



**AAVIS**

Australian Association of Vaginal  
Incontinence Surgeons



**IPFDS**

International Pelvic Floor Dysfunction  
Society

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**ABSTRACTS**

**PODIUM PRESENTATIONS**

**Outpatient mid-urethral TFS sling operation  
- a documentary of day surgery in Women's Clinic  
LUNA. (1)**

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The TFS (Tissue Fixation System) is a new "minisling" device with a one-way tightening system. We will demonstrate the management of outpatient mid-urethral TFS sling operation in detail in a free-standing outpatient facility.

**Materials and Methods:** Patients were given hydroxyzine hydrochloride 25mg and atropine sulfate 0.5mg i.m. and diclofenac sodium 50mg p.r. before operation. The operations were performed under local anesthesia(LA), using 1% xylocaine 10ml + physiologic saline 40ml+vasopressin 10units. Patients under 70 years were given midazolam 2.5mg additionally. The LA was injected at the sites of the surgery: anterior vaginal wall, peri urethral spaces and below the pubic symphysis, into the tissues behind the perineal membranes (urogenital diaphragm). The mid-urethral TFS sling operation is identical to the first part of a midline 'tension-free tape' operation. A full thickness midline incision was made into the vagina from just below the urethral meatus to midurethra. The vagina was dissected off the urethra with dissecting scissors, and the dissection was carried a few millimeters beyond the perineal membrane (urogenital diaphragm), the space created being just sufficient for the passage of the applicator. The applicator was placed into the dissected space, and triggered to release the TFS anchor. The tape was pulled with a short sharp movement to 'set' the prongs of the anchor into the tissues. Adequate 'gripping' of the anchor was tested by pulling on the free end of the tape. The procedure was repeated on the contralateral side. Taking care to pull in the axis of the anchor's base, the tape was tensioned over a urethra distended by an 18G Foley catheter just sufficiently without indenting it, and the free end cut. The vaginal hammock fascia and the external ligamentous attachment of the external urethral meatus were now tightened with 2-0 Dexon sutures.

**Results:** We performed 37 mid-urethral TFS sling operations for "Genuine stress Incontinence" (GSI) proven by pre-operative urodynamic testing. All patients were discharged the same day. Mean operating time including administration of LA was 22.9 minutes (15-43). Mean blood loss was 14.6 ml. Four patients who could not pass urine within 8 hours were discharged with an indwelling Foley catheter, but passed urine normally within 48 hours. Cure rate at 6 months was 91% (34/37). The 3 failed cases were cured with another TFS midurethral sling- inserted at 3 months.

**Conclusion:** TFS mid-urethral sling operation is a simple effective procedure, and can be done without difficulty in a free standing clinic as an outpatient.

**Mechanical aspects of different tapes in incontinence surgery - Are requests according to Amid I classification enough? (2)**

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**Background:** Macroporous and monofil tapes are a request for Amid I classified grafts in mesh supported incontinence surgery. There is consensus, that low - weighted materials are preferable. The aim of this study was to evaluate mechanical characteristics of different tapes as they are thought to play an important role in e.g. the causation of erosion and inflammation.

**Methods:** The physical characteristics of six different tapes (TVT, Uretex, Monarc, Serasis PP, Serasis PA, IVS ) are compared with each other. The subjects are: weight, breaking strength, flexural rigidity, strain, thickness, width with and without tension, pore content, area of the pores and diameter of the threads. Static and dynamic properties were tested under "dry" lab conditions.

**Result:** All tapes consist of Polypropylen (PP). One graft is a partially resorbable material out of PP, polyglycolacid (PGA) and ε caprolacton (PCL) as components of a monofilament thread. After 120 days PGA and PCL are absorbed. There is a wide range concerning the mechanical characteristics of the different tapes. The partial resorbable tape features low flexural rigidity ( 8 mg after resorption. Range of other tapes: 3- 71 mg ) without reduction of breaking strength ( 80 N. Range: 50- 70 N ). According to absorption of PGA and PCL the tape loses half of its weight ( 0,41 g/ me . Range: 0,57- 1,98 g/ me ). The smooth surface allows adjustability until to 48 hours postoperative in preliminary clinical tests.

**Conclusion:** Beside Amid I category a number of parameters are likely to affect the ability of a synthetic material to act as the perfect graft. A partial resorbable tape is supposed to have advantages like weight reduction, monofilament surface during critical postoperative phase, masking the hydrophobic surface of polypropylene and more softness in the tissue.

**Trans obturator tape (TOT) procedure for stress urinary incontinence: results at 4-years follow-up (3)**

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**Objective:** To evaluate the long-term results of transvaginal transobturator tape (TOT) in the treatment of female stress urinary incontinence (SUI). Almost all the studies available in literature report a maximum followup of 1-3 years. Aim of this study is to confirm, on a large sample of patients, that results in term of continence and QoL are maintained over time with a minimum follow-up of 48 months

**Patients and Method:** Out of 197 consecutive women, undergoing TOT for SUI between September 2002 and October 2003,

160 women were available at the four year follow-up and were included in the analysis. Main criteria for the patients' selection was positive stress test at clinical examination, absence of bladder outlet obstruction or acontractility, no previous surgery for urinary incontinence, no need for associate procedure for prolapse reai further surgical procedure other than.

Preoperative evaluation included history taking, voiding diary, ICIQ-SF questionnaire for the assessment of quality of life, uroflowmetry, cystometry, pressure-flow study, abdominal and pelvic ultrasound, pelvic organ prolapse quantification system (POPQ).

The TOT (Aris® -Porges) procedure was carried out as described by Delorme. No other surgical procedure was performed at the same time.

According to the POPQ system, 102 ( 64%) patients had a I° cystocele (Aa/Ba < -1), 36 (22,5%) had a II° cystocele (Aa/Ba > -1 but < +1) , 79 (49%) had rectocele <II° (Ap/Bp < +1), 42 (26%) had a I° hysterocele (C<-4) and 10 (6%) had a I° vault prolapse (D<-4), 21 patients had previously undergone hysterectomy. After one and four years, all patients underwent a followup evaluation, inclusive of urodynamics and ICIQ-SF questionnaire. Patients were defined cured or improved according with interview (subjective) and stress test (objective).

**Results:** 118 patients (74%) had genuine stress incontinence, 42 patients (26%) had mixed incontinence with dominant stress component. At 1 year, SUI was cured in 130 (81%), improved in 25 (16%) and persistent in 5 (3%) cases (table 1). Post-operative QoL was very satisfactory, satisfactory and unsatisfactory in 126, 31 and 3 patients respectively. At the 4 year follow-up visit, cure rates were unmodified.

Intra/peri-operative complications included pelvic pain, bladder perforation, urinary retention, headache in 20, 1, 1, 1 cases respectively. Long-term complication included "de novo" urge incontinence and vaginal erosion in 2 and 1 cases respectively.

