this patient and physician troubling thigh pain, suggested Folke Flam (Stockholm, 2007) a technical modification with the needle and tape passage of the TVT Obturator (TVTO). With the TVT Obturator Folke Flam Modification (TVTO-FFM) is the needle conducted as reported by de-Leval (2003) from the sub-urethral anterior vaginal cut, under the vaginal wall, laterally, up to the posterior aspect of the inferior pubic ramus. There, instead of being directed laterally to the thigh fold, it is advances medially to the fold, shaving the bone, exiting at the lateral aspect of the grate labia. Thus, the needle and tape are not crossing tangentially through the central region of the obturator complex of muscles and membrane but rather perpendicularly, at the antero-medial border of this complex. The passage is then definitely shorter and might probably cause less tissue damage, yielding less thigh pain.

**Patients and Methods:** 80 patients suffering urodynamically proved urinary stress incontinence were enrolled to undergo TVTO or TVTO-FFM. This was approved by the institutional board and conducted and patient informed consent was obtained. Peri-operative and curative data was prospectively collected. This included operative complications and post operative patient estimated vaginal and thigh pain levels according with visual analogue scale (VAS: from 0 = painless, to 10 = unbearable pain). VAS 0-3 was defined mild, 4-7: moderate and 8-10: severe.

**Results:** demographic, peri-operative and curative data was similar among the two patient groups. Vaginal pain was not recorded, yet by 9 TVTO patients and 7 TVTO-FFM patients had mild thigh pain. Moderate pain was experienced by 3 TVTO and none of the TVTO-FFM patients. No severe pain was mentioned. The pain was managed successfully with oral analgetics and lasted for up to 4 days.

**Conclusion:** the TVTO-FFM seems to reduce the TVTO related thigh pain, while not altering the cure rates. This deserves further estimation by larger patient series.

### OVERACTIVE BLADDER BEFORE AND AFTER SURGERY FOR PELVIC ORGAN PROLAPSE. PRELIMINARY RESULTS

Gianni Baudino\*, Brigida Rocchi\*, Oreste Risi\*\*,  
Antonio Manfredi\*\*, Pasquale Gallo\*\*\*

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\*\*\*Ob./Gyn. Second University of Naples

**Background:** Overactive bladder (O.A.B.) is associated with pelvic organ prolapse (P.O.P.). Traditional anterior repair improves both urgency and urinary urge incontinence (U.U.I.). In this study we report the prevalence of O.A.B. before and after vaginal surgery for P.O.P.

**Methods:** Post-menopausal women with pelvic floor defects  $\geq 3$  ICI POP-Q complaining of pelvic dysfunction were eligible for this open prospective trial. From February 2007 to September 2008 46 patients underwent surgery with autologous or prosthetic repair. The pre-operative assessment included: clinical history, W-IPSS, voiding diary, pelvic floor defects assessment according to the ICI POP-Q, standard urodynamic investigation.

**Results:** Forty-five patients were available for medium follow-up of 10.1 (6-12) months. The outcome is shown in tab. 1.

Obstructive symptoms with W-IPSS gave a medium pre-operative score of 16.7 (0-41). The medium score post-operatively was 4.7 (0-14). Anatomical results of the Ba point by the POP-Q are reported in tab. 2. The mean value of the Ba point at post-operative stage 2 is -0.5 cm.

TABLE 1. – Prevalence of O.A.B. before and after surgery for P.O.P.

	Urgency n. (%)	U.U.I. n. (%)	Urodyn. OAB n. (%)
Pre-op.	20/45 (44.5)	9/45 (20)	14/45 (31.1)
Post-op.	7/45 (15.5)	3/45 (5.5)	7/45 (15.5)
Cure rate	65%	66.6%	50%

TABLE 2. – Anatomical results of the POP-Q Ba point.

	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
Pre-op.		1 (2.2%)	6 (13.3%)	36 (80%)	2 (4.5%)
Post-op.	7 (15.5%)	17 (37.8%)	19 (42.2%)	2 (4.5%)	

**Conclusion:** Forty-five patients underwent vaginal surgery for POP with a medium follow-up of 10.1 months. Urgency was cured in 65%, U.U.I. in 66.6% and urodynamic O.A.B. in 50% of patients. The majority of patients had good to excellent anatomical results. Though surgery improves bladder dysfunction, in this study the anatomical outcome was not related with O.A.B. improvement.

## SEXUAL FUNCTION AFTER MESH SURGERY

L Ravikanti, VP Singh

Hamilton, New Zealand

Female sexual dysfunction is a highly prevalent condition in women with pelvic organ prolapse and in women with urinary incontinence. However only 30% of the clinicians screen their patients for sexual dysfunction in urogynecology clinics. Sexual function in women is multifactorial and is affected by psychological, biological, sociocultural and interpersonal factors. Pelvic organ prolapse seems likely to adversely impact on sexual function, potentially causing discomfort, urinary incontinence, or embarrassment during sexual activity.

There are only a few high quality studies assessing sexual function after mesh repair for pelvic organ prolapse and urinary incontinence. I would like to present a comprehensive review of literature on this subject along with the results of retrospective study of 38 women who had pelvic organ prolapse surgery using mesh in our own practice.

## IMPROVED SURGICAL TECHNIQUES TO MINIMISE COMPLICATIONS

Anthony Cerqui

Toowoomba, Queensland - Australia

Surgical complications are related to patient selection, surgical technique and choice of prosthesis. Improvements in surgical techniques help minimise complications in surgery with mesh prosthesis. Surgical techniques which allow attention to anatomical principles of level 1, 2 and 3 supports reduces risks of recurrence. Neuropathic, vascular and visceral injury are minimised with attention to techniques of dissection and improved instrumentation. Although mesh selection is clearly important in avoiding mesh erosion, avoidance of haematoma formation, appropriate mesh placement, surgical training, avoidance of hysterectomy, and appropriate patient selection help reduce risks of mesh erosion and dyspareunia. Close attention to surgical technique will continue to see steady improvements in the rates of complications related to pelvic reconstructive surgery.

## COMPLICATIONS OF TRADITIONAL PELVIC SURGERY

Philip Paris-Browne

Nowra, NSW - Australia

Complications of traditional vaginal prolapse surgery are frequently under reported. Numerically the most likely complication is failure to achieve cure of prolapse.

## IMPROVING THE EFFICIENCY OF THE TVM PROCEDURE

ON Shalaev, LY Salimova, TA Ignatenko

Department of Obstetrics and Gynecology, People's Friendship University of Moscow, Russia

For an improvement of results of POP surgery we modified the classic total TVM technology with additional fixing points in all

mesh parts. It'll reduce relapses risk considerably in better mesh smooth out, incomplete healing and vaginal erosions reduction. In new concept we offered synthetic implant Pelvix EVO by Lintex®. Total TVM in original form found by non-absorbable mesh block with laser processed edges for the purpose of falls prevention. There are eight implant arms – 4 in anterior and 4 in posterior part. Method essence in three-level vagina support and tension free strong pelvic organs fixation by mesh skeleton. Implant arms with introducers lead through reliable support points (anterior – AAFP symmetrically, posterior-sacrospinal ligaments). Non-absorbable thread passes through proximal and distal anterior arms symmetrically. That one and subcutaneous anterior arms sewing allows to straighten and strengthen implant completely. For posterior part strengthening and distal shrinking prevention posterior distal arms lead for puborectalis muscle on perineum above anus symmetrically. At hysterectomy, before mesh installation on rectum it leads in tunnel under vaginal mucous "isthmus". For vagina vault fixation, mesh smooth out and vaginal shortening prevention the mesh isthmus fixed additionally and tightened in sacral direction with non-absorbable thread leads through sacrouterine ligament, mesh isthmus and vaginal mucous isthmus without it piercing. With this method we operated 55 women. Follow-up in 2 years and one asymptomatic anterior relapse (I stage POP-Q), no erosions, incomplete healing. Thus additional support points allows to use light mesh that reduces complications rate in erosions, incomplete healing, dyspareunia.

## ANATOMY, PELVIC PAIN & SURGICAL CHOICES

### ANATOMICAL PRINCIPLES FOR STRESS INCONTINENCE SURGERY

Johan Lahodny

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During 1988 and 2008 the bladder neck heights of 350 healthy females were determined. All women were aged between 23 and 28. Only patients without incontinence and decensus were evaluated. None of the patients had given birth before. The definition of the term bladder neck height is the position of the bladder neck in relation to the posterior wall of the symphysis. The bladder neck height is determined by the lateral x-ray urethrocytogram. The bladder neck height is determined by the insertion height and the length of the ligamenta urethrotendinea and the ligamenta pubourethralia posteriora. Due to the anatomical differences (different insertion heights and lengths of the ligaments) every female has as continence feature different bladder neck heights. In 350 females we found 1% with a suprasymphysis bladder neck position (above the upper edge of the symphysis), in 9% a high located bladder neck (upper third of the posterior wall of the symphysis), in 36% a high mid position of the bladder neck (in the mid third of the posterior wall of the symphysis) and in 54% a low position of the bladder neck (lower third of the posterior wall of the symphysis). Through incontinence operations the descending bladder neck should be lifted to its original position. Knowledge about the different bladder neck heights is a prerequisite when selecting the correct operation procedure and to evaluate the success of the applied operation technique.

### FOOD INTOLERANCE AND IRRITABLE BOWEL SYNDROME - OR WHY THE NATUROPATHS HAVE GOT IT RIGHT FOR ALL THE WRONG REASONS

Susan Evans

Adelaide, Australia

We all have patients who have been to a naturopath and been put on a variety of restrictive diets for their bowel symptoms and pelvic pain. Sometimes our patients describe feeling so much better. Why is this?

Is there a better way of managing diet to achieve less pain, fewer symptoms and yet eat a 'healthy and well balanced diet'?

The latest scientific information on irritable bowel syndrome describes a mix of:

1. malabsorption of specific dietary components, rather than whole ranges of foods, and,
2. neuropathic sensitisation of the bowel

A more scientific approach to the management of bowel symptoms in women with pelvic pain is needed. So it can be explained

why some foods affect the bowel, which foods have to be avoided, and the interplay between nerves and the bowel can be understood.

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2. Kim DH, Murovic JA, Tiel RL, Kline DG. Surgical management of 33 ilioinguinal and iliohypogastric neuralgias at Louisiana State University Health Sciences Center. *Neurosurgery* 56: 1013-20, 2005.
3. 'Endometriosis and Pelvic Pain'. 2nd Edition. Dr Susan Evans. ISBN 978-0-646-51358-4. Available from [www.drsusanevans.com](http://www.drsusanevans.com)

### NEUROPATHIC PAIN AND ILIO-INGUINAL NERVE ENTRAPMENT

Susan Evans

Adelaide, Australia

Ilio-inguinal nerve entrapment causes pain in an area the size of a palm in either (or both) iliac fossae. Despite its abdominal wall origin, it is described as being intra-abdominal by the patient. Typically, it is worse with exercise or lifting heavy objects. It improves with rest or curling up into a ball. Frequently the diagnosis is missed, often for many years. It may develop spontaneously or come on after surgery including appendicectomy or laparoscopy.

Ilio-inguinal nerve entrapment can be diagnosed by being aware of the typical symptoms, using straight forward clinical tests in rooms, followed by resection of the ilioinguinal nerve at its exit point near the anterior superior iliac spine. This surgery is within the skill level of all gynaecologists, once they are aware of the technique.

This presentation describes how to diagnose ilio-inguinal nerve entrapment and how to resect the nerve.

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### PELVIC FLOOR PROLAPSE MESH RECONSTRUCTION - MESH CHOICE

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

be ruled out according with any particular mesh prior to usage, so should any mesh related bacteria nesting or harboring. This is generally the case with type 1 mono-filament macro-porous knitted meshes, not interfering with macrophages migration. Long lasting anchoring method were reported to involve ligament through passing mesh arms, thus the particular mesh attachments to the pelvic chosen supportive points should be proved before hands for long lasting support, preferably with mesh arms through ATPF or SS ligaments anchoring. Mesh and arm delivery systems for mesh individually prepared or pre-cut kits should be proven to yield the desired correct mesh and arms placement at the pelvic floor. Some pre-cut meshes might be too small to provide the necessary complete coverage of the whole fascial defects, thus easier to place because less dissection is required. Others might provide relatively easy arm placing devices, but at the price of improper arm passage at the deep ligaments of the pelvis for appropriate high support. These meshes might be prone to operative failure and recurrent prolapse. One should not be tempted for these easy to apply kits but rather go for the highly curative ones. Bio meshes where not proven to yield any advantage over the synthetic ones and one should not endanger his patients with bio-hazards. Smilingly, the absorbable meshes where not reported to entail any superiority and one should ask himself is there any potential benefit of a vanishing mesh in herniation repair at all. The list of available commercially manufactured products expands fast and the existing ones are regularly re-shaped, thus there is no point in referring to any particular currently available mesh. With this atmosphere of many newly designed meshes popping up almost monthly, one must be extra couches when choosing his own mesh. Of huge importance is solid clinical data, proving high cure rate and low rate of complications of mild nature. One should seek for proper training before adopting any new operation and maintain his skills with frequent operation performance.