**Conclusions:** Good short term results obtained with TOT are maintained also after 4 years from surgery. TOT is effective, safe and reliable in the long term treatment for female stress urinary incontinence.

### Pelvic Lymphedema (4)

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**Backgrounds:** The pelvic floor is a functional unit. After surgical resection of pelvic cancer, conservative or demolitive surgery with or without post-operative therapy, the patients develop pelvic floor dysfunction; the reason actually is unknown. This disease without an appropriate rehabilitation, leads to: progressive pathologic condition, adipose tissue hypertrophy, and fibrosis. The lymphedema describes a progressive pathologic condition of lymphatic system in which there is interstitial accumulation of protein-rich fluid and subsequent inflammation, adipose tissue hypertrophy and fibrosis. It's possible to hypothesize that lymphadenectomy induces the pelvic floor dysfunction with a lymphedema: a pelvic or better blind lymphedema with symptom but without signs. The clinical evidence indicates that lymphatics pathway play a role in pelvic floor disease.

**Methods:** We choose three patients submitted to rectal surgery. The timing to value the presence of tissue alteration are: T0 one week by the surgery and T1 one month after the surgery. We examine the perineum tissue with magnetic resonance imaging using T1 and T2 weighted sequence. T2 weighted with signal subtraction of fatty tissue on axial plane and T2 weighted on sagittal plane. In this way it's possible to view lymphatic fluid into the perineum and see the presence of damage .

**Results:** Patients number one and two have been submitted to anterior resection of rectum and low anterior resection of the rectum with stoma respectively. The third patient has been submitted to high resection of the rectum without total mesorectal excision (intraperitoneal lesion). In the case number one and two (patients with the alteration of pelvic floor and perineum) it's possible to view a pelvic lymphedema. in the case number three, in which there is no pelvic surgery, there isn't any alteration of pelvic floor and perineum so there is only a low degree lymphedema in rectum muscle.

**Conclusion:** The diagnosis of pelvic lymphedema requires care-

ful attention to patient risk factor, but to be aware of this correlation is the first step and there is so much more to do in order to define the terms of action. The study of pelvic lymphedema is the tool in therapeutic change of pelvic disorders after surgery.

### How do the latest developments in anti-incontinence surgery effect the attitude of an urogynecology clinic in choosing treatment type. (5)

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**Background:** To evaluate the attitude of an urogynecology clinic to the latest developments at antiincontinence surgery.

**Methods:** All the antiincontinence operations were scrutinized between the dates of 01.01.2000-01.05.2008. The total number of antiincontinence procedures was 1012. The objective cure rates for each procedure were also noted.

**Results:** In 2001, the most performed antiincontinence procedure was Burch colposuspension. In 2003, the paraurethral retropubic midurethral slings (Tension Free Vaginal Tape=TVT / Intravaginal slingoplasty=IVS) were the leading operations. Since 2004, the transobturator tape (TOT) procedure has been the most preferred antiincontinence surgery.

It has already been documented that there were no statistically significant difference between the antiincontinence procedures in terms of efficacy (p=0.7). The objective cure rates for Burch, TVT/IVS and TOT were 84%, 86 and 87, respectively

**Conclusion:** Although the objective cure rates are similar there is an inclination towards performing TOT procedure for antiincontinence surgery. The ease of the procedure seems to be the major reason. Hence, we developed a clinical approach: if there is a pathology necessitating laparotomy we perform Burch colposuspension, TVT/IVS is chosen for the patients who have sphincteric insufficiency as well as older than 45 years old, TOT is preferred for the patients who are younger than 45 years old and have sphincteric insufficiency. For special circumstances such as history of radiation therapy, morbid obesity and very old women (>75 years old) periurethral injections are applied. If there is a sealing defect at urethra we perform prepubic sling.

### Impact of suburethral mini-sling (TVT-S) on sexual life: short term outcomes. (6)

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**Background:** The aim of this study was to assess the impact of suburethral mini-sling (TVT-S) on sexual life of women who underwent this treatment for stress urinary incontinence (SUI).

**Methods:** 25 sexually active women with pure SUI and without concomitant pelvic organ prolapse scheduled for TVT procedure completed a sexual function questionnaire at baseline and 3 months after surgery.

**Results:** Preoperatively 10 women experienced urine leakage during intercourse, 22 during penetration and 20 on orgasm. Coital incontinence was cured in 86.5% of patients. No significant difference in the incidence of dyspareunia was found postoperatively. Two patients reported intercourse to be worse following surgery, one because of a vaginal erosion and one cited de novo anorgasmia as the main reason. No patients developed de novo incontinence during intercourse after the operation. Three patients referred reduced libido after the operation and one patient felt the operation to be the cause.

**Conclusion:** Among sexually active women treatment of SUI with TVT-S is associated with an significant improvement of coital incontinence. Moreover, data from this study suggest that TVT-S for SUI improves sexual function in women. The risk of deterioration of sexual life after the operation is very small. Additional prospective studies are required to verify these preliminary findings in longer periods and to compare the impact of the TVT-S with that of other anti-incontinence procedures.

### Experience of pelvic floor reconstructive surgery using TVM technology in young women (less than 40 years). (7)

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**Background:** The number of young women with pelvic organ prolapse is on the increase, and often it is based on connective tissue dysplasia. The prosthesis technologies are actual in modern medicine. Mesh surgery complications as relapses, erosion, prolonged healing and subsequent sexual dysfunction give the reason of technology modification search.

**Materials and methods:** With TVM technologies have been operated 42 women from 2006 to 2008. We've analysed young women (31-40 years) including 2 reoperative cases. In 60% we used total pelvic floor repair system; 32% - anterior system; 8% - posterior system. A case of complicated leiomyoma had hysterectomy. Some operations were simultaneous with Sturmdorf operation (3), radiowave cervix conization (5), TVT-O (15), vaginal sterilization (2). There were 2 concomitant Longo's rectal resection. Levatoroplasty finished all operations.

**Results:** Complications were observed in 16,8% (anterior vaginal wall haematoma - 4,2%; vaginal mucous erosion - 4,2%; mesh wrinkling - 4,2%; asymptomatic relapsed cystocele - 4,2%). Dyspareunia de novo - 4,2% in view of sexual function improvement in 8,4%.

**Conclusion:** TVM reconstruction reveals efficacy with young sexual active women: no vaginal shortage and considerable contraction, tension free technology minimizes dystrophy that decreases postoperative complications, durable mesh structure is adequate on connecting tissue dysplasia state.

### Different methods of surgical treatment of genital prolapses: Prolift and laparoscopic sacrocolpopexy (8)

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**Background:** Pelvic organ prolapse is a common condition and one of the most common surgical indications in women. Urinary incontinence, voiding difficulties, constipation and anal incontinence are all related to these anatomic disturbances.