### THE ROLE OF SURGERY IN VULVAR PAIN SYNDROMES

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Historically, complaints of chronic vulvar pain were generally attributable to one of several well-defined somatic diseases. Since the 1980s, however, there has been a flood of women presenting with introital dyspareunia and chronic unexplained vulvar discomfort, for which no clear-cut somatic diagnosis can be found. Consequently, there is now increasing consensus that vulvodynia is actually a *complex regional pain syndrome* (in past terminology, a "sympathetically maintained pain syndrome" or a "reflex sympathetic dystrophy"), rather than a structural disease process. In essence, vulvodynia is a spinal reflex, with afferent (sensory), central (dorsal horn) and efferent (motor) arms. There is no simple cure for vulvodynia. However, effective conservative therapies now exist. Whatever trigger factors initiated the vulvar hyperalgesia must first be nullified, and attention then directed to breaking the self-sustaining pain loop. This objective can potentially be achieved in several ways:

1. the *afferent limb* of this spinal reflex can be broken by use of a vascular laser to selectively destroy engorged blood vessels within the painful erythema on the vulvar vestibule. If successful, laser photothermolysis will disrupt transmission of pain messages within the hyperaesthetic perivascular nerve fibres
2. pain transmission within the *dorsal horn* can be down regulated with membrane stabilizing drugs, such as Allegron or Lyrica
3. myofascial pain within the chronically hypertonic pelvic floor musculature can be targeted using biofeedback to stabilize electrical transmission within the *efferent arm* the spinal pain reflex. Biofeedback is a specialised technique, which measures baseline muscle function via surface EMG electrodes, and then transmits these signals to a television monitor in real time. By studying the monitor, patients can be taught to isolate and break their chronic pelvic pain loops
4. occasionally, such additional measures as remedial massage for refractory myofascial pains in secondary muscle groups or hormone creams for symptomatic skin fissuring may be needed. Some couples also benefit from relationship counselling for secondary psychosexual disorders.

Overall, about 85% of patients will respond permanently to conservative therapy. However, small subsets of patients require a combination of medical and surgical treatment. Surgery is used in two circumstances:

- to break an otherwise refractory local pain reflex, by excising an area of tissue from which the most intense pain signals are arising. This objective can often be accomplished by either *vestibulectomy* or *microsurgical removal of the Bartholins' glands*. The

latter procedure requires special operative skills, but has the advantage of being less 'anatomy-altering' and more effective – reconstructive surgery may also require releasing a fourchette scar or widening the introital circumference to normal dimensions. Small contracture bands can be corrected by YV advancement. Otherwise, the best strategy is vulvoplasty with transposition of a pair of sensate skin flaps (based on the terminal distribution of the posterior labial artery and nerve).

## **RECTAL PROLAPSE, OBSTRUCTED DEFECATION SYNDROME AND RECTOCELE**

### **ASSESSMENT OF POSTERIOR COMPARTMENT PROLAPSE WITH ULTRASOUND**

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Approximately 30% of operations performed for posterior compartment prolapse (PCP), including rectocele, rectal prolapse, enterocele, peritoneocele, recto-anal intussusception, are re-operations. This indicates the need for treatment improvement, however many operations fail because of the causative mechanisms of various dysfunctions are not comprehensively clarified. Efforts at treatment improvement will only be possible through a diagnostic improvement. To understand what disease processes are involved in each woman's condition allows that treatment will be directed at a specific lesion. Ultrasonographic imaging, including high-resolution three-dimensional and dynamic endovaginal (EVUS), endoanal (EAUS) and transperineal (TPUS) ultrasonography, has become a valuable tool in the diagnostic work-up of patients with PCP. Scanning technique is performed according to the following steps:

**FIRST** - overall view of the relevant anatomic structures of pelvic floor with 3D-EVUS performed by a 12-16 MHz 360-degree rotational transducer. Assessment includes evaluation of anal sphincters, anorectal angle, pubovisceral and perineal superficial muscles, perineal body, levator and urogenital hiatus, and paravaginal spaces.

**SECOND** - posterior compartment anatomy and function is further evaluated with 2D/3D-EVUS performed by a 5-12MHz 180-degree rotational biplane transducer and with 3D-EAUS performed by a 12-16 MHz 360-degree rotational transducer

**THIRD** - assessment is concluded with B-mode and 3D and real time 4D-TPUS performed by a 6MHz convex transducer to have dynamic information on the mobility of the posterior compartment and levator ani.

Dynamic TPUS and EVUS provides measurement of the puborectalis contraction and the anorectal angle comparable with those obtained during defecography and can distinguish between different forms of PCP (true rectocele, perineal hypermobility and enterocele). Three-dimensional EVUS and EAUS allows the evaluation of levator ani damage, anal sphincters defects, perineal body deficiency, levator hiatus enlargement, lateral detachment of the pubocervical fascia to the arcus tendineus fascia pelvis. These techniques help in planning the type of prolapse surgery offered to a patient and to monitor the results after treatment.

### **THE ROLE OF THE STARR PROCEDURE**

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The physiology of defecation is a complex and poorly understood process. Obstructed defecation syndrome (ODS) is a disorder of the inability of the rectum to evacuate stool. Affected individuals report a sense of a 'blockage' in the anal canal, incomplete rectal evacuation and often the need to manually assist defecation. Clinical features include the presence of a rectocele, rectal intussusception, perineal descent, anismus, and solitary rectal ulcer. Individuals with ODS may be investigated by colonoscopy, intestinal transit studies, anorectal physiology, defecating proctogram and magnetic resonance defecography. The severity of ODS can be measured quantitatively by one of several scoring systems. ODS should be initially managed non-surgically with general supportive measures, dietary advice, laxatives, and pelvic floor rehabilitation in a multi disciplinary setting. The stapled transanal rectal resection (STARR) procedure involves circumferential resection of full thickness rectal wall, thereby addressing the dual pathology of rectocele and

intussusception. Complications including bleeding, infection and rectovaginal fistula are rare. The STARR procedure produces an improvement in bowel function in two thirds of patients who have been carefully selected.

### **EARLY COLORECTAL EXPERIENCE WITH VAGINAL MESH SURGERY**

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Outlet obstruction is a common symptom in patients presenting to colorectal surgeons, with rectocele the commonest diagnosis. Colorectal surgeons have either ignored the problem, referred to gynaecologists or attempted a trans-anal repair, usually a Delorme's type procedure. Posterior vaginal mesh repair with sacro-spinal fixation is an easy to learn technique. The plane of dissection is useful in other colorectal procedures such as prolapse repair, artificial bowel sphincter placement and recto-vaginal fistula repair. This paper will present the first 25 vaginal mesh repairs. All had proctograms prior to surgery. There were three mesh erosions, each successfully treated with partial removal and debridement of the mesh. One patient has pain at the buttock incision. One patient had serious urinary tract sepsis. All patients have had improvement in symptoms; 20 no longer need aperients. Three patients have had repeat proctograms; all have shown objective improvement in rectocele size and emptying. Vaginal mesh repair would seem to be an effective method in the treatment of rectocele with a low complication rate.

### **EVOLUTION OF A NEW MESH TECHNIQUE IN THE POSTERIOR COMPARTMENT**

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**Background:** In our Pelvic Floor Unit the treatment of POP has been modified through the years. Before 1997 genital prolapses were corrected by a Y shaped polypropylene mesh fixing, after adequate mobilization, the bladder, the vault/cervix, and the rectum (in case of complete or internal prolapse, with preservation of the rectal stalks), to the sacrum. In order to improve the results and to avoid recurrences due to lateral defects, we developed a so called "butterfly mesh", creating an abdominal *total pelvic floor repair*. The mesh was fixed to the sacrum, the vault/cervix, the bladder, the Cooper's ligaments, the psoas muscles and, if necessary, to the rectum. The overall correction rate was of 96%. The elaboration of the Integral Theory by Petros and Ulmstein<sup>1</sup> and its evolution<sup>2-6</sup>, has introduced new mini-invasive techniques to treat urinary incontinence and genital prolapses. The main interesting features of this new surgical approach have been the good anatomical and functional results associated to short hospital stay, rapid recovery, reduced postoperative pain and invisible scars. The first reports in Infracoccygeal slingplasty (ICS) had showed a prolapse recurrence of 6-9%<sup>2,8</sup>. Searching a less invasive approach than the abdominal one, in 2006 we designed a prospective randomized study to compare the safety and the efficacy of the trans-vaginal ICS and of the abdominal butterfly mesh procedure. The ICS success rate was 60% with recurrent genital prolapse in 40% of the cases. There were no recurrences in the abdominal group.

The high failure rate of ICS drove us to look for a different mini invasive transvaginal technique and, from 2007, we have adopted the advanced pelvic floor repair (AMI CR-Mesh<sup>TM</sup>).

#### **RANDOMIZED STUDY: ICS VS ABDOMINAL SURGERY**

**Methods:** From February 2006 to September 2007 thirty consecutive patients with genital and rectal prolapse (HWS>2, POP-Q≥2) were randomized into two groups (Tab. 1): fifteen patients were treated with ICS technique (group A) and fifteen with a trans-abdominal colpo-(recto)-sacropepy technique (group B). Patients were evaluated preoperatively with a multidisciplinary visit (urological, gynaecological, proctological), imaging (cysto-colpo-defecography, transanal ultrasound, abdominal ultrasound, barium enema) and with functional exams (anal manometry, solid sphere test, urodynamic study, colon transit time). Faecal incontinence if present was evaluated before and after surgery with CCIS (Cleveland Clinic Incontinence Score),<sup>8</sup> AMS (American Medical System score)<sup>9</sup> and FIQL (Faecal Incontinence Quality of Life)<sup>10</sup> and the constipation with constipaq<sup>11,12</sup> / CSS (Constipation Scoring System)<sup>13</sup> and PAC-QoL.<sup>14</sup> Pre and postoperative quality of life was evaluated with SF-36. IPGH<sup>15</sup> classification system was used to resume all data concerning incontinence, pelvic floor and prolapse, general factors and handicap.

TABLE 1. – Patients of the randomized study.

	Infracoccygeal Sacropexy Group A	Abdominal Surgery Group B
mean age (range)	69,3 (53-81)	61,7 (62-75)
parity (range)	2,5 (1-5)	2,6 (1-4)
menopause	14	6
hysterectomy	4	5
rectal prolapse/intussusception	2 (r1)	3
urinary incontinence	3	1
fecal incontinence	1	1
previous surgery for U.I.	-	-
previous surgery for genital prolapse	6	4
previous anal/rectal surgery	1	-
sexually active	4	4

**Results:** None of the patients were using hormone replacement therapy at time of surgery. Three patients of group A had stress urinary incontinence and one had fecal incontinence (CCS=9) associated with rectal recurrent prolapse after Delorme's procedure. One patient of group B had urinary stress incontinence and one with associated rectal prolapse had fecal incontinence (CCS=6). Constipation was present in four patients in group A with a mean constipation score of 9 and in two patients of group B with a mean constipation score of 6.

The association between rectal and genital prolapse was present in three patients in group B. The patient of group A with rectal prolapse was treated in the same session with an Altmeier procedure with recurrence of the rectal prolapse at one month after surgery. The recurrence was treated with Thiersch encirclement. All rectal prolapses in group B were successfully corrected in the same operation. The mean time for abdominal surgery was 165±20 minutes and for ICS surgery 47±10 minutes. Volumes of blood loss were greater in trans-abdominal surgery (mean 195±50 cc) than in ICS where the blood loss was virtually zero. The mean hospital stay was 7.9±1.9 days for abdominal surgery and 5.8±2.8 days for ICS surgery. There was a mean follow-up of thirty months. No recurrences of genital prolapses (POP-Q>2) were detected in group B. In group A there were six (40%) recurrences: one POP-Q stage IV, three POP-Q stage III and two symptomatic POP-Q stage II. One of the recurrence was actually a "new prolapse" in the anterior compartment following the posterior compartment prolapse correction. Fecal incontinence associated to rectal prolapse disappeared after the correction of the prolapse and all four patients (3 in group A and 1 in group B) suffering of urinary incontinence showed a resolution of their dysfunction. In group A during the post-operative period, a patients developed an unexplained severe urinary retention needing long term bladder intermittent catheterization. This patient was operate to correct a posterior vaginal wall prolapse.

**The evolution:** From 1996, sixty six abdominal surgical procedures for treatment of isolated genital prolapse or the association of genital and rectal prolapse were performed in our department with a correction rate of 96% (postoperative HWS stage <2). There were four severe postoperative complications: two urethral obstructions (one treated with urethral stenting and one with necessity of re-operation) and two femoral nerves lesions. The development of Integral Theory and the evolution of the transvaginal techniques suggested us to try a new less invasive surgical approach with the expectation of a lower morbidity and of comparable results. In our study the ICS technique showed consistent advantages such as a short operative time, no need for extensive dissection and no intraoperative complications, but the cure rate was unacceptably low (60%), and a postoperative unexplained urinary retention was observed. This high incidence of recurrence forced us to look for a more efficient, still mini-invasive, surgical approach. From 2007 we started using a different transvaginal technique with a mesh fixed to the sacrospinous ligament and to the perineal body for posterior compartment and to the obturator membrane for the anterior compartment (advanced pelvic floor repair surgery (APFR) (Tab. 2). Until now we have treated 23 patients with symptomatic POP: five POP-Q grade IV, 16 POP-Q grade III and 2 POP-Q grade II. After a mean follow-up of 8.1 months eleven patients have a POP-Q grade 0, seven a POP-Q grade I and five a POP-Q grade II. Interestingly all five patients with a POP-Q grade II (21%) after

TABLE 2. – Patients treated with advanced pelvic floor repair.

mean age (range)	59,9 (41-85)
parity (range)	2 (1-4)
menopause	19
prior U.I. procedure	1
prior prolapse surgery	11
prior hysterectomy	14
prior rectal surgery	2
rectal prolapse/intussusception	2 (r4), 3(r2), 3 (r1)
sexually active	12

surgery have a prolapse in the non treated compartment. So they are not considered a relapse of POP but affected by a new prolapse probably created by the new force vectors.