**Methods:** In our clinic the most popular procedures in treatment of genital prolapses are laparoscopic sacrocolpopexy (Ls SCP) and vaginal extraperitoneal colpopexia (Prolift method).

**Results:** Since 1996 we have done 261 Ls SCP in patients with genital prolapses POPQ III - IV. We combine SCP with hysterectomy in 232 (89%), with colporrhaphy and levatoroplasty in 167 (64%) cases. This type of treatment has proved to be efficient in 96% of patients. We have 2 erosions and remove of MESH in one case. The most important advantages of Ls SCP are: low risk of infection, because there is minimal vaginal incision; no dyspareunia, because we create physiological direction of vaginal tube. The disadvantages are: long operation time (> 2 hours); high risk of complications in patients with cardio-vascular problems, difficulty in obese women and women who had open surgery before. Since 2005 we have done 163 procedures with Prolift in cases with POPQ IV. The advantages of Prolift are: universalism of operation, it can be done under regional anesthesia. The disadvantages are high risk of infection, because there are big size of synthetic prosthesis and big incision of the vaginal mucosa, dyspareunia as a result of decreasing vaginal length.

**Conclusion:** we prefer Ls SVP in patients with long history of activities life (sex incl.). It should be better to use Prolift system in old patients with extra- genital pathology, obesities women and women who had open surgery before.

### Transvaginal extraperitoneal neofasciogenesis in pelvic floor reconstruction. (9)

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**Background:** Despite the development of pelvic organ prolapse surgery, relapse frequency remains high.

**Methods:** Modern treatment concept should base on the destroyed fascia substitution with new fascia fixation to strong pelvic structures. Our modification in these concept calls transvaginal extraperitoneal neofasciogenesis (patenting \_2008105403, Russia), bases on TVM technology. We tried to improve some classic technology demerits. We reveal the absence or poor structure of arcus tendineus fascia pelvis (ATFP) at 50-70% of women, that increases anterior vaginal wall relapse probability. The absence of mesh isthmus strong fixation leads to post hysterectomy enterocele. No reliable posterior part fixation is the cause of prolonged healing and vaginal mucous erosion with mesh wrinkling and incomplete mesh straight in isthmus and posterior parts. Our technique (3 supplemental fixation points): anterior part of mesh system we have under bladder. Four anterior arms of mesh symmetrically lead through ATFP, each part of arms must be tension free sewing under obturatorium membrane. Posterior part of system lays down to anterior rectum wall, posterior arms leads through sacrospinal ligament. Distal part of posterior mesh cut in 5cm long. New arms leads symmetrically under m. levator ani in abdominal direction from anus. In vaginal hysterectomy mesh isthmus must be fixed to the sacrocrural ligament and posterior vaginal wall without mucous by resolving seams to prevent mesh wrinkling in vaginal vault. Levatoroplasty carried out at end of operation makes hymen physiologically narrow to keep biocenosis and cosmetic effect.

**Results:** From March 2007 till June 2008 we operated 45 patients (26 to 80 years of age, mean 50,4). Patients were followed up for 1,2 years. There were no complications and relapses. In one case there was dyspareunia de novo vs. 2 with sexual function improvement.

**Conclusion:** Transvaginal extraperitoneal neofasciogenesis may be recommended in wide usage as effective and safe concept at pelvic organ prolapse surgical treatment.

### Prolift system in treatment of P.O.P. (10)

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**Background:** Pelvic organ prolapse (POP) is one the most common reasons of pelvic floor dysfunctions and could significantly reduce quality of life (QoL). There are a lot of surgical techniques for treatment different forms of POP.

**Methods:** In this study we assessed anatomical and functional outcome of repair of severe forms of POP using all variants of PROLIFT system (ant, post, total). All operations performed a standardized technique in one center by senior surgeon. All data regarding preoperative hospital stay and follow-up were recorded in standard protocol.

**Results:** From June 2005, 115 symptomatic patients with POP II-IV were operated. Prolift anterior (47), posterior (24), total (27), anterior and posterior (17) in case of preservation of the uterus were used for this purpose. Mean age was 62.3 (37-86). We use standard examination, POP-Q measurements, vaginal and perineal ultrasonography, anorectal manometry, electromyography of EAS to assess pelvic floor to all patients. Proctodefecography was done if necessary. As QoL assessment tools we use PISC-12, PFDI-20 and PFIQ-7. In case of anal incontinence and anterior anal sphincter defects we use sphincteroplasty combined with levatoroplasty (62 [54%]). In case of SUI including latent SUI we use transobturator sling (TVT-O) (47[40.8%]). In case of cervical elongation we performed amputation of cervix (20 cases (17%). Mean operation time was 83±19min, hospital stay - 3 (2-10). Intraoperatively in 5 cases (4.3%) diagnosed and sutured bladder injury with no consequences. In 3 cases (2.6%) massive bleeding in excess of 500ml from pudendal artery and paraurethral venous plexus, which requires laparotomy and remove prosthesis for adequate haemostasis in 1 case. Mean follow-up was 16 (2-37) month. In 7(6%) cases there was exposure of mesh, treated by excision small part of the mesh with vaginal suturing. 1 patient (0.8%) has recurrence in Prolift total group due to incorrect operative technique. In QoL there are statistically significant decrease score in PISC-12, PFDI-20 and PFIQ-7 (p>0,05)

**Conclusion:** Prolift system<sup>(TM)</sup> is highly effective in treatment of severe and recurrent POP, but future randomized comparative trials with long-term results are needed.

### **Vaginal hysterectomy. Bipolar vs. suture. (11)**

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**Background:** In 19th century professor DO Ott reported the removal of an 8 kilo uterus vaginally. Have our surgical achievements advanced since then?

**Method:** We compared duration, blood loss and period of recovery following vaginal hysterectomy using conventional technique and electrosurgical bipolar vessel sealer (EVBS) using GYRUS generator.

**Results:** Since 2005 250 consecutive patients were scheduled for VH with 0-1 stage of POPQ; age was 36-80 years with pathology: adenomyosis, uterine fibroids, necrosis of myoma after embolisation, uterine cancer (1A). Uterine size was up to 16 weeks (1500 g). Patients were divided into two groups: 65 with suture (Vicryl) as haemostatic modality, 185 with bipolar coagulation (Gyrus PlasmaKinetic SuperPulse Generator). In this group suture were used to restore vaginal cuff. Duration of the procedure was defined as time from mucosal injection to closure of the vaginal cuff. Blood loss was estimated by swab wedding. Mean operation time was 58 and 29 min respectively ( $p>0.05$ ). Blood loss was 130ml in 1 group and 60 ml in 2 group. For prophylaxis of vault prolapse we used McCall high culdoplasty. For concomitant SUI we used TVT, TOT slings and needle suspension techniques. We had one bladder injury in a case of morcellation of a big myoma, detected and repaired intraoperatively. No expected thermal or hemorrhagic complications in both groups.