Comparing APFR surgery with the ICS technique, the mean duration of operation (144±78 minutes), the blood losses (150±93.5 cc), the mean duration of hospital days (8.2±3.7 days) and the intraoperative and postoperative complication were significantly higher. These data are probably due to the more complicated procedure (wider dissection for the correct positioning of the mesh) and the learning curve. The intraoperative complication were a bladder perforation occurred during the dissection of paravesical spaces in an anterior-posterior correction, and a rectal perforation in a patient with a wide rectal prolapse previously corrected with a Thiersch anal encirclement. The postoperative complications were two cases of pelvic haematoma treated conservatively (antibiotic therapy and blood transfusion), two with urinary infection and a case of obturator neuropathy. We observed 3 cases of mesh erosion between 2 and 9 months postoperatively. The high hospital stay observed was due to a difficult recovery of the bladder function. In our protocol 48 hours after the operation we remove the bladder catheter and we evaluate the amount of post-voiding residue that has to be less than 100 cc for the discharge of the patient. Preoperatively constipated patients reported a mild improvement in defecation. The correction of the posterior vaginal wall prolapse significantly reduced the mean CSS from 10 to 7.5. A very interesting observation was the simultaneous correction of genital and complete rectal prolapse in two patients: one rectal prolapse relapsed at six month and the other is reduced after four months. The main postoperative symptom reported from patients is pain during sexual intercourse. Fifty eight per cent of the sexually active treated women reported this dysfunction. This problem isn't reported by patients treated with ICS technique or abdominal approach.

**Conclusions:** Surgical approach for the treatment of genital prolapse remains subject of controversy. The choice of operation has to be made evaluating carefully patient's ages, symptoms and associated pelvic defects (rectal prolapse). The aims of reconstructive pelvic surgery are to relieve symptoms, to correct the prolapse restoring the pelvic anatomy, to correct if possible the co-existing voiding and bowel dysfunctions, and to improve the quality of life. In our study the ICS technique had a low success rate. The APFR has shown a high correction rate: the genital prolapse disappeared in all patients. Five patients with postoperative POP-Q stage=2 have not to be considered a relapse but just a new prolapse due to a modification of pelvic force vectors that acting in a diffuse pelvic connective tissue alteration. These data could represent, if confirmed by other studies, an indication to support also the opposite compartment during the same procedure, in order to avoid a new operation for a problem that the patient perceives like a failure. About half of the sexually active patients reported pain during intercourse. This symptom is not present in patients after ICS or abdominal surgery. This dysfunction may be related to the dimension of the mesh and the fibrosis or shrinkage reducing the vaginal compliance. To avoid postoperative pain seems to be the main problem in our patients. A solution to be considered might be a balance between the anatomical results (relapse) and the reduction of the mesh size (fibrosis).

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## MALE PELVIC DYSFUNCTION

### **“FLOWSECURE™” ARTIFICIAL URINARY SPHINCTER: A NEW ADJUSTABLE ARTIFICIAL URINARY SPHINCTER CONCEPT WITH CONDITIONAL OCCLUSION FOR STRESS URINARY INCONTINENCE**

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**Objectives:** Despite the fact that the AMS-800 artificial urinary sphincter (AUS) has shown good long term clinical results, a surgical revision rate of over 30% has been reported. A number of these revisions are secondary to reappearance of incontinence following tissue atrophy. Others are the result of complications including erosion, mechanical failure and infection. The novel FlowSecure AUS with conditional occlusion was designed to address these problems and preliminary clinical results were published in 2006. Our objectives are to spread surgical technique and management of patients with the new device.

**Methods:** The FlowSecure sphincter consists of an adjustable pressure-regulating balloon, a stress relief reservoir, a control pump and valve assembly unit with self-sealing port and a urethral cuff. The pressure regulating balloon determines the operating pressure of the device; the pressure is adjustable in the range 0-80 cm H<sub>2</sub>O and can be altered by injection or removal of normal saline through the self sealing port. The stress relief balloon transmits transient intrabdominal pressure to the cuff during periods of stress. An adjustable circular urethral cuff minimises creasing and possible stress fractures.

**Results:** The surgical technique is simple for both bulbar urethra and bladder neck and associated with little handling, reducing risk of infection and potential assembly errors. The adjustable pressure

regulating balloon in association with the stress relief reservoir enables the cuff occluding pressure to be set at a low range, therefore reducing the risk for atrophy and erosion.

**Conclusions:** Medium term results suggest that the FlowSecure device may be an alternative to the AMS-800. However, long term results are needed to compare performance of both artificial sphincters. The new FlowSecure urinary artificial sphincter with conditional occlusion is designed to provide good continence rates adjusting regulating pressures when needed and conceived to reduce the risk of potential complications associated with excessive occluding pressures and mechanical failures.

### **THE ARTIFICIAL URINARY SPHINCTER IN THE MANAGEMENT OF MALE URINARY INCONTINENCE**

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The Artificial Urinary Sphincter (AUS) has been used in clinical practice since 1973. With multiple modifications to the original design the current model of AMS 800 prosthesis was developed for clinical practice from 1983. It is now considered the gold standard for treatment of male urinary incontinence. This paper reports a personal series of AUS implantation in 81 patients from 1982. All patients suffered intrinsic sphincter deficiency with a urodynamically proven compliant bladder with acceptable bladder capacity. Surgical approach, cuff position and pressure were dependent on the aetiology of the incontinence with some type of prostatic surgery being the most common cause of the incontinence. The paper outlines the quality of continence that can be achieved but acknowledges the potential problems of prosthetic surgery. With attention to detail, rates of infection, urethral erosion and device failure can be minimised. The implantation of the AUS can provide a continence rate superior to that obtained with more conservative techniques.

### **THE ARGUS SLING**

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The ideal sling to treat male incontinence would be effective and reliable, easy for patient to use, able to cope with all degrees of incontinence, and would be safe, with no long-term complications as well as being simple to implant and able to be removed easily if any problems develop. The Argus and Argus-T slings are soft silicone pads placed around bulbar urethra and suspended on “notched” silicone columns and supportive washers.

The sling is adjustable, able to be tightened or loosened any time after implantation. The pad is outside bulbo-spongiosis, not directly on the urethra and it is a compressive device, able to be tensioned to achieve a desired urethral retrograde leak point pressure. Argus is a “bottom-up” approach, can be “top-down” and the Argus-T is a trans-obturator “top-down” approach. The results and details of 37 patients (5 Argus-T) treated between November 2005 - May 2009 will be presented showing, that of 35 patients with slings in situ 68 % are dry, 26 % are improved and 6 % failed (removed slings and not replaced).

## CONTROVERSIES IN URINARY INCONTINENCE

### **HISTORY, URODYNAMIC DIAGNOSIS AND DISEASE-SPECIFIC QUALITY OF LIFE IN WOMEN PRESENTING TO A GYNAECOLOGY CLINIC WITH URINARY INCONTINENCE**

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The bladder has historically been considered an “unreliable witness” such that the majority of experts recommend urodynamic evaluation before surgery for stress incontinence. This recommendation is backed up with data from several now quite old studies that show that even in the simplest presentation of a history of pure stress incontinence the diagnosis is altered by urodynamics in a clinically significant way in about 18% of cases. Despite that, it has never been convincingly shown—possibly because the question is yet to be properly addressed—that preoperative urodynamics improve patient outcome, although one, recent small randomised trial tended to statistically significant benefit in women having stress incontinence confirmed urodynamically. More recent litera-

ture has challenged the older notion that mixed incontinence is a poor prognostic indicator for surgery, with many authors now showing that the outcome for tension free vaginal tape procedures is similar whether the patient has pure stress or mixed incontinence. It is, therefore, reasonable to challenge the value of preoperative urodynamics. This paper will present data from a prospective study of 444 women presenting to the gynaecology unit of the Lyell McEwin Hospital, Elizabeth Vale, South Australia for urodynamic evaluation, relating the clinical and urodynamic diagnoses and Quality of Life (QoL) parameters using the Kings Health Questionnaire. The main findings were: (1) of the 349 women presenting with a history of stress or mixed incontinence, 39% did not have urodynamic stress incontinence - with or without or detrusor overactivity (thus by our criteria would not be considered suitable surgical candidates); (2) the QoL of women with a normal urodynamic study was significantly better than the remainder of the cohort; (3) the QoL of women with urodynamic stress incontinence was as poor as women with other abnormal urodynamic diagnoses; (4) 15% of the 95 women with a history of pure urge incontinence had urodynamic stress incontinence - with or without or detrusor overactivity (thus by our criteria would be considered candidates for surgery). These data indicate that in our referral population the clinical diagnosis is even less reliable than expected from published data. This is best explained by selection bias in favour of more complex or severe cases evident in earlier studies. The very clear difference in QoL observed between diagnostic categories supports the notion that urodynamic studies are identifying women with more severe forms of urinary incontinence. We can debate whether women with a clinical diagnosis of stress incontinence that is not confirmed by urodynamic studies should be considered for surgery. However, women with urodynamic stress incontinence are a different, more severely affected group of patients. This is very relevant when considering surgical techniques, comparative data on surgical outcomes, and the probability of cure from non-surgical methods.

#### AN INTERNATIONAL UROGYNECOLOGICAL ASSOCIATION (IUGA) - INTERNATIONAL CONTINENCE SOCIETY (ICS) JOINT REPORT ON THE TERMINOLOGY FOR FEMALE PELVIC FLOOR DYSFUNCTION

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**Objective:** To develop a user-friendly, clear and clinically-based consensus Report on the Terminology for Female Pelvic Floor Dysfunction.

**Background:** Terminology for Female Pelvic Floor Dysfunction has become more complex, whereby there is a need for it to be more clearly defined in a female specific approach. Such terminology, in any form, has not been updated for seven years. Such a Report should involve joint sponsorship from the two International Organizations involved in such Terminology, ICS and IUGA. It was the intention that a process of collective opinion (consensus) could be developed between representatives of these Organizations with an appropriately diverse range of expertise and special interests to facilitate the production of such a large Report.

**Methods:** A Draft Report was prepared organizing the Terminology for Female Pelvic Floor Dysfunction into appropriate clinical categories: (1) Symptoms; (2) Signs; (3) Investigations; (4) Diagnoses. An appropriate sub-classification was developed such that each definition in the Report had an appropriate alpha-numeric descriptor. Definitions were drawn from a wide range of sources including previous ICS and other Society Reports, and a multitude of other sources and references. Fifteen rounds of Committee review then ensued, three involving members of the IUGA Standardization and Terminology Committee, a further four involving a joint IUGA/ICS Working Group (ICS representatives were from their Terminology and Standardization Committee) and a further eight rounds involving the full eleven co-authors representing both IUGA and ICS. Each round involved independent review by relevant Committee Members, collation of comments and final decision-making on definitions, additions and deletions based on collective opinion. The review process by consensus involved live Meetings on four occasions in London, Taipei, Cairo and Lake Como. Versions 9, 10 and 12 were subject to review by a total of six invited external reviewers. There were further extensive comments by eight interested reviewers following presentation on the

websites of both IUGA and ICS. Eight experts chosen by ICS and IUGA Executives reviewed version 16. On each occasion, the independent comments were collated, submitted to co-authors for further independent review with decisions again made on the basis of collective opinion (majority or unanimity).

**Results:** A Terminology Report encompassing over 250 separate definitions has been developed over 2 years. It is clinically-based with the six most common diagnoses (evidence for prevalence of 10% or more in women with symptoms of pelvic floor dysfunction) clearly defined. New definitions for the diagnoses of voiding dysfunction, bladder oversensitivity and recurrent urinary tract infections have been added to the existing ones of urodynamic stress incontinence, detrusor overactivity and pelvic organ prolapse. The process for achieving this result has involved very extensive review and, at times, healthy debate. Consensus between hard-working, motivated, knowledgeable and flexible Committee Members, assisted by expert and committed reviewers, has proved successful in bringing to completion a most complex document. Clarity and user-friendliness have been key aims to make it interpretable by practitioners and trainees in all the different specialty groups involved in female pelvic floor dysfunction. Female-specific imaging (ultrasound, radiology and MRI) has been a major addition whilst appropriate Figures have been included to supplement and help clarify the text. Ongoing review is not only anticipated but required to keep the document updated and as widely acceptable as possible.

**Conclusions:** Consensus has proved to be a successful process for developing a complex Report such as that for the Terminology for Female Pelvic Floor Dysfunction. It requires hard-work, knowledge, flexibility and goodwill amongst those involved in the process. The overriding motivation needs to be the development of a Report as widely acceptable in its content as possible, so that it will advantage both the clinical and research aspects of the field. Regular updates will be required.