**Conclusions:** Bipolar VH can be performed in standard technique in challenging patients: with compromised history, pathologic obesity, nulliparous, no prolapse, enlarged uterus and cancer of uterus (1ε). Electrosurgical bipolar system is a safe procedure which decreases timing of the operation, blood loss and provides practically painless postoperative period. Moreover, this technology can enable more gynecologists to perform vaginal surgery in difficult patients. Increasing the number of hysterectomies performed vaginally should reduce morbidity and increase productivity for women while decreasing hospital stay and overall costs.

## **JOINT MEETING WITH THE ITALIAN COLORECTAL SOCIETY**

### **CURRENT APPROACH TO FAECAL INCONTINENCE**

#### **The dynamic anatomy and surgery of idiopathic fecal incontinence. (12)**

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The pelvic suspensory ligaments and muscle are presented. Based on video x-ray data, a new musculo-elastic sphincter is presented: the rectum is stretched around an immobilized anus by contraction of the levator plate and longitudinal muscles of the anus muscles acting against competent pubourethral and uterosacral ligaments. Data from 4 separate surgical studies are presented demonstrating >80% cure of idiopathic fecal incontinence following repair of lax pubourethral and/or uterosacral ligaments.

#### **Pathophysiology of faecal incontinence. (13)**

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The pelvic floor sustains continence. Stress urinary and faecal incontinence may occur when the external urinary and/or anal sphincter is weakened by direct trauma, by damage to its innervation, or both, as in childbirth. However, there are other features of pelvic floor dysfunction in stress incontinence, including laxity, perineal descent on straining and organ prolapse, indicating a more general dysfunction, and stress incontinence may develop even when there is no direct injury to the external anal sphincter. We pro-

vide evidence that perineal dysfunction in incontinence, whether of its anterior part in stress urinary incontinence, or its posterior part in stress faecal incontinence, is associated with ligamentous laxity together with damage to the muscles of the pelvic floor. A histological study of biopsies taken from the mid portion of the pubococcygeus muscle in women with stress urinary incontinence, during the midurethral slingplasty procedure, revealed fibrous scar tissue, indicative of severe muscle damage in half the cases, and myopathic and neurogenic features in the remainder. Reinforcement of the pubourethral and uterosacral ligaments by slingplasty restored urinary and faecal continence, indicating that weakened perineal muscles could function sufficiently well to restore pelvic floor function if their ligamentous attachments were tightened. Intra-operative experiments revealed features of ligamentous laxity that were correctable by intra-operative experiments. We conclude that ligamentous laxity can cause muscle dysfunction by unloading pelvic floor muscles sufficiently to cause stress incontinence. This dysfunction is analogous to tenotomy in limb muscles. This Musculo-Elastic concept of perineal function brings together the Integral Theory of Petros and Ulmsten (1990), with the neurogenic and muscle trauma evidence of Swash and colleagues (1985), to provide a unified theory of perineal function in health and disease.

#### **Diagnosis of faecal incontinence. (14)**

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A thorough clinical history of the bowel function, including dietary, medication, surgical and social history together with a detailed anorectal examination remain the most important basis in the assessment of patients with faecal incontinence (FI). Much of the specialized investigations such as anorectal physiology, endoanal ultrasound (EAUS) and magnetic resonance imaging (MRI) serve to confirm the clinical impression.

Endoanal ultrasound provides good images of the anatomy of the pelvic floor and anal sphincters. Its main function is to define the presence of and extent of sphincter defect(s) and scarring, and if the process involves either or both the internal and external sphincters. This has largely replaced the need for the painful needle electromyography. In addition, high-resolution three-dimensional EAUS, constructed from a synthesis of standard 2D cross-sectional images, provides information on anal canal length and on longitudinal extent, area and volume of sphincter defects. Endoanal ultrasound is portable, easy-to-perform, and should be part of the armamentarium of any colorectal surgeon interested in the pelvic floor. MR imaging may provide information on external sphincter atrophy due to fat replacement, however it is costly, and not readily accessible.

Functional assessment with anorectal physiology remains important. A low resting anal canal pressure in the presence of an intact internal sphincter suggests internal sphincter dysfunction, especially if the patient complains of passive FI. The presence of a poor resting and squeeze anal pressures in the presence of sonographically intact sphincters suggest a stretched anal injuries, especially if there is diffuse hypoechogenicity within the external sphincter. By contrast, presence of prolonged pudendal nerve terminal motor latency is an additional contributing factor to FI.

Diagnostic modalities aid the decision making in the management of FI. Presence of an isolated defect of the external sphincter on EAUS is an indication for a sphincter repair, if the defect exceeds 25% of the circumference, and the patient is significantly symptomatic. A co-existing defect of the internal sphincter is a poor prognostic factor to a successful sphincter repair, and patients should be appropriately counselled as injectable therapy with a bulking agent, such as silicone biomaterial, might be necessary at a later stage. On the other hand, if there are multiple deficits, such as concomitant pudendal neuropathy, internal sphincter dysfunction and multiple defects of external sphincter, then sacral neuromodulation is more likely to be effective. In patients with internal sphincter dysfunction, presenting with passive FI and reduced resting anal pressure injectable bulking agent is the preferred initial treatment.

**Sacral Nerve Stimulation in faecal incontinence. (15)**

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**Aim:** The long term results of patients treated with permanent sacral nerve modulation (SNM) for faecal incontinence in one unit were reviewed from analysis of a prospectively maintained database.

**Method:** Between January 1996 and March 2007 26 patients underwent permanent sacral nerve modulation after peripheral nerve evaluation (PNE) in every case. There were 22 (84.6%) females and 4 (15.4%) males of median age 55 years (range 23-80 years). Follow-up was recorded up to September 2007.

**Results:** One patient was lost to follow-up having been referred to other units. Median follow-up in the remaining 25 patients was 38 months for the incontinence group (1-24). Of the patients in the incontinence group failed and the device was removed. Four patients partially lost initial effectiveness after a median interval of 42 months from insertion of permanent electrode. They required further treatment [bulking agent injection (n=1), anti-diarrhoea medication (n=1), surgical repair of rectocele (n=1), manual evacuation (n=1)], but in no case was the device removed and incontinence scores had been recorded at every follow-up assessment. Median Incontinence Wexner Score was 11.95 (range 3-21) before treatment and 3.52 (range 0-17) at the last follow-up ( $p > 0.001$ ). The 85.71% of patients had a score  $> 5$  before SNM compared to the 23.8% at the last follow-up. The 76.19% of patients experienced and improvement over 50% of basal score.

**Progress in Sacral Neuromodulation understanding:** Patient selection for SNM remains empiric and successful trial stimulation is the best indicator and should be used a routine diagnostic test. Current research on SNM points to the hypothesis that it acts as afferent modulation. Evaluation of somatosensory afferent pathways by somatosensory evoked potentials (SEPs) allow evaluation of the integrity of the peripheral nerve sensory branch, spinal nerves, posterior columns, lemniscus pathways of the brain stem and thalamus and parietal cortex. The pudendal nerve carries sensory fibers from the sacral area to somatosensory cortex and the Pudendal Evoked Potentials (PSEPs) are the neurophysiological tool for afferent

activity. The PSEPs are easily recorded with stimuli applied to the dorsal nerve of the clitoris or penis. Between October 2007 and March 2008, 16 patients underwent to Tined Lead implant for FI and bilateral SEPs of the pudendal nerves were recorded at T0: baseline before implantation, T1: 1 month after stage 1 stimulation set at 21 Hz and T2: 1 month after stage 1 stimulation set at 40 Hz. Based on clinical evaluation patients were divided in two groups: group A (13 patients) with good improvement to proceeds to second stage implant of IPG and group B (3 patients) that failed SNM. Overall episodes of liquid or solid incontinence per week decreased from 8 at baseline to 1,81 post implant ( $P = 0.000$ ). Cleveland Clinic Score improved from 13,69 at 7,44 post implant ( $P = 0.000$ ). Ability to postpone defecation improved in 92,1% of patients (Tab 1). FIQoL significantly improved ( $P = 0,001$ ) as for physic ( $P = 0,004$ ) and mental ( $P = 0,012$ ) domains of SF36. SNM produced a significant decrease in pudendal SEP Sensory threshold and P40 latency among T0 to T1 in group A (Tab 2). The increase in pulse rate (from 21Hz to 40Hz) leads to a decrease of cortical latency of Pudendal SEPs facilitating the afferent impulse transmission. The change in P40 pudendal nerve SEPs observed in our study supports the current hypothesis of a specific action of SNM on the somatosensory pathway. The action of SNM on the afferent pathway from the sacral area to the somatosensory cortex is specific and pudendal SEPs evaluation provides evidence to this effect.

**Conclusion:** A modification of SEPs induced by SNM seems to be a prognostic factor of clinical outcomes.

TABLE 1.

	Urgency pre		Urgency post		
	< 1 min	<10 min	<15 min	30 min	
< 1min	2	5	2	4	81,2%
<5 min	0	2	0	1	18,7%
	12,5%	48,3%	12,5%	31,3%	
		92,1%			

TABLE 2. – SEPs Results

Nerve	Baseline	Hz 21	Hz 40	p Value		
	Mean T0	Mean T1	Mean T2	T0 vs T1	T0 vs T2	T1 vs T2
<b>Group 1</b>						
Rt pudendal:						
Sensory threshold ( $\mu$ V)	3.30	3,01	2.91	0.029*	0.038*	0.665
P40 latency (msec)	40.82	38.96	38.46	0.015*	0.003 *	0.796
Lt pudendal:						
Sensory threshold ( $\mu$ V)	3.61	2.84	3.21	0.244	0.032 *	0.078
P40 latency (msec)	40.17	38.98	38.06	0.006 *	0.004 *	0.039 *
<b>Group 2</b>						
Rt pudendal:						
Sensory threshold ( $\mu$ V)	8.76	9,50	8,00	0.404	0.309	0.270
P40 latency (msec)	38.69	37.94	37.73	0.333	0.148	0.668
Lt pudendal:						
Sensory threshold ( $\mu$ V)	6.44	6.16	6.97	0.196	0.152	0.395
P40 latency (msec)	37.96	37,36	38.35	0.273	0.026	0.267

### **Management of fecal incontinence. (16)**

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Fecal incontinence is one of the most debilitating and depressing functional disease of the digestive tract. Its prevalence in the population is uncertain and its severity ranges from minor incontinence to flatus to disastrous major incontinenes to solid feces.

In the last 30 years there has been an increasing interest among colorectal surgeons on its treatment, together with an increasing knowledge of the pathophysiology of the pelvic floor and the continence mechanisms. While in early periods any efforts were addressed to increase the sphincter tone in order to prevent the involuntary passage of feces, (sphincteroplasty, postanal repair, artificial bowel sphincter, dynamic graciloplasty, etc), nowadays there is great interest on the multiple and still incompletely known effects of sacral nerve stimulation (SNS). This is achieved by means of an implantable pulse generator connected with the pelvic plexus via a sacral electrode placed percutaneously under local anesthesia and fluoroscopic control. This new treatment, inherited by the urologists, has extended greatly the surgical armamentarium available to the surgeons, with an unexpected possibility to influence rectal sensitivity and, probably, motility, together with some effects on the pelvic floor muscles. Although the correct indication is still uncertain and no predictive factors have been identified, SNS can be tested virtually in any form of incontinence except from patients with complete spinal lesions.

The wide range of indications of SNS, together with an increased attention toward the rehabilitative techniques and the use of injectable anal bulking agents, respond to an increasing request of minimal invasive procedure, virtually riskless for a benign and functional disease like fecal incontinence.

### **New innovations in management of faecal incontinence. (17)**

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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.

### **Submucosal carbon microsphere injection is effective in treating passive faecal incontinence. (18)**

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Thirty two consecutive patients with passive faecal incontinence were treated with sub-mucosal injection of carbon microspheres. Patients were evaluated by endoluminal ultrasound, anal manometry and electrophysiology pre-operatively and at 6 weeks, and by SF36 quality of life score and Wexner incontinence score pre operatively and at 6 weeks and 6 months.

Mean resting pressure by anal manometry increased significantly (28 to 34 mmHg,  $p=0.035$ ), however maximal squeeze pressure did not (58 to 59mmHg,  $p=0.94$ ). SF36 quality of life scores did not change significantly in the physical domain (55 to 64,  $p=0.11$ ), but

did change in the social domain (52 to 69,  $p<0.05$ ). Wexner incontinence scores were significantly improved at 6 weeks (14 to 7,  $p=0.05$ ) and 6 months (14 to 8,  $p<0.05$ ). Patients with proven internal sphincter injury on anal ultrasound appeared to do better than those without.

Submucosal carbon microsphere injection appears to be an effective treatment for passive faecal incontinence, particularly in those with an internal sphincter injury.

### **Surgical treatment of fecal incontinence with the A.M.I. Soft Anal Band. (19)**

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Fecal incontinence (FI) has great impact on professional, social and sexual life. When conservative treatments (nutritional regimen, pelvic re-education, biofeedback, bulking agents) fail 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 improve FI gracilo-plasty or an Artificial Anal Sphincter (AAS) is offered to the patient. This lecture deals with the indication, results and, especially, with the technique of AAS implantation, demonstrated by a video clip. Although we have implanted very few soft anal bands so far (14) it already is obvious that the AAS implantation is a very valuable surgical procedure for FI with good functional results and low morbidity.