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### FECAL INCONTINENCE

#### A PILOT STUDY: THE ANAL SPHINCTER SUPPORT PROCEDURE FOR THE TREATMENT OF ANAL INCONTINENCE

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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 with up to 30% having 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, however presents a novel way of supporting the external anal sphincter with a circlage tape prosthesis. Based on the experience of a tension-free mid sub urethral tape used to treat stress urinary incontinence which has been so successful, a pilot study was devised for patients presenting with mild faecal incontinence and who were all parous amongst other etiological conditions. Study results were of 14 patients over a mean follow up period of eighteen months. Outcomes were very encouraging with between 70 & 100% resolution of symptoms. There were no observed complications of note. This pilot study demonstrates that the Anal Sphincter Support Procedure (ASSP) provides a safe and effective method of restoring ano rectal continence and can be used successfully with concomitant procedures which may be necessary for restoration of pelvic floor anatomy and function.

**Addendum:** Since this study commenced in June 2006 the mean average time of patient follow up has been 3 years. The Mean

Wexner Score Grading profile of 12 of these patients (two patients were lost to follow-up) was sustained with quality of life profiles remaining at a mean improvement with respect to anal-continence of between 70%-90%. A further 25 patients have benefited from the procedure with similar results since the study was commenced.

#### CLINICAL APPROACH TO FAECAL INCONTINENCE

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Decision making in faecal incontinence begins with appropriate clinical assessment. It is important to determine whether patients have mainly passive, active or mixed incontinence, as well as to assess the severity of symptoms and impact on lifestyle. Possible causes of incontinence should be looked for such as obstetric injury (use of forceps during vaginal delivery is a useful pointer to such injury) and previous anal surgery for fistula and fissure. Clinical assessment to exclude rectal prolapse is very important as occult prolapse is often missed and yet is a surgically treatable cause of incontinence. Finally, pelvic floor studies are very useful to confirm the presence of anal sphincter injuries with ultrasound and to correlate such injuries with reduced resting and squeeze pressure. Prognosis for sphincter repair in the presence of pudendal neuropathy is probably less good but the reliability of pudendal nerve latency testing has been questioned. Treatment options for faecal incontinence usually begin with non operative approaches. These include bulking agents, constipating drugs like Imodium, physiotherapy and treatment of underlying colonic diseases such as colitis. Surgical treatment of faecal incontinence has evolved over several decades with many operations described and then abandoned or superseded. At present the principal operations used in the treatment of faecal incontinence are direct sphincter repair, repair of rectal prolapse, injection of biological agents like PTQ and sacral nerve stimulation. It is still generally accepted that the first surgical approach for patients with anterior obstetric injuries is surgical repair, either direct apposition or with overlap of scar. This can be performed via a perineal or transvaginal approach. Wound breakdown and delayed healing can cause significant distress for patients in the early post-operative period and while most patients experience good improvement in continence after sphincter repair, the results tend to deteriorate over time. Patients who have incontinence associated with rectal prolapse, either overt or occult, are usually better after the prolapse is repaired. Even when continence is not improved there is likely to be slower deterioration and therefore surgery should be offered to all patients with prolapse, even the elderly. Results for perineal operations are nearly as good as for abdominal procedures although recurrence is certainly more common. Patients with active incontinence in the absence of a major external sphincter injury, or after failed sphincter repair should be offered sacral nerve stimulation. This procedure has been widely reported in the world literature with consistently good results in at least two thirds of patients and with an impressively low morbidity. This is especially in comparison with the operations it has superseded such as dynamic graciloplasty and artificial bowel sphincter insertion. This procedure is relatively expensive but has the advantage of a trial period of temporary stimulation to select out patients who are likely to benefit from permanent stimulation. In the Australian context it is very pleasing that the government has determined to support this operation with a Medicare item number and it is important that it becomes available to public patients as well as in the private system. Injection of agents such as collagen, Duraspheres or PTQ is the latest surgical approach available in Australia. This procedure has failed to qualify for a Medicare number and its availability is likely to be restricted in future. It is used in patients with isolated internal sphincter dysfunction due to degeneration or injury such as following sphincterotomy, and who experience mainly soiling. Agents are injected into the inter-sphincteric space and may be more effective if ultrasound is used to direct injection. It has a very low complication rate and is effective in more than two thirds of appropriately selected patients.

#### SACRAL NEUROMODULATION

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Sacral nerve stimulation (SNS) is a form of neuromodulation in which an electrode is placed into the S3 foramen and attached to an implantable pulse generator (IPG). It acts by stimulation of the sacral motor nerves causing contraction of the external sphincter ani. However there is also stimulation of ventral and dorsal nerve roots resulting in sympathetic and parasympathetic effects on the

colon, rectum and internal sphincter. These effects will be demonstrated. A short video of the procedure will be shown. The technique is efficacious in treating faecal incontinence in up to 90% of patients who pass a trial of stimulation. Infection rate is 4%. Initial costs are high but ongoing costs are negligible making the technique cheaper than a stoma in the long term. There is a trial of SNS for treatment of slow transit constipation currently underway and this will be presented.

#### THE IMPLANTATION OF THE A.M.I. SOFT ANAL BAND SIGNIFICANTLY IMPROVES FECAL INCONTINENCE AND QUALITY OF LIFE

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Faecal incontinence (FI) challenges patient's professional, social and sexual life. Although widely applied conservative treatment (like dietary measures, pelvic re-education, biofeedback, bulking agents) may not be very successful. Then, surgical options become important. If possible, a sphincter defect is reconstructed. If not, in our institution a sacral nerve stimulation (modulation) is the next step to treat FI. If that does not help to improve FI the soft anal band (Fa. A.M.I.) is offered to the patient. This artificial sphincter is a mechanical system consisting of a circular cuff surrounding the anal canal, a water containing balloon which closes the anus when squeezed by ballooning the membrane of the cuff and a valve allowing the anus to open up when pressed by evacuation of the cuff. So far, 21 patients received a soft anal band without any infection or penetration problems. The system is operated by the patient easily and is very effective in preventing FI episodes. Judgement by the patients reveals very great improvement of the quality of life. In conclusion, implantation of the soft anal band is a ultimate and very valuable surgical procedure for FI with good functional results and low morbidity.

#### CURRENT ROLE OF PERIANAL BULKING AGENTS

Peter Loder

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Bulking agents have proved useful in the management of sphincter dysfunction in the larynx and the urethra. The accepted role of the anal cushions in anal continence has encouraged the use of silicone polymers (PTQ) and carbon particles (Duraspheres) for the treatment of anal incontinence. A number of small uncontrolled studies and my own personal experience suggest that two thirds of patients with severe passive incontinence, not responding to diet and anti-motility agents report improvement in continence. Adverse events have been rare. There is no consensus as to the site of injection: either intersphincteric or submucosal placement being chosen by different investigators. If the intersphincteric position is used, ultrasound guided placement is superior. Despite impressive clinical effectiveness in uncontrolled studies, benefit was not confirmed in the single randomised, placebo-controlled trial. The place of this treatment remains uncertain but there remain few effective alternatives for the management of passive faecal incontinence not responding to the usual conservative measures.

#### NEW OPTIONS IN FAECAL INCONTINENCE

Peter Petros

Perth, Western Australia

Data from several separate centres demonstrate that repair of the pubourethral and/or uterosacral ligaments can cure not only urinary incontinence, but also, >80% of patients with "idiopathic faecal incontinence", i.e. those with intact external anal sphincters.

### RELEVANCE OF ULTRASOUND TO CLINICAL PRACTICE OF PELVIC FLOOR MEDICINE

#### PRACTICAL APPLICATION OF ULTRASOUND IN PELVIC MEDICINE

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The complex anatomy and function of the pelvic floor is not yet fully understood. How muscles, nerves, ligaments and fasciae inte-

tract and relate to pelvic organs is fundamental to establish what disease processes are involved in pelvic floor disorders (PFD). In the last two decades, growing attention has been dedicated to increasing both understanding on the pelvic floor anatomy (particularly related to physiology and pathophysiology) and improving technologies for diagnosis. Ultrasonographic imaging has become a valuable tool in the diagnostic work-up of patients with PFD, however with the currently available two-dimensional (2D) techniques many elements of the image cannot be correctly recognized as components of the three-dimensional mechanical apparatus of the pelvis or at least not perceived in their true spatial relationships. As consequence, a good deal of relevant information may remain hidden. This could explain why many urogynecologists still consider clinical examination the main diagnostic tool to plan the management of PFD. In addition, the absence of guidelines and standardisation of the ultrasonographic procedures that could overcome the operator-dependency further limits their usefulness. The advent of high-resolution three-dimensional and dynamic endovaginal (EVUS), endoanal (EAUS) and transperineal (TPUS) ultrasonography promise to revolutionize diagnosis of PFD, providing excellent visualisation of normal and pathologic pelvic floor structures. Multi-compartment scanning techniques includes the following steps:

**FIRST** - assessment of pelvic floor starts with 3D-EVUS performed by a 12-16 MHz 360-degree rotational transducer to have an overall view of the relevant anatomic structures: urethra and bladder neck, anal sphincters, anorectal angle, pubovisceral and perineal superficial muscles, levator and urogenital hiatus and paravaginal spaces;

**SECOND** - anterior and posterior compartments anatomy and function are further evaluated with 2D/3D-EVUS performed by a 5-12MHz 180-degree rotational biplane transducer and with 3D-EAUS performed by a 12-16 MHz 360-degree rotational transducer. Colour Doppler, vascular render mode, maximum intensity projection and Pixel-Flux modality are applied for qualitative and quantitative measurements of vasculature;

**THIRD** - assessment is concluded with B-mode and 3D and real time 4D-TPUS performed by a 6MHz convex transducer to have dynamic information on the function of pelvic organs and levator ani. Pelvic floor ultrasonography allows the processes and changes involved in PFD (urinary and fecal incontinence, pelvic organs prolapse, obstructive defecation, pelvic floor dissynergy) to be viewed in great details. Identification of levator ani damage, anal sphincters defects, rhabdosphincter hypotrophy, urethral vasculature deficiency, bladder neck and urethral hypermobility, levator hiatus enlargement, lateral detachment of the pubocervical fascia to the arcus tendineus fascia pelvis represent important factors predicting a course of progression of the severity of the PFD, aid the decision making in the management and may be markers for recurrence after corrective surgery.

## URINARY INCONTINENCE UPDATE

### ULTRASOUND IMAGING FOR FEMALE URODYNAMICS: TECHNIQUE, FEASIBILITY AND PATIENT ACCEPTANCE

Lewis Chan

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**Introduction:** There is increasing interest in the use of ultrasound for assessment of voiding dysfunction. The aim of this study was to evaluate the technique, feasibility, patient acceptance and the learning curve of adopting ultrasound imaging for urodynamics.

**Methods:** 270 female patients underwent urodynamics with ultrasound imaging between February 2004 and September 2008. Transabdominal ultrasound was carried out to image the bladder and kidneys during the filling phase. Transperineal ultrasound was conducted with the patient in the standing position prior to leak point pressure measurements. Imaging findings including bladder neck position, urethral mobility and pelvic organ prolapse were recorded into a prospective database. Urodynamic reports were reviewed to evaluate the imaging findings. A cohort of 28 patients completed a 22 item questionnaire assessing their discomfort and emotional responses to the procedure. Responses were rated on a scale from 0 (no trouble) to 10 (worst they could imagine). This was compared to 28 female patients who underwent urodynamics with fluoroscopic imaging. During this period 4 trainees with no prior ultrasound

experience were taught the technique and the learning curve assessed with a 12 point checklist for competency.

**Results:** Of 270 patients, 117 had evaluation for stress or mixed incontinence, 90 had overactive bladder symptoms, 41 had neurogenic bladder and 22 had voiding dysfunction. Bladder neck and urethral mobility were satisfactorily assessed in all patients with incontinence except 4 who had significant detrusor overactivity. All 15 patients with a suburethral sling had good visualization of the sling on transperineal ultrasound. 5 patients with neurogenic bladder had hydronephrosis on renal imaging and 1 patient had an adnexal mass. Patients rated ultrasound urodynamics less troublesome than fluoroscopic urodynamics on all 22 items of the questionnaire. Patients who underwent ultrasound urodynamics reported less trouble in "pain" (0 vs 18% scoring  $\geq 7$ ,  $p = 0.026$ ), "discomfort" (4 vs 21% scoring  $\geq 7$ ,  $p = 0.045$ ), "feeling embarrassed" (7 vs 32% scoring  $\geq 7$ ,  $p = 0.02$ ) and "feeling undignified" (4 vs 21% scoring  $\geq 7$ ,  $p = 0.045$ ) compared to those who had fluoroscopic urodynamics. All four urological trainees were able to learn the technique within 3 supervised urodynamic sessions and demonstrated competence in basic instrumental controls, image acquisition/optimization and identification of anatomical features. **Conclusions:** Ultrasound is a good modality of imaging for female urodynamics. The technique is easy to learn and allows good assessment of the bladder, urethra and urethral mobility. Patients who underwent ultrasound urodynamics reported significantly less discomfort and embarrassment compared to those who had fluoroscopic urodynamics.

### URINARY INCONTINENCE IN TANZANIA

Bernie Brenner

*Auckland, New Zealand*

Although the incidence of Vesico-vaginal Fistulae is decreasing a little in Africa because of C Section being more readily available, it is still a common post-obstetric complication. Urodynamic studies have been reported from the Fistula Hospital in Addis Ababa and there is a known incontinence problem following even successful fistula repair. This presentation describes the experiences of the author in Arusha Tanzania with the setup of basic testing facilities and the introduction of minimally invasive treatment options for female bladder dysfunction.

### HOW TO TENSION A TENSION FREE TAPE

Paul Duggan

*Discipline of Obstetrics and Gynaecology, University of Adelaide Australia*

When originally described, the tension free vaginal tape (TVT) for stress urinary incontinence used a transvaginal, retropubic approach under local anaesthesia and a cough stress test to tension the tape sufficiently to minimise leakage. Since this original description there have been a plethora of new tapes and new surgical approaches. Regional and general anaesthesia is now commonly employed, with and without attempts to replicate an intraoperative stress test to tension the tape. A large number of descriptive, case control and randomised studies have been published on the various tension free vaginal tape procedures. Apart from noting that the retropubic TVT is as effective as and less morbid than the Burch colposuspension and has a significant rate of bladder perforation, we can draw few firm conclusions. There is some evidence that more severe cases of incontinence could be better managed by a retropubic approach than by a transobturator approach. The paradox of tensioning the so-called "tension free" tape in cases of severe incontinence is the subject of this presentation. Two different methods of tensioning a retropubic TVT in cases of severe, mixed incontinence will be discussed.

### A NEW METHOD FOR SURGICAL STRESS INCONTINENCE THERAPY

Johan Lahodny, Barbara Lahodny, Alexandra Kaider

*Vienna, Austria*

This study was performed to prove the advantages of UST (Urethra Surrounding Tape) as a new and safe operation to cure stress incontinence in the future. Forty three patients underwent a UST operation in 2004 after preoperative clinical urodynamic and x-ray clarification. Patients with a preoperative positive stress test were treated with a 1.5 x 2.6 cm sized mesh which was sutured onto the middle third of the urethra. After 16 months the patients had a clinical and urodynamic follow up. In the meantime 376 operations have been performed with the same results.

In clinical tests a continence rate of 97.7% was found. After subjective evaluation 83.7% patients were completely cured. In 2.3% no improvement was recorded.

Precise reproducible operation steps, no intraoperative complications, no postoperative complications and excellent results justify the assessment of an improved and minimally invasive incontinence operation.

## VAGINAL PROLAPSE

### PROSPECTIVE STUDY OF THE PERIGEE™ SYSTEM FOR TREATMENT OF CYSTOCELES OUR 5 YEAR EXPERIENCE

Ajay Rane

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**Objectives:** The Perigee™ Transobturator Cystocele repair system (AMS) was designed and first used on the 10th of March 2004 in Townsville, Australia. This prospective study evaluates our 5 year experience with the Perigee™ system assessing the efficacy and safety of this device for the management of anterior vaginal prolapse.

**Materials:** Patients who underwent surgery with the Perigee™ system between March 2004 and June 2008 were followed up for cure rate, recurrence and complications.

**Methods:** Local institutional ethics approval was sought and the study commenced in 2004. The study involved answering detailed questionnaires and POP-Q assessments pre and post operatively at 6 weeks, 3 months, 6 months, 12 months and subsequently biannually. A cohort of patients underwent annual transperineal 3D ultrasound to assess the behaviour of the mesh.

**Results:** A total of 368 patients underwent surgery with the Perigee™ system between March 2004 and June 2008. 350 patients were followed up during the study period. The duration of follow up varies from 6 months to 4 years. All patients had stage 3 and above cystoceles and 39 patients (11 %) had a concomitant stage 3 Level 1 defect with the cystocele as the leading prolapse. There were no immediate life threatening complications associated with the procedure. Fourteen patients (4%) complained of a lump sensation post operatively but had a prolapse less than stage 2 while 6 (1.71%) patients had prolapse of grade 2 or more. Of the 14 patients, one patient required vaginal hysterectomy and McCaul's culdeplasty for grade 3 uterocervical prolapse. The other 13 patients were managed conservatively. Of the 6 patients with recurrence of >stage 2, two patients have had repeat surgery so far. The mesh erosion rate was 11.1% (39 pts) in this study. Thirty four patients required mesh excision and trimming under general anaesthesia while five patients were managed with outpatient trimming and vaginal oestrogen therapy. Of the 34 patients, 1 patient had an infected mesh that required two attempts to remove the same. Two other patients required a total of 6 attempts to completely resolve the issue of persistent small erosions of the mesh (< 2 cms in diameter). Intraoperatively, two (0.5%) patients had bladder perforation during the procedure and both were identified immediately and managed conservatively with in dwelling catheter. One patient was taken back to theatre immediately afterwards for buttock pain and had a 100 ml haematoma evacuated. Another patient required blood transfusion after a haematoma (6 cm) was diagnosed on CT scan and falling HB but did not require any further surgery. Nineteen percent of patients stayed overnight after the procedure due to medical reasons and distance factors. Only 3.4% of patients needed stay more than 24 hours and the longest stay was 72 hours. The most common concomitant procedures performed included posterior defect specific repair (49%), sub urethral slings (19.1%) and perineoplasty (10.8%).

**Discussion:** Invention of the procedure involved taking a lot of experience from the Monarc slings and cadaveric dissections done by Mark Walters from the Cleveland Clinic. The intuitive design was the deeper pass of the Perigee needle which not only penetrated the obturator complex but also the levator muscle 1.5 cms proximal to the ischial spine.

**Needle curvatures:** The needle curvature was indeed a challenge, opening the curvature too much resulted in gluteus muscle injury and rectal injury in cadavers. Closing the curvature too much resulted in sub optimal distance from the ischial spine. Consequently the current design has had an increase in its tip length but 2.5 centimeters but no change in the curvature.

**Changes to technique:** the first change was the technique of insertion of the deeper needle. This involved using the 'Harley'

technique holding the needles at 45 degrees to the horizontal. With the increase in length of the needle in our hands this technique resulted in two patients with gluteal pain and 1 haematoma as described in the results. We now use a two movement technique which has worked very well for us.

**Anatomy:** The deeper needle is inserted in the lowermost portion of the obturator foramen which is directly perpendicular to the ischial tuberosity on external palpation. The landmarks are palpated and also roughly correspond to 2 cm lateral and 3 cm below the superficial needle marking. For the superficial needle the entry point is 0.5 cm medial to the genito crural fold, below the adductor longus tendon and roughly at the level of the clitoris.

**Changes to mesh:** The mesh has undergone changes only one change from Interpro – a monofilament medium density polypropylene mesh to Interpro Lite – an even lighter density, monofilament polypropylene mesh.

**Technique:** The technical changes that have evolved over the last five years in our unit involved – full thickness vaginal dissection, hydro dissection of the tissues, small tunnels for dissection, dissection of the bladder base right upto the vault or isthmus of the cervix, separate colpotomy incisions for each compartment repair, tailoring the length of the mesh to suit the length of the anterior fornix, using PDS sutures to help lay the mesh flat in 5 points – two near the bladder neck and three at the lower part and double layered vaginal closure to name a few.

**Conclusion:** Our 5 year experience with Perigee™ system is perhaps one of the longest experiences with this type of operation. Although subtle changes have been introduced in our technique over the last 5 years, overall the procedure appears to be a robust one with minimal recurrence and complications. The mesh erosion rate is comparable to existing literature reports.

### ROUTINE UTEROSACRAL LIGAMENT (LEVEL 1) SUPPORT AT ANTERIOR COLPORRHAPHY (MUSPACC AND MUSSACC PROCEDURES)

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**Objective:** To demonstrate that the intermediate section of the uterosacral ligament (USL) can be used for vaginal vault suspension at anterior colporrhaphy to provide thus both level 1 and level 2 support.

**Background:** It has been shown that about half of anterior vaginal wall descent can be explained by the degree of apical descent present (1). Failure to address the apical defect at anterior colporrhaphy may contribute to the high rate of suboptimal outcomes. Fresh cadaver studies and live surgical experience have demonstrated to us that the intermediate section of the USL is conveniently, safely and universally accessible at the time of anterior colporrhaphy, be it with prior or concomitant hysterectomy or with uterine preservation. The key to seeing it in either circumstance is to put it under tension when the fibromuscular tissues contained within this endopelvic fascial structure appear to coalesce and the full strength and constancy of the ligament is witnessed. In the midline, with bladder retracted, the strong intermediate segment of the USL is readily identified by an initial shallow horizontal needle passage in the dorso-lateral aspect of the exposed vaginal vault. This section of the USL is more than 2 cm from the ureter. We wish to demonstrate that the intermediate section of the USL can be used in a midline vaginal vault suspensory role at anterior colporrhaphy to provide thus both level 1 and level 2 support (2). Options are plicatory uterosacral sutures (MUSPACC - Midline Uterosacral Plication Anterior Colporrhaphy Combo) or (MUSSACC Midline Uterosacral Suspension Anterior Colporrhaphy Combo) i.e. adding direct suspensory sutures to the vaginal vault to MUSPACC.

**Methods:** After the experience of hundreds of MUSPACC cases without ureteric or other major complications due to this procedure, an analysis of 41 patients who underwent a MUSSACC procedure was performed. All women had grade 2 or more anterior vaginal wall prolapse (cystocele). Women were assessed by Baden-Walker site-specific vaginal examination preoperatively, intraoperatively, immediately postoperatively and at the clinical postoperative visit. On the latter three occasions, an observer other than the surgeon was present to confirm the staging and two specific measurements: (i) vaginal vault to distal end of anterior colporrhaphy (anterior); (ii) vaginal vault to posterior introitus

(posterior). Intraoperatively, these measurements were performed prior to the midline anterior vaginal wall incision (following closure of the vaginal vault in cases of concomitant hysterectomy). Immediately postoperatively, these measurements were taken at the completion of all repairs.

**Results:** The prolapse repair was a primary procedure in 30 (73%) cases whilst recurrent prolapse surgery was being performed in 11 (27%) cases. Concomitant surgeries will be presented. Mean duration of the MUSSACC procedure (excluding the duration of concomitant surgeries) was 23 minutes (range 17-30 minutes). Mean blood loss was under 50mls in 35 (85%) cases and never over 100 mls. A mean 4 USL sutures were inserted, 2 of which in each case incorporated vaginal vault with a permanent suture. There were a mean 4 anterior colporrhaphy fascial plication sutures. There were no ureteric complications (cystoscopy universally performed) with only one incident of one small cystotomy managed with a two layer oversew. Posterior vaginal length was reduced by a mean 6% (end of operation) reducing to 0% when measured at the postop clinical visit (mean 6.6 weeks; range 5 to 9 weeks). Anterior vaginal length was reduced by a mean 7% (end of operation) though only 2% when measured at the postop clinical visit. There was no recurrent vault descent though 3 (7%) women had early (up to Grade 1) asymptomatic recurrent cystocele. Two of these women had preop Grade 3 cystocele whilst the other woman had a history of 5 previous anterior colporrhaphies including mesh and mesh removal.

**Conclusions:** Our studies has confirmed that the MUSSACC/ MUPACC procedures are safe with consistent access to the intermediate section of the USL. A MUSSACC procedure can be performed comfortably in a median 23 minutes through a single midline anterior vaginal wall incision. Blood loss is generally minimal to small. Dissection is relatively limited with the ureters not deemed to be at risk. Short term anatomical results are very promising with no apparent vaginal shortening. Overall, we believe that the MUPACC/ MUSSACC procedures can be readily learnt by a competent vaginal surgeon, once the additional anatomical understanding is acquired.

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### THE EXTRAPERITONEAL NEOFASCIOGENESIS AS PATHOGENETIC SURGICAL TREATMENT IN YOUNG WOMEN WITH HIGH RISK OF POP

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Relapses in perineology is one of "not considered" problem. It's occurs in 33-61,3% within three years postoperative [Shull B. L. et al., 2000]. The problem is aggravated with that about one third of patients – women of reproductive age [Bump R.C., 1998]. 2-26% of young women have heavy POP degree [Krasnopolsky V.I., 2005]. Some relapses after own structures surgery explain with connective tissue insufficiency (CTI). In our research ATFP was absent or badly expressed at 33,4%, four times more at CTI group and directly depended on CTI severity. Thus, pelvic floor structures changes reveal decreased own tissues POP surgery efficiency, define necessity of pathogenetic prosthetic materials treatment. In particular for CTI women in reproductive age with "aggressive" and combined POP forms. Our principle: "The first operation - unique operation". In our research CTI young women operation efficiency has made more than 90%. In prospective research 2006-2009 - 75 multiparous women with POP up to II stage (POP-Q). POP surgical correction based on pathogenetic extraperitoneal neofasciogenesis concept in broken fascia "replacements" with synthetic "new", making reliable pelvic skeleton.

Relapses frequency has made 10% without CTI dependence. In detail – anterior relapses is more frequent (9.2%). Subclinical vaginal mucous erosion marked in 4.6%, incomplete healing - 10%. We noted sexual life improvement after synthetic implants POP cor-

rection. The dyspareunia was in 1.5%. Thus, extraperitoneal neofasciogenesis with mesh is pathogenetic well-founded and effective POP correction method.

### ALLOGRAFT IMPLANTATION IN POP SURGERY

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**Background:** Prosthetic surgery for Pelvic Organ Prolapse (POP) repair has spread very quickly in the past few years, even as first line treatment. Xenograft implants are associated with low morbidity, unknown risk of long term failure rate and high costs. Synthetic meshes are related to vaginal erosions, sexual dysfunction and risk of post-operative apical defect. Surgery for POP using allograft tissues is controversial for cure rates are reported to range from 68 to 100%.