### **Artificial bowel sphincter for faecal incontinence: the Italian experience. (20)**

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The study report long term results on 37 patients with previous artificial bowel sphincter (ABS) implant for faecal incontinence (FI). Thirtythree were females and 4 males, with mean age of 50,7 yo (23-79). Cause of FI were: idiopathic in 46%, obstetric 19%, neurologic 16%, previous surgery 8%, malformation 8%, trauma 3%. Twentytwo patients (59%) had previous surgery for pelvic or perineal diseases. Early complications were observed on 12 pts (32%) with substitution of components in 8 (21,6%). Complesively 22 pts (59%) had ABS removal, 4 early 18 late: among these pts 5 (13%) show a continence improvement. In 15 pts the device is still in place (41%), in 9 inactivated and in 6 working. Causes of inactivation were obstructed defecation (OD) in 4, inability in 2 and pain in 2. Three of these pts were lost at f-u; the others had a mean f-u of 58 months: 4 are incontinent, 7 complain OD, 3 anal pain. Complesively 8 (66,6%) show good continence and 6 (50%) no F.I. and no other symptoms (OD or pain). Among the 6 pts with ABS still working, 4 (66%) show good results. One main cause of poor results is the association with rectal prolapse: 1 good result in 10 pts (10%). In conclusion ABS implant is burden by a worrying incidence of post-operative complications and long term failure rate, the control of the continence seems not related to a dynamic sphincter mechanism, obstructed defaecation and anal pain are the major concern in the small proportion of patients with success. Careful patient's selection is mandatory.

### **Trans-Obturator Anal Sling (TAS) (video). (21)**

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*Introduction:* Faecal Incontinence (FI) is defined as a loss of voluntary control of the passage of liquid, stool or flatus. The prevalence of faecal incontinence in the general population is poorly understood. It is likely that the prevalence is between 11% and 17%(1,2). This appears similar for both genders and increases age and varies by socioeconomic status and ethnicity. Faecal Incontinence is a complex problem and its pathophysiology is often multifactorial, involving both suprasphincteric and sphincteric dysfunction.

Risk factors for FI are obstetric trauma, anal surgery, anal dilatation, fistula and haemorrhoid surgery, rectal prolapse. Many specific (Parkinson's disease, multiple sclerosis, diabetes mellitus) and non-specific(aging) may be associated with their effect on continence

through their effects on mobility, ability to carry out activities of daily living which make cause effects associations even harder to determine.

Different kind of operation are describes in the international literature in order to cure completely the faecal incontinence. Here are listed the more frequent operation:

Surgical Procedure	Results	Complications
Spincteroplasty (3)	50- 60%	None
Postanal Repair	8,5- 38%	None
Dynamic Gracilo-plasty (4)	45- 80%	Infection, Constipation, Insufficient contraction of the m.gracilis
Artificial Sphincter	Bowel Up to 50%	Infections, revision surgery, explantion (20%)
Gluteoplasty	73%	Perirectal abscess, dysesthesias, severe chronic pain
Sacral nerve Stimulation (5)	50%	None
Injectable Agents	Bulking Up to 60% improvement	

As we can see, the long term results of these operations dealing with full continence are poor. We are developing this new surgical technique in order to have a new tool for the cure of faecal incontinence with promising results.

*Description of surgical technique:* A paranal vertical incision, nearly 3cm long is required. This incision is usually made on the left part of perianal area. After this, it proceeds with blunt and sharp dissection of subcutaneous fat until the medial raphe that will be overcrossed by the finger in order to overcome the anal canal to the other side. The type of mesh we use is composed by Polypropylene. The mesh is a rectangular shape 6 x 2cm. attached to 4 arms 1cm x 25cm each (2 each side). A small incision of 1cm at the inferior level of obturator foramen is carried out bilaterally. Then a curved Deschamp's needle is introduced out-in until the tip of the needle reach the space prepared before, the mesh is then placed under the anal canal in a smooth and easy manner. In order to moderate the mesh's tension, a double combined manoeuvre is accomplished with the apposition of the finger into anus, meanwhile with the other hand it pulls the arms of the mesh, until we feel a strong and reliable support below the sphincter. In this way we evaluate the lift and the competence of anal sphincter. This procedure can be made in male gender, as well. In our preliminary experience the procedure has been carried out in 10 pats. with an overall results of 70% (cured/improved) after a mean follow-up of 6 months.

*References are available from the author on request.*

## MALE PELVIC DYSFUNCTION SYMPOSIUM

### Overview of male incontinence. (22)

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Prostatectomy, especially when performed for control of cancer, continues to be an important cause of incontinence in the male. The major cause is impaired function of the external urethral sphincter. Incontinences rates following radical prostatectomy vary widely among different series due to disparities in patient selection and in the definition of incontinence. After 1 year, the incidence of total incontinence is 0-5%, 5-15% of the patients requiring some degree of protection.

The artificial sphincter implant is the most widely used surgical procedure but complications, limited durability and high cost have favoured the emergency of new surgical therapies.

Surgical therapies for post prostatectomy stress incontinence can be now classified into compressive devices, relocation slings

(ADVANCE) and STEM CELLS. The compressive systems can again been classified as non adjustable systems (BULKING agents and INVANCE), adjustable systems (PRO-ACT, ARGUS, REMEX, ATOMS) and pressure regulators (AMS, FLOW SECURE).

The long term success rate and complications of AMS are well known. New therapies have been studied only in a reduced number of cases with a short follow up. As far as mild and moderate stress incontinence is concerned it seems that incontinence status are quite similar for all techniques. AMS has shown better results in severe incontinence.

New techniques are not free of complications, bladder perforations, perineal pain, acute urinary retention, infection and urethral erosion have all been described. The need for adjustment has happened, depending on the adjustable technique, in up to 82% of the cases.

In conclusion, although slings and new technologies alternatives look very promising they should continue being evaluated.

### Assessment of post-prostatectomy incontinence. (23)

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Recent increase in the understanding of male pelvic anatomy together with an explosion of technology have witnessed a significant evolution of the technique and the surgical approach to radical prostatectomy. Despite of our best efforts, urinary incontinence remains a bothersome complication for both the patient and the treating urologist. This is the first session of a series of lectures focussing on the management of patients with post-prostatectomy incontinence. It will begin with an outline of the surgical anatomy and physiology of the male continence mechanism, followed by the epidemiology and pathophysiology of post-prostatectomy incontinence. Clinical assessment will then be presented together with a discussion on the use of urodynamics and its relevance on treatment decision-making. The lecture will then be followed by other speakers on the various surgical approaches now available to treat post-prostatectomy incontinence.

### The development of the AdVance retroluminal transobturator male sling. (24)

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*Introduction:* Compression of the urethral lumen is not the only way to treat male urinary stress incontinence. Intrinsic sphincter deficiency is the concept used to describe the reason of postprostatectomy incontinence. More and more evidence demonstrates the need to further define the precise reason why the sphincter mechanism fails. Not a single incontinent individual is identical in terms of the reason for his urinary incontinence. Hypermobility of the membranous urethra or laxity of the dorsal sphincter complex may disfigure the membranous urethra so much that during straining the lumen is not coapted or occluded anymore. This distal membranous urethral prolapse is the focus of attention in cases of postprostatectomy incontinence that can be treated with a retroluminal transobturator sling focusing on proximal relocation.

*Early days 2003:* At least 22 individuals or groups worldwide worked on the concept of using a transobturator sling to treat male urinary incontinence in 2003. The only group that believed that by using a transobturator sling, positioned at the proximal urethral bulb, a non-compressive proximal relocation can be attained correcting urethral prolapse was Gozzi and Rehder (Abstract SIU Meeting on Prostatic Disease: Recent Advances and New Technologies. Bariloche, Patagonia, Argentina September 29-October 1, 2005). This was based on the theory that male urethral prolapse plays a vital role in the etiology of male urinary incontinence. These urologists wanted to create an operation that supports the midperineum.

*Male pelvic weakness and membranous urethral prolapse:* During radical prostatectomy the urinary sphincter mechanism may be weakened in a number of ways. These include injury to the rhabdosphincter directly, shortening of the functional membranous urethral length, damage to the nerves and blood supply of the whole sphincter complex, fibrotic fixation of the dynamic sphincter layers inhibiting sliding and compressive potential and damage to all the support structures causing distal membranous urethral prolapse. In summary damage may be related to the blood supply, nerve supply,

muscle fibres, support structures and plasticity of the dynamic sphincter mechanism. Severe fibrosis causes fixation and immobility of the membranous urethra, whereas damage to the support structures causes hypermobility especially on the dorsal side of the urinary sphincter mechanism.

*The retroluminal nature of the male transobturator sling:* A male transobturator sling with a broader middle portion positioned underneath the bulbospongiosus muscle on the proximal corpus spongiosum and tensioned moves the latter cranially in a pendulum-like manner<sup>1</sup>. The final position of the centre-piece of the sling is a straight line between both inferior pubic rami. Checked by intra- and postoperative transrectal or perineal ultrasound the sling is retroluminal or retrourethral<sup>2</sup>. This is also confirmed by cadaver dissections. The measured distance between the membranous urethral lumen and the sling is 5-10mm (average 8.7, n= 16). This means that in a patient after a straight forward prostatectomy and in a normal patient, it should be highly unlikely to anatomically obstruct the urethral lumen by compression. The retroluminal sling position minimizes the risk of erosion.

*Urothelial coaptation:* A positional reflex is responsible for occluding the lumen of the membranous urethra. In a continent male the membranous urethral lumen is coapted but not obstructed. By performing a urethroscopy in the lithotomy position irrigation fluid easily runs through the urethra into the bladder. As soon as the irrigation is stopped the membranous urethral lumen snugly occludes by way of urothelial coaptation. When the dorsal sphincter support structures are damaged and these structures prolapse distally, then the sphincter mechanism is distorted and the lumen is not effectively occluded anymore. Endoscopically this can be appreciated by non-coaptation of the urothelium within the membranous urethral lumen, even when the irrigation is stopped. The membranous urethra becomes hypermobile and descends distally out of reach of the pelvic zone of normal anatomy. The pelvic floor musculature does not transmit pressure directly onto the membranous urethra. The membranous urethra in its correct position enables a positional reflex to cause urothelial occlusion. When the dorsal aspect of the membranous urethra prolapses urothelial coaptation is not possible anymore and the resting functional membranous urethral length is shortened. A retroluminal transobturator sling supports the dorsal membranous urethra indirectly by cranial relocation of the proximal corpus spongiosum.

*International multiprofessional cooperation:* After having performed more than 10 prototype male transobturator slings (prototype study n=20 published in Eur Urol)<sup>3</sup> in incontinent men starting in 2003, the AMS (American Medical Systems, Minnetonka, Minn, USA) research and development engineer Suranjan Rowchowdury contacted Rehder and Gozzi in Innsbruck. These patients were well documented and the proposed reason for incontinence was hypermobility of the membranous urethra (sphincter complex). To treat this urethral prolapse the proposed mechanism of action of the male transobturator sling was central pelvic floor support. This could be easily attained by placing a transobturator sling at the proximal corpus spongiosum and tensioning it. The path of the helical introducer needle from outside-in is through both obturator fossae perforating the gracilis fascia and muscle directly underneath the insertion of the adductor longus tendon. It then continues through the obturator externus muscle, obturator fascia, obturator internus muscle and a condensation of fascia at the medial border of the inferior pubic ramus on the inside of the pelvis, but underneath the pelvic floor. After clicking the gripping device of the sling onto the introducer needle the sling is pulled through both obturator fossae by back-rotation of the needles. AMS was very keen on learning more and organised a telephone conference among George Webster, Ed McGuire, Christian Gozzi and Peter Rehder. This fruitful conversation culminated in George Webster and Ed McGuire visiting the Medical University Innsbruck observing four cases of surgery performed by Gozzi and Rehder. George Webster wanted to see the endoscopic appearance of the sphincter and the degree of coaptation of the urothelial lumen intraoperatively, and then realized... "You've got something there!" Extensive and exhaustive cadaver dissections performed by Rehder and Gozzi followed at the University of Minnesota, USA, sponsored by AMS. A new introducer needle and sling specifically designed to fit male anatomy was then designed by Kevin Arnal (R&D engineer from AMS), Christian Gozzi and Peter Rehder.

The cooperation of experienced reconstructive urologists in Inns-

bruck, world renowned key opinion leaders in the field of reconstructive urology and the treatment of incontinence in the USA, the genius of excellent R&D engineers and the enthusiasm and go of a private medical device company, culminated in the introduction of a new theory of male postprostatectomy incontinence and a novel way of treating it. This has spearheaded a new era in the treatment of male incontinence, similar to the way that the integral theory of Petros and Ulmsten have changed the way of understanding and treating female incontinence.

*References available on request from the author.*

### **The retrourethral transobturatoric sling as a treatment of male stress incontinence: preliminary results on 51 patients. (25)**

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*Introduction:* In the last years male patients who suffered from stress incontinence as a complication in 20-40% following radical prostatectomy could only be offered the artificial sphincter as a final solution, beside the conservative treatment options. Recently several surgical treatment options based on implantation of alloplastic material have been developed. These procedures compete against each other and need to be evaluated.

*Material and methods:* We treated 51 patients suffering from mild, moderate and high incontinence with the retrourethral transobturatoric sling Advance from AMS. The aim is to resolve the laxity around the sphincter-zone in order to improve continence. All 51 patients, incontinent because of open radical prostatectomy surgery done before, were operated between January 2007 and June 2008. Examinations were done preoperatively and 2 to 4 times postoperatively. The examination focused on pad usage during day and night, urination frequency and quality of life in a 6 point scale. Additionally we treated a subset of 4 patients with preceding radiation and 3 patients with preceding artificial sphincter implantation who failed therapy.