**Methods:** Ten patients with pelvic floor defects >3 stage HWS have been operated on with human pericardium. All donor tissues came from Veneto Regional Tissue Bank. The donors' average age was 42 years. Our human pericardium was cryoconserved, not irradiated, not dehydrated. All patients were pre-operatively evaluated with symptomatic questionnaires, ICI POP-Q and HWS classification of POP, cough stress test, post voiding residual urine, standard urodynamic investigation. All patients underwent bilateral sacrospinous fixation of the vaginal apex with interposition of a posterior patch (12x10 cm). The lateral edge of the patch was fixed to lateral pelvic sidewalls at ileococcygeal fascia. The lower edge of the patch was sewn to the perineum body. Anteriorly the patch (10x8 cm) was attached to the pelvic walls with the paravaginal repair technique.

**Results:** Nine patients have been evaluated at a medium follow up 4.3 months. Two patients out of nine reported a stage 2 cystocele that till now has not required any further operation. All other patients resulted in stage < 1. Q-max is unchanged. P-det max flow is reduced from 17.3 to 12 cmH<sub>2</sub>O, P.V.R. from 160.5 to 4.1 ml while Stress test (positive) passed from 44.4% to 12.5%.

**Conclusion:** Direct costs are zero. The tissue didn't cause middle term morbidity. It seems to give good functional results: bladder emptying and continence were improved. Anatomical data must be evaluated long term.

### VAGINAL PROLAPSE SURGERY WITH MESH. INITIAL RESULTS OF THE AUSTRIAN REGISTRY

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**Background:** Various meshes have been used in recent years for the vaginal correction of prolapse, with limited data on complications and results. We established a voluntary nationwide registry to collect data on the perioperative course and follow-up at 3 months and 1 year of patients undergoing transvaginal correction of genital prolapse with mesh.

**Methods:** 20 gynecology departments in Austria participated in the registry begun in 2006. The centers were asked to complete a questionnaire for every mesh prolapse procedure. The questionnaire contained items regarding the patient, the operation, the postoperative course. In patients available for clinical follow up we asked for information on mesh exposure, urinary and bowel symptoms and dyspareunia as well as patient and physician assessment of the results of the operation and quality of life.

**Results:** Data on a total of 545 operations with 11 different mesh systems were collected by May 2009. Overall, 49% patients had undergone previous gynecologic surgery, including 225 (80%) with previous hysterectomy. 347 (64%) operations were done as isolated procedures, whereas 198 (36%) were done in combination. The most frequent concomitant operations were hysterectomy ± colporrhaphy (52%). In 34% mesh was used for combined anterior and posterior repair. Intraoperative and perioperative complications are listed in table 1.

Follow up at 3 months was possible for 336 (tab. 2) and 1 year for 182 patients.

**Conclusion:** This preliminary reports provides an initial assessment of complications seen with transvaginal mesh procedures.

TABLE 1. – Intra- and perioperative complications (N = 545).

Increased bleeding	15 (2%)
Bladder injury	6 (1%)
Rectum injury	1 (0.2%)
Ureteral impingement	1 (0.2%)
Postoperative stroke	1 (0.2%)
Reoperation (bleeding)	5 (1%)

TABLE 2. – Follow up.

	3 mo	1 yr
Mesh exposure	39 (12%)	21 (12%)
Bowels problems	38 (11%)	18 (10%)
Voiding problems	92 (28%)	51 (28%)
Dyspareunia*	13 (10%)	20 (10%)

## IMAGING

### THE ROLE OF PROCTOGRAPHY

Susan Gaden

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The part that proctography plays in the investigation of pelvic floor disorders is discussed. The technique used will be presented, and the indications for the procedure discussed. A normal study will be shown, with pre-evacuation, evacuation and post-evacuation phases. Proctograms show structural abnormalities, such as rectocele, intussusception, enterocele, and pelvic descent well. Functional disorders such as anismus are also demonstrated. Examples of these conditions will be shown on video. A discussion regarding the usefulness of performing this procedure and the information which can be obtained from it will be presented. Some of the difficulties in interpretation, advantages and disadvantages will be presented.

### PELVIC ORGAN PROLAPSE AND SAGGING OF THE LEVATOR PLATE:

#### A STUDY USING FUNCTIONAL CINE-MRI

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**Background:** It is generally accepted that the sagging of levator plate (LP) leads to progressive widening of the urogenital hiatus and the development of pelvic organ prolapse (POP). This study attempts to find the relationship between the sagging of LP and POP.

**Methods:** We retrospectively evaluated the functional cine-MRI studies of 63 symptomatic POP patients (mean age 62.4y) and 7 females with normal pelvic support (mean age 42.3y). All subjects underwent MR imaging of the pelvis in the supine position at rest and at straining (Valsalva maneuver) in the evening at around the time of 5 pm. The angle between the pubococcygeal line (PCL) and levator plate was calculated (sagging angle, SA).

**Results:** The values of SA were  $+35.31 \pm 11.2$  deg. in POP group and  $-8.9 \pm 10.6$  deg. in control group, respectively  $p < 0.01$ . Among 63 POP patients, 44 (69.8%) has larger SA (more than 30 deg. mean 41.3 deg.) and 19 (30.2%) has small SA (less than 30 deg. mean 21.6 deg.).

**Conclusion:** Patients with POP had significantly greater SA than control female. However, about 30% of POP patients do not have overt LP sagging. This may suggest the mode of the development of POP is varied.

## PELVIC FUNCTION

### FIRST EXPERIENCES WITH AMI-CR-MESH IN 33 WOMEN

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The OP-technique with the AMI-CR-mesh was begun in Tettmang in April 2008. In the Waldburg-Zeil-Klinik Tettmang, 53 CR-meshes were implanted in the last year. Twenty patients had pelvic floor

defects in the anterior and posterior compartments. In these cases we inserted two CR-meshes: One for the reconstruction of the cystocele and one for the reconstruction of the rectocele. Nine patients were only operated in the anterior vaginal wall and 4 only in the posterior part. In all cases the level one reconstruction was done with the AMI-suture device with suspension at the medial and posterior part of the sacrospinous ligament. In cases of younger women, two sutures were made on each side. The uterus was removed in previous surgery in 16 cases and 17 women still had the uterus in place. Six times the uterus was removed simultaneously with the pelvic floor reconstruction. In 11 cases the uterus remained and was suspended with the CR-mesh. There were no intraoperative complications in all surgeries. One suture through the sacrospinous ligament had to be cut after 6 days, because the woman had pain on one side. The suture irritated a root of a sacral nerve. After the cut the pain was gone. There were no recurrent prolapses in all women in the reconstructed compartment. In one case with only one CR-mesh for rectocele a new cystocele occurred. Two women developed a de novo stress incontinence after the surgery. They got a retropubic tv-t-sling for treatment with good results. One woman had after 3 months an erosion of the mesh in the lower posterior vaginal wall. After the removal of the small eroded part, the defect healed well. Ninety percent of the patients are satisfied with the results and have an improvement of quality of life. One patient is not satisfied with the result.

### A NEW UNDERSTANDING OF ANAL PHYSIOLOGY

Peter Petros

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Video xray studies are consistent with the following:

The rectum is a reservoir for storage of faeces, and the anus an emptying tube.

Closure The anal tube is closed by external muscular forces, levator plate (LP) and longitudinal muscle of the anus (LMA) which stretch the rectum backwards and downwards against and anus immobilized by the puborectalis muscle (PRM). Evacuation Relaxation of PRM allows the LP/LMA vectors to stretch open the posterior anal wall for evacuation to occur. The vector forces pull against the pubourethral and uterosacral ligaments. Laxity in these ligaments will invalidate the closure forces, and may result in faecal incontinence, evacuation disorders, or both.

### EFFECTS OF CHILDBIRTH ON THE PELVIC FLOOR

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There is much speculation about the effect of childbirth on the pelvic floor. Computer generated models show a mathematical impossibility for a fetal head going through the pelvis without disrupting muscle. Numerous surveys of obstetricians show an increasing trend to prefer elective caesareans mostly for pelvic floor reasons. What is available in the literature deals with three issues – nerves, fascia and ligaments and muscles. For a long time there was data suggesting pudendal neuropathy after vaginal childbirth – longitudinal studies have shown a high rate of re-nervation and a minor persistence of neuropathies. Further the forces and time required for nerve damage (axotomesis) or nerve severance (axonolysis) are not congruent with the forces of labour. Fascial and ligamentous tearing has been visually seen and repaired immediately post delivery, however no one to one causal effect as far as pelvic floor dysfunction has been clearly reported. The issue with muscle tearing and ballooning has generated much more interest since this can be studied with MRI and ultrasound. Endoanal ultrasounds first started the wave of analysing and treating sphincter tears and recently there has been prolific publications on the concept of levator avulsion. The challenges that we face are: who is prone for this dysfunction during childbirth?, can we screen them before birth? Will selective intervention reduce pelvic trauma? Will this reduced pelvic trauma reduce the burden of incontinence and prolapse? And finally which part of the pelvic trauma really matters?

### RECONSTRUCTION OF PELVIC FLOOR USING SYNTHETIC MESH IN WOMAN WITH BLADDER EXSTROPHY AND TOTAL UTERINE PROLAPSE

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Congenital bladder exstrophy affects 1 in 125 000 to 250 000 females. It's frequently associated with genital prolapse. We pre-

sent a case of total uterus prolapse in woman of 26 years old after ureterosigmoidostomy for bladder exstrophy, bilateral inguinal hernioplasty, plastic surgery of abdominal wall and vestibule of vagina. The total uterus prolapse (IV stage) was developed after the single delivery by Caesarean section. There was the splitting of pubic bones up to 11 cm on X-ray imaging of pelvic bones. Whereas the age, absence of uterine abnormality, the decision to save uterus and perform total reconstruction of pelvic floor using prosthetic implant Prolift® total with simultaneous sterilization by transvaginal approach was made. The reason of sterilization was unfavorable influence of probably pregnancy on kidney function and woman's desire who has one health child. During the spinal anesthesia the anterior compartment of system implanted under the mucous vaginal wall, the distal arms were led out via obturator foramen, proximal arms – behind pubic bones towards abdominal wall where the ends were connected to each other subcutaneous to provide additional support. The uterus disposed hyperanteflexio because of frontal wall's fixation to anterior compartment of implant by nonabsorbable suture. Through posterior vaginal fornix the sterilization with excision of tubes was performed. Distal end of posterior compartment cut like the "swallow's tail" for a distance of 5 cm, after these subsidiary arms were performed behind of levator ani muscles towards the skin of perineal area. This procedure, in our opinion, allowed to strengthen the posterior vaginal wall. The duration of operation was 2 h 10 min, loss of blood – 400 ml. Early postoperative period was taken normal course, in 26 months on control examination the patient didn't note any complaints. The positive result of performed surgical treatment is encouraging, however further observation is required to evaluate longer term follow up. Thus in this case report for the first time the possibility of uterus saving surgery using prosthetic implant in young woman after reconstructive operations due to bladder exstrophy was demonstrated.

#### PRESERVATION OF THE PROLAPSED UTERUS IN PELVIC SURGERY

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- Is uterine prolapse an (absolute) indication for vaginal hysterectomy?!
- Is vaginal hysterectomy an (essential) part of pelvic floor reconstruction?!
- Is the uterus an innocent victim?
- Are we performing vaginal hysterectomies only because we were trained to?
  - Hysterectomy is a *complication related* operation
  - Hysterectomy *mutilates physiologically* the patient
  - Hysterectomy *defects the endo-pelvic fascia integrity* and makes the pelvic floor vulnerable
    - Hysterectomy impairs the pelvic floor blood supply, increasing the risk of vaginal mesh exposure
    - Preservation the Uterine isthmus provides the benefit of recruiting the *cervical ring* and the attachments to it's ligaments for reinforcement

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

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

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

# Pelvic organ prolapse repair with Prolift® mesh: a prospective study

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**Abstract:** Our objective was to evaluate anatomical and symptom specific outcome measures of prolapse repair with prolift mesh®. In this longitudinal prospective observational study we collected data on a total of 64 women with International Continence Society pelvic organ prolapse stage 2 or more. In the anterior prolift group, objective success rate for the anterior compartment was 85.7% and 88.9% at 6 and 12 months respectively. The posterior prolift corrected vault and posterior compartments successfully in 85.2% and 78.9% respectively and the total prolift mesh had a success rate of 82.6% and 81.3% respectively. Bladder injury occurred in 6.3% and one patient required a blood transfusion. The mesh erosion rate was 4.7%. De novo bladder symptoms developed postoperatively in 9.4% of the women. P-QOL and UDI-6 scores improved significantly at 6 and 12 months follow up in all groups ( $p < 0.001$ ). Vaginal surgery with prolift mesh® is an effective and safe procedure to correct pelvic organ prolapse over one year follow up.

**Key words:** Pelvic organ prolapse; Prolift; Tension-free vaginal mesh; TVM.

## INTRODUCTION

The long term durability of conventional surgical repair of vaginal prolapse has been questioned in recent years. In a frequently quoted publication Olsen et al.<sup>1</sup> estimated that the lifetime risk (up to age 80 years) of undergoing surgery for vaginal prolapse was 11%. Between 29% and 40% of prolapse surgery is for recurrence<sup>1,2</sup> and in 60% of re-operations the prolapse is at the site of the original procedure.<sup>3</sup> There is no widely accepted and standardised technique for the management of recurrent prolapse. Multiple surgical techniques have evolved each supported enthusiastically by their proponents and some of the techniques involve the use of synthetic mesh material. The abdominal sacral colpopexy with mesh is well accepted and has been found to be superior to the vaginal sacrospinous ligament suspension for correcting upper compartment prolapsed.<sup>4,6</sup> However, little comparative data are available suggesting the superiority of vaginal prolapse repair with mesh overlay.<sup>7-9</sup> Despite this lack of long term data, the use of vaginally implanted mesh to correct the perceived poor durability of conventional surgery is expanding rapidly due to the enthusiastic marketing of surgical mesh kits with a perceived simplicity of use. Currently most information on the outcomes of vaginal surgery with synthetic implants comes from short term follow up<sup>10-12</sup> or exists in non-peer review publications such as conference abstracts.<sup>13,14</sup> This paper describes a prospective cohort study using monofilament polypropylene mesh kits (Gynecare Prolift®, Ethicon, Somerville, NJ, USA) for the management of vaginal prolapse over the first year of implantation including complications, anatomical success rates and functional outcomes using longitudinal QOL data.

## MATERIALS AND METHODS

Sixty four women were recruited between July 2005 and June 2007 for transvaginal pelvic floor repair with mesh in a single urogynaecology practice. Before surgery, all women underwent an assessment for prolapse at maximal straining in the semi recumbent position using the pelvic organ prolapse quantification system (POP-Q). The examination conformed to the standards recommended by the International Continence Society.<sup>15</sup> Urodynamic studies were performed when bladder symptoms were present. Inclusion criteria were a POP-Q stage  $\geq 2$  with recurrent prolapse or cases that were judged to be at significant risk of failure of con-

ventional repair in view of their activity level, employment history or associated conditions such as chronic pulmonary disease and constipation. Satisfactory physical and mental health and fluency in English on order to complete the questionnaires were also required. Postoperative surgical outcomes were evaluated by the operating surgeon (MIF) and patients were invited for review at 6 and 12 months after surgery. With regards to anatomical outcome, a POP-Q stage 2 or more on follow up was considered a surgical failure irrespective whether the patient complained of symptoms. We used the prolapse quality of life questionnaire (P-QOL)<sup>16</sup> and the short version of the urogenital distress inventory (UDI-6)<sup>17</sup> to assess subjective outcomes. Prolapse-related bowel symptoms were estimated based on five bowel specific questions extracted from the P-QOL questionnaire.

### Some points of surgical technique

Tension free vaginal mesh kits for anterior, posterior or total repair were utilised according to the general manufacturer guidelines for Gynecare Prolift®. We also adhered to the following principles:

- Patients were given ev antibiotic prophylaxis at induction of anaesthesia and oral antibiotics for 5 days post operatively.
- The operative field was cleaned with iodine antiseptic solution following our routine practice. The mesh was not washed in any antibiotic solution nor handled in any special manner.
- Vaginal tissues were liberally infiltrated with a 0.125% solution of marcain with adrenaline 1:800,000 prior to dissection. Up to 40ml of solution was used in each compartment.
- Short surgical incisions were made where possible and care was taken to keep the endopelvic fascia adherent to the vaginal skin by careful dissection.
- The mesh was placed completely tension free and was not divided in case of total Prolift®.
- There was minimal fixation of mesh at the bladder neck and the vaginal vault only with 2-0 polydioxone sutures (PDS - Ethicon).
- In case of posterior Prolift the lower third of the vagina was kept free of mesh. Low rectovaginal fascia defects were repaired with two layers of 2-0 PDS. There was no corresponding fascial repair of the anterior compartment.

– The vaginal incisions were closed loosely with a continuous non-locking 2-0 polyglactine suture.

– An indwelling catheter and lubricated vaginal pack were inserted after the procedure and removed 24 hours later.

A more detailed description of the surgical technique and anatomical landmarks are published elsewhere.<sup>11, 18</sup>

Descriptive statistics were used on demographic and surgical characteristics. Between groups comparison of non-parametric skewed dependent variables were performed using the Wilcoxon matched-pairs test and with a significance level of 0.1%. All data were analysed with SPSS software (SPSS inc., Chicago, Illinois, USA).

This study was approved by the Human Research Ethics Committee of the Gold Coast Hospital, Queensland, Australia and followed the Declaration of Helsinki (approval number 200546).

## RESULTS

Fourteen patients were found suitable for pelvic floor repair with anterior vaginal mesh, 27 underwent repairs with posterior vaginal mesh and in 23 cases the total Prolift® mesh kit was used. The mean age in our study population was 60.1 ± 9.0 (SD), mean BMI was 26.0 ± 3.4 (SD) and median parity was 2 (range 0-5). In the anterior mesh group, 28.5% (4/14) of the patients has had previous anterior compartment repairs. In 40.7% (11/27) of the posterior mesh group and 8.7% (2/23) of the total mesh group a previous repair had been performed in the respective compartment that was subsequently reinforced with mesh. In total, 41 patients (64.1%) had previous pelvic floor surgery which was dominated by hysterectomy (57.8%), vaginal wall repairs (34.4%) and surgery for urinary incontinence (14.1%). Demographics are summarized in table 1 and listed per type of surgery performed.

We performed concomitant vaginal surgery in 43.8% (28/64) of the cases including a vaginal hysterectomy in 14.1% (9/64), anterior or posterior fascial repairs in 10.9% (7/64) and suburethral tapes for stress urinary incontinence in 25% (16/64). Intra-operatively, four bladder injuries occurred (6.3%) including one bladder puncture with a trans obturator trocar and three cystotomies during dissection. The trocar was withdrawn from the bladder and replaced. The cystotomies were repaired in two layers intra-operatively and the mesh repair completed. An indwelling catheter was left for 48 hours in these cases. One patient suffered a significant haemorrhage (>500 ml) from the obturator area requiring a blood transfusion.

Post-operatively, one patient was taught intermittent self catheterisation for short term urinary retention. A suburethral tape for stress urinary incontinence had been inserted

TABLE 1. – Demographics.

Total group n = 64	Anterior mesh n = 14	Posterior mesh n = 27	Total mesh n = 23
Age mean ± SD	62.4 ± 9.1	62.4 ± 9.0	56.2 ± 7.0
BMI mean ± SD	25.5 ± 4.0	26.4 ± 3.1	26.2 ± 3.3
Parity median (range)	2 (1-4)	2 (0-5)	2 (0-5)
Previous surgery: n (%)			
– None	3 (21.4)	5 (18.5)	15 (65.2)
– Hysterectomy	9 (64.3)	21 (77.8)	7 (30.4)
– Vaginal repairs	7 (50)	13 (48.1)	2 (8.7)
– Vault suspension	1 (7.1)	1 (3.7)	0
– Colposuspension (Burch)	2 (14.2)	3 (11.1)	0
– Suburethral tape	2 (14.2)	2 (7.4)	0

TABLE 2. – Surgical characteristics including concomitant surgery, inter and post operative complications.

	Anterior mesh n = 14	Posterior mesh n = 27	Total mesh n = 23
Concomitant surgery: n (%)			
– vaginal hysterectomy	1 (7.1)	0	8 (34.8)
– anterior colporrhaphy	0	4 (14.8)	0
– posterior colporrhaphy	3 (21.4)	0	0
– Suburethral tape	3 (21.4)	7 (25.9)	6 (26.0)
Per operative complications: n (%)			
– cystotomy	2 (14.3)	1 (3.7)	1 (4.3)
– haemorrhage > 500 ml	0	0	1 (4.3)
Post operative complications: n (%)			
– CISC	0	0	1 (4.3)
– mesh erosion	1 (7.1)	1 (3.7)	1 (4.3)
– dyspareunia	2 (14.3)	0	2 (8.7)
– de novo SUI	0	0	2 (8.7)
– de novo urgency	1 (7.1)	3 (11.1)	0
– RUTI	0	1 (3.7)	0

CISC: clean intermittent self catheterisation; RUTI: recurrent urinary tract infections.

at the time of repair. Three mesh exposures (4.7%) were diagnosed over the time of follow up two of which were diagnosed only at 12 months after surgery. The exposed mesh areas were surgically excised in a day case setting. Four patients (6.3%) reported dyspareunia after vaginal mesh repair. Three cases settled within the first six months of follow up and one patient required division of an arm anchored through the sacrospinous ligament of a total Prolift® mesh for relief. De novo bladder symptoms were found in six patients (9.4%) postoperatively. Two women (3.1%) presented with de novo stress urinary incontinence after total prolift mesh repair and underwent a subsequent successful suburethral tape surgery. Four patients (6.3%) suffered with short term de novo urgency and were treated conservatively with exercises and anticholinergic therapy. Surgical characteristics as well as postoperative complications are summarised in table 2. The objective anatomical success rate for the anterior compartment in the anterior Prolift® group was 85.7% (12/14) at 6 months follow up. The two patients considered as failures developed a POPQ stage 2 cystocele. One of them was also diagnosed with a stage 2 rectocele at the same time. Nine patients of the anterior prolift group were available for 12 months postoperative review. All presented with unchanged POPQ measurements except for one patient who developed a stage 2 rectocele. Twelve months after surgery, the objective success rate for anterior vaginal mesh repair was therefore 88.9% (8/9) for the anterior compartment alone and 77.8% (7/9) when taking all vaginal compartments into consideration. POPQ measurements per compartment are listed in table 3. We registered significant improvement in median POPQ measurements for the anterior and middle compartment at 6 and 12 months in the anterior mesh group. For the posterior mesh group, prolapse of the posterior and middle compartment was successfully corrected in 85.2% (23/27) at 6 months follow up. Seven patients developed recurrent prolapse of the anterior compartment of whom two underwent a subsequent successful anterior mesh repair. At the 12 months postoperative review, two women (2/19) were found to have de novo stage 2 rectocele and cystocele respectively. The POPQ score for all other women was not

TABLE 3. – Pelvic organ prolapse quantification measured in cm and ordinal stages at baseline, 6 and 12 months postoperative follow up for anterior Prolift® mesh repair.

Pelvic component	Pre-operative n = 14	6 months postoperative n = 14	P value *	12 months postoperative n = 9	P value *
<i>Anterior</i>					
Aa	2.5 (–2 to 3)	–2.5 (–3 to 0)	.001	–2 (–3 to –1)	.007
Ba	3 (0 to 4)	–3 (–3 to –1)	.001	–3 (–3 to –2)	.007
Stage	3 (2 to 3)	1 (0 to 2)	.001	1 (0 to 2)	.007
<i>Posterior</i>					
Ap	–2.5 (–3 to 0)	–3 (–3 to –1)	.176	–3 (–3 to –1)	.236
Bp	–3 (–3 to –2)	–3 (–3 to –1)	.206	–3 (–3 to –2)	.046
Stage	1 (0 to 2)	0 (0 to 2)	.140	0 (0 to 2)	.129
<i>Middle</i>					
C	–5.5 (–8 to 1)	–8 (–9 to –5)	.005	–8 (–9 to –8)	.007
D	–9 (–9 to –5)	–9 (–9 to –8)	.157	–9 (–10 to –8)	.102
Stage	1 (0 to 2)	0 (0 to 1)	.003	0 (0)	.007
gh	5.5 (4 to 8)	5 (4 to 6)	.017	5 (4 to 6)	.317
pb	3 (2 to 6)	4 (3 to 5)	.341	4 (3 to 4)	.041
ttl	9 (8 to 10)	9 (8 to 10)	.414	9 (8 to 10)	.317

gh: genital hiatus; pb: perineal body; ttl: total vaginal length. All figures are median (range). \* Wilcoxon matched-pairs test ( $p < 0.001$ ).

significantly different from their previous 6 months postoperative assessment. The objective success rate for posterior vaginal mesh repair at 12 months was 78.9% (15/19) considering the middle and posterior compartment separately and 63.2% (12/19) when taking all vaginal compartments into account. These findings are reflected in the calculation of the POPQ stage for the middle and posterior compartment that were significantly improved at 6 and 12 months and listed in table 4. Prolapse in the total mesh group was successfully corrected in 82.6% (19/23) at 6 months follow up. Two women were diagnosed with a recurrent cystocele, one with a rectocele and one with significant uterine descent. At 12 months postoperative review, the objective success rate was still 81.3% (13/16) and with

one recurrent cystocele in the group. Median POPQ scores for the total prolift mesh group are summarised in table 5. All three vaginal compartments measured a median POPQ score that was  $\leq 1$  (range: 0-3) at 6 and 12 months after surgery. Results of the prolapse quality of life questionnaire (P-QOL) are shown in table 6. Scores were combined and transformed into nine health dimensions, with a potential score between 0 and 100. Lower scores indicating a better perceived quality of life. At 6 months, outcome for all groups improved significantly except for women's general health perception, social limitations and personal relationship domains and these findings remained stable at 12 months review. Five bowel symptom specific questions could be extracted from the P-QOL questionnaire. Answers

TABLE 4. – Pelvic organ prolapse quantification measured in cm and ordinal stages at baseline, 6 and 12 months postoperative follow up for posterior Prolift® mesh repair.

Pelvic component	Pre-operative n = 27	6 months postoperative n = 27	P value *	12 months postoperative n = 19	P value *
<i>Anterior</i>					
Aa	–3 (–3 to 0)	–3 (–3 to 2)	.921	–3 (–3 to 0)	.257
Ba	–3 (–3 to 0)	–3 (–3 to 2)	.746	–3 (–3 to –1)	.317
Stage	1 (0 to 2)	0 (0 to 3)	.409	0 (0 to 2)	.059
<i>Posterior</i>					
Ap	2 (–3 to 3)	–3 (–3 to 0)	.000	–3 (–3 to 0)	.000
Bp	2 (–3 to 5)	–3 (–3 to 0)	.000	–3 (–3 to 0)	.000
Stage	3 (0 to 3)	0 (0 to 2)	.000	0 (0 to 2)	.000
<i>Middle</i>					
C	–3 (–9 to 4)	–9 (–10 to –6)	.000	–9 (–10 to –6)	.000
D	–4.5 (–9 to 4)	–9.5 (–10 to –9)	.068	–10 (–10 to –9)	.109
Stage	1 (0 to 3)	0 (0 to 1)	.000	0 (0 to 1)	.000
gh	5 (4 to 8)	5 (3 to 6)	.000	4 (3 to 6)	.002
pb	4 (2 to 6)	4 (3 to 7)	.006	4 (3 to 7)	.114
ttl	9 (7 to 10)	9 (7 to 10)	.480	9 (7 to 10)	.705

gh: genital hiatus; pb: perineal body; ttl: total vaginal length. All figures are median (range). \* Wilcoxon matched-pairs test ( $p < 0.001$ ).

TABLE 5. – Pelvic organ prolapse quantification measured in cm and ordinal stages at baseline, 6 and 12 months postoperative follow up for total Prolift® mesh repair.

Pelvic component	Pre-operative n = 23	6 months postoperative n = 23	P value *	12 months postoperative n = 16	P value *
<i>Anterior</i>					
Aa	3 (–2 to 3)	–2 (–3 to 1)	.000	–2 (–3 to –1)	.000
Ba	4 (–3 to 6)	–3 (–3 to 3)	.000	–3 (–3 to –2)	.000
Stage	3 (1 to 3)	1 (0 to 3)	.000	1 (0 to 2)	.000
<i>Posterior</i>					
Ap	0 (–2 to 2)	–3 (–3 to –1)	.000	–3 (–3 to –1)	.000
Bp	–1 (–3 to 6)	–3 (–3)	.000	–3 (–3)	.001
Stage	2 (1 to 3)	0 (0 to 2)	.000	0 (0 to 2)	.001
<i>Middle</i>					
C	0 (–7 to 8)	–9 (–10 to 3)	.000	–9 (–10 to –5)	.000
D	–5.5 (–8 to 2)	–9 (–10 to –2)	.017	–9 (–8 to –9)	.068
Stage	2 (1 to 3)	0 (0 to 3)	.000	0 (0 to 1)	.000
gh	6 (4 to 8)	4 (3 to 6)	.000	4 (3 to 5)	.001
pb	4 (2 to 6)	4 (4 to 6)	.004	4 (3 to 5)	.265
ttl	9 (9 to 10)	9 (8 to 10)	.166	9 (8 to 10)	.157

gh: genital hiatus; pb: perineal body; ttl: total vaginal length. All figures are median (range). \* Wilcoxon matched-pairs test ( $p < 0.001$ ).

ranging on a scale from ‘not at all’, ‘little’, ‘moderate’ to ‘a lot’ were transformed into scores between 0-3 and their median outcomes are summarised in table 7. At 6 as well as 12 months from baseline, the sensation of a bulge interfering with defecation and the feeling of incomplete emptying improved significantly.

We divided the UDI-6 questionnaire in three bladder specific subgroups including irritative symptoms, stress urinary symptoms and symptoms of voiding obstruction/discomfort. Outcomes were converted to a score between 0-100 with a lower score representing less symptoms. At 6 months follow up, irritative symptoms as well as obstructed voiding/prolapse discomfort were significantly improved. It was mainly the reduction in obstructive/discomfort symptoms that contributed to a significant improvement of the total score at 12 months (Tab. 8).

## DISCUSSION

Dissatisfaction with conventional surgical repair of prolapse has led over the last decade or so to the use of vaginally implanted mesh to reduce recurrences, which is been a problem especially for the anterior compartment and the vault following hysterectomy. The success of mesh use in general surgical hernia repair seems to have added impetus to this increase. Regardless of the modifications in technique, choice of suture material and changes in perioperative care, the risk of recurrence of inguinal and abdominal hernia repair is high if mesh is not used. Since the introduction of mesh the failure rate of hernia repairs has decreased markedly.<sup>19, 20</sup> Of course it is one thing to implant artificial material in the groin or abdominal wall and quite another to introduce a potentially irritant material into a structure such as the vagina. Lessons have been from experiences with the tension free suburethral tape which is by now one of

TABLE 6. – Prolapse - Quality of life.

P-QOL	Pre-operative n = 49	6 months postoperative n = 47	P value *	12 months postoperative n = 32	P value *
Madian (range)					
General Health	25 (0 - 100)	0 (0 - 100)	.268	0 (0 - 50)	.021
Prolapse Impact	66.7 (0 - 100)	0 (0 - 100)	.000	0 (0 - 66.7)	.000
Role Limitation	33.4 (0 - 100)	0 (0 - 66.7)	.000	0 (0 - 16.7)	.000
Physical limitation	33.4 (0 - 100)	0 (0 - 66.7)	.000	0 (0 - 33.4)	.000
Social Limitation	0 (0 - 100)	0 (0 - 55.6)	.002	0 (0 - 16.7)	.007
Personal Relationship	16.7 (0 - 100)	0 (0 - 100)	.003	0 (0 - 66.7)	0.112
Emotions	22.2 (0 - 100)	0 (0 - 77.8)	.000	0 (0 - 22.2)	.000
Sleep / Energy	25 (0 - 100)	16.7 (0 - 66.7)	.000	8.3 (0 - 33.3)	.000
Severity measures	25 (0 - 100)	0 (0 - 50)	.000	0 (0 - 25)	.000

\* Wilcoxon matched-pairs test ( $p < 0.001$ ).

TABLE 7. – Bowel specific questions.

Bowel symptoms	Pre-operative	6 months postoperative	P value *	12 months postoperative	P value *
Madian score (range)	n = 51	n = 49		n = 33	
Vaginal bulge interfering with you emptying your bowels	1 (0 - 3)	0 (0 - 2)	.000	0 (0 - 3)	.000
Straining to open bowels	1 (0 - 3)	0 (0 - 3)	.001	0 (0 - 3)	.002
Bowels do not feel completely empty after opening	1 (0 - 3)	0 (0 - 3)	.000	0 (0 - 3)	.000
Do you help emptying your bowels with your finger	0 (0 - 3)	0 (0 - 2)	.055	0 (0 - 1)	.023
Constipation; difficulty in emptying your bowels	1 (0 - 3)	0 (0 - 3)	.038	0 (0 - 3)	.027

\* Wilcoxon matched-pairs test ( $p < 0.001$ ).

TABLE 8. – Urogenital distress inventory – 6.

UDI-6	Pre-operative	6 months postoperative	P value *	12 months postoperative	P value *
Madian score (range)	n = 51	n = 49		n = 33	
Irritative symptoms	11.1 (0 – 33.3)	0 (0 – 27.8)	.000	5.7 (0 – 33.3)	.025
Stress symptoms	5.6 (0 – 33.3)	5.6 (0 – 27.8)	.219	0 (0 – 22.2)	.119
Obstruction / discomfort	16.7 (0 – 33.3)	0 (0 – 16.7)	.000	0 (0 – 16.7)	.000
Total score	33.3 (0 – 100)	11.1 (0 – 61.1)	.000	11.1 (0 – 38.9)	.000

\* Wilcoxon matched-pairs test ( $p < 0.001$ ).

the most thoroughly investigated and documented minimal invasive procedures to treat stress urinary incontinence.<sup>21</sup> The use of type I monofilament polypropylene mesh with large pore sizes is currently recommended to reduce complications such as mesh erosion, extrusion, inflammation or infection.<sup>22,23</sup> Nevertheless, in our current state of knowledge enthusiastic reinforcement of entire vaginal compartments with synthetic material should not and cannot be recommended uncritically. Its use may cause change in functionality and will confront us with potential dilemmas in case of surgical failure.

This study reports on 64 women who underwent pelvic floor reconstructions with anterior, posterior or total mesh reinforcement. The overall cure rate at 6 and 12 months respectively was 85.7% and 88.9% for the anterior Prolift® group, 59.3% and 63.2% for the posterior Prolift® and 82.6% and 81.3% for the total Prolift® group. In the group with Posterior Prolift® mesh, five patients (18.5%) developed de novo cystoceles. The appearance of a new prolapse in a previously well supported compartment is an issue which occurs after all prolapse surgery whether conventional or using mesh. This finding seems to be comparable to what has been reported after sacrospinous colpopexy and, given that the mesh is fixed through the sacrospinous ligament bilaterally, may well be for the same reason.<sup>24,25</sup> We used an ordinal POPQ stage 2 as a definition of anatomical failure irrespective of symptoms. Because of this, a reported failure in this paper does not necessarily mean an unhappy patient. We saw improvement in all nine health dimensions of the P-QOL questionnaire which remained stable at 12 months review and also bladder and bowel specific symptoms related to prolapse improved considerably. In retrospect it would have been valuable to have included some measure of overall patient satisfaction with the mesh sur-

gery as well as more detailed data on sexual function. Such data is beginning to emerge now and rates of dyspareunia varies from 14-36% after pelvic floor reconstruction with mesh.<sup>22,26</sup> In contrast to our results, Fatton et al.<sup>11</sup> stated explicitly that they did not consider postoperative asymptomatic stage 2 prolapse as failure at all. As an obvious consequence their “success” rate with Prolift® was higher than we have reported. How cure is defined makes comparisons between published papers difficult and sometimes confusing. Well accepted guidelines on how success should be reported in trials of prolapse treatments would be extremely useful to researchers in the area.

But what is “cure” and how are we to define it? A woman presenting with a prolapse seldom asks for an “anatomical cure”. What she wants is a resolution of her symptoms of a vaginal lump as well as a resolution of any associated bowel and bladder dysfunction. A woman who is sexually active clearly does not want a new problem of painful intercourse. A perfect result is sometimes not achievable in our current state of knowledge – perhaps a perfect result may never be achievable. A colpocleisis is a classic example of a very “non-anatomical” treatment that nevertheless has high satisfaction rates in a highly selected population.<sup>27</sup> So if we do not need to produce a perfect anatomical result to resolve symptoms, what in that case is “cure”?

If we suggest that cure is complete resolution of current symptoms without the production of new problems then we may be setting ourselves a very high bar indeed. In case of the celebrated TVT versus colposuspension study of Ward and Hilton,<sup>28</sup> if cure was defined in this way, then the TVT “cured” only 9% and colposuspension 6% of patients.<sup>29</sup> Hilton’s comments in the same paper regarding the difficulties of performing studies on the surgical outcome of stress incontinence procedures have equal relevance to prolapse

surgery. Hilton emphasised the need for a multidimensional approach to the evaluation of continence. He suggests no single outcome measure is likely to be adequate to summarise the effects of treatment. If this is true for stress incontinence it is likely to be even truer for the complexity of prolapse repair outcomes.

In our series, surgical complication rate directly related to the use of mesh placed with trocars was 3.1% (2/64) including one bladder piercing and one haemorrhage from the obturator area. Thorough but careful dissection of the surgical field is believed to be a key element contributing to the reduction of trauma to surrounding organs and a Breisky-Navratil retractor was used where appropriate for extra protecting of bladder and bowel. While the three cystotomies that had occurred during dissection did not cause the surgeon to refrain from mesh use after repair, we believe that mesh should never be introduced in a potential contaminated area as would be the case after a proctotomy.

Concerns continue to be voiced regarding risks of chronic infection, mesh erosion or exposure<sup>30</sup> and the potentially disastrous consequences of mesh within a hollow viscus such as the bladder or rectum. We found only minor instances of mesh exposure in our follow up and all were easily managed with excision and suture resulting in complete resolution of symptoms. None of the mesh erosions in our series were in association with a hysterectomy. Since we performed vaginal hysterectomy in only 9 out of 64 patients our study may be too small to make any definitive comment on whether concomitant hysterectomy increases the risk of mesh exposure. The intervention needed to repair failure would be far more significant. Commentators continue to persistently fear mesh exposure more than the substantial procedure required for recurrence.

We are well aware of some of the deficiencies in our paper. A decrease in study population after prolonged follow up is a common problem which was also the case in this study. Secondly, for convenience, all follow up examinations were performed by the operating surgeon which may be a source of potential bias. We would make the point that many previously reported studies do not specify the status of the post operative assessor at all. Nevertheless, it is one of the first case series of its kind with medium term follow up.

## CONCLUSIONS

This prospective study confirms the intra-operative safety of the Prolift® mesh kits for prolapse correction. Follow up at one year shows minimal serious morbidity, continued anatomical support and significant improvement in QOL measures. Large randomised trials of conventional surgery versus mesh insertion will be necessary to answer detailed questions of efficacy, both anatomical and functional. Of necessity such trials will require to be large, probably multicentre and expensive to mount.

CONFLICTS OF INTEREST: None.

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