*Results:* Pad usage reduced from 7,6 pads preoperatively to 2,1 pads postoperatively in average. QoL improved from an average score of 4,9 to 2,5. Both pad usage and QoL improved in the first 6 weeks after surgery and worsened slightly in the 12 month survey. Patients with moderate and severe incontinence improved from 4,4 and 7,8 pads during daytime to 2,8 and 3,0 pads. QoL improved from 5,3 preoperatively to 3,4 four months postoperatively. There were no serious complications. One Patient needed revision (without using a new sling) because of postoperative bleeding. Results after radiation and artificial sphincter implantation were not so promising. Most treatment intentions failed.

*Conclusion:* For patients after open radical prostatectomy surgery the implantation of the retrourethral sling is a safe and effective treatment option of stress incontinence. This sling was designed to cure mild stress incontinence but it seems to cure patients with moderate and severe incontinence as well.

### **The Advance male sling procedure for treating urinary incontinence in patients after prostatic surgery, the first sling procedure recreating the sphincteric zone. (26)**

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*Introduction:* In the treatment of urinary incontinence after radical prostatectomy or TUR-P actually there exist only some minimal-invasive treatment options. Bulking agents show only a minimal effect on the continence in a long time follow-up. Different sling procedures and an obstructing balloon system work with a compression of the urethra and or the bladder neck and elevate the LPP for 35 cm H<sub>2</sub>O. The success rates vary from 50-80%. Complication rates (bleeding, infection, migration) differ in the literature from 10-20%. We evaluate the effect of the Advance-male sling procedure prospective in 3 different european centers. We observe a descensus of the bulbus urethra / the bladder neck in male patients after RPE/TUR-P, similar to a female prolaps. The Advance-sling procedure relocates the bulbus urethra in its former anatomic correct position, minimizing the descending of the sphincteric zone during micturition and recreating its function.

*Material and methods:* 180 male patient after RPE (95%) and



TUR-P(4%) with urinary incontinence were treated with the Advance-male sling system, 60% of the patients were treated before with bulking agents and or stemcells. Two patients had an obstructing balloon system before, 3 patients had an artificial sphincter in the past. Patient used in average 4 pads/day, urine loss 190 g/1-h pad test. Preoperative an evaluation of each patient with urethroscopy, 1-h-pad-test, 24-h pad test, an urodynamic evaluation, post voiding residual, ICIQ-UI-SF and I-QOL-questionnaires was performed. Follow-up was dated 1 week, 6 weeks, 1,3,6,12,18 months after the procedure.

**Results:** 180 patients in three centers were treated, by 4 surgeons. Follow-up 0-22 months (median 7 months), Hospitalization time  $\bar{O}$ 4,5 days (3-6 days). Cured (no pads) 126/180 patients (70%), 34/180 (19%) improved (1-2 pads/24h, no cure 20/180 patients (11%). 10 patients were retreated with an Advance. 3 patients were treated with an artificial urinary sphincter. 11/13 are cured, 1 patient needs 1 pad/24h. No significant intraoperative blood loss occurred, wound infection was diagnosed in 1 patient, and treated with antibiotics, the sling had not to be removed. Significant residual volume had to be treated in 18 patients (10%), the residual volume had to be treated in 9, 4/9 patients need a SPK, 1 patients were on IC for 6 weeks, all patients had no residual volume at the 3-month follow-up.

**Conclusion:** The Advance-male sling-system is a safe minimal-invasive functional therapy to treat urinary male incontinence after prostatic surgery comparable to the female anterior slings. In our patients we observe a high cure rate of 70%, or substantially improved (19%). Patient satisfaction was high with a low risk profile.

### Adjustable Continence Therapy for the treatment of male stress urinary incontinence. (27)

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**Introduction:** The ProACT device, developed by Uromedica Inc for the treatment of male stress urinary incontinence is a minimally invasive treatment for this condition, with the unique feature that it is post operatively adjustable if required. It consists of two silicone elastomer balloons placed paraurethraly at the bladder neck in post radical prostatectomy patients or at the level of the membranous urethra in patients who have residual prostatic tissue following benign surgery. Each balloon is attached via a conduit to a titanium port buried in the anterior lateral aspect of the scrotum. Post operative adjustment of the balloon is facilitated by percutaneous injection of the port, a minimum of 4 weeks post operatively, with a 4 week interval between further adjustments. The implant is available in 12 and 14cm length and each balloon can be inflated up to 8cc over time if necessary. The ProACT device can be simply inserted using general, spinal or local anaesthesia as required. The procedure was first performed by Huebner et al. With the patient in lithotomy position, the bladder is emptied and filled with 100 cc of contrast solution. The filling cystoscope is retained to maintain horizontal positioning of the urethra. Two small perineal stab incisions are made on each side of the urethra, to allow passage of the balloons via designated blunt and sharp trocars and outer cannula. The trocar is designed to perforate the pelvic floor and is gently rotated to advance it towards the bladder neck or membranous urethra as appropriate. Image intensification is used to identify the position of the trocar in relation to the urethra and final position. Once in position, the trocar is removed and a tissue expanding device (TED) inserted through the U shaped channel of the cannula. This device dilates only the area where the balloon will be inflated. The choice of device length is generally made based on the patient anatomical configuration. Prior to insertion, the device is primed to remove all air and is soaked briefly in antibiotic solution. The trocar is removed and the balloon inserted with the assistance of a push wire. Once in position, the balloon is inflated using an isotonic contrast and water mixture using a dedicated non coring 23G needle and syringe. The process is repeated on the contralateral side. A urethrogram should be performed to verify position and a 12 Fr Foley catheter inserted overnight. A superficial pocket is created in the sub dartos fascia of the anterior lateral aspect of the scrotum taking care to ensure that the ports are well separated and able to be accessed easily during post operative adjustments.

**Material and methods:** We set out to evaluate this procedure in a group of males with urodynamic stress urinary incontinence. Post prostatectomy incontinence was the major reason for patient pres-

entation. Patients were evaluated using daily pad count (0-1 safety pad/day -dry;  $\geq 2$  pad/day but  $> 50\%$  pad reduction - improved;  $\geq 2$  pad/day and  $< 50\%$  reduction -failure); Incontinence Quality of Life (IQOL) questionnaire, PGI and Visual Analogue Scale (VAS) at baseline and at 1, 3, 6, and 12 months, then annually thereafter. 64 patients have been implanted with ProACT between July 2000 and September 2004. Mean follow up was 19.51 months (range 12 - 62 months). Mean age of patients at time of implantation was 65.4 years (range 25 -79 years). Operative time was 19 mins (range 10-35). All patients underwent implantation of the ProACT balloons utilising spinal anaesthesia. Blood loss was  $< 20$ mls in each case. Analgesia was not required post operatively and all patients could be discharged within a mean of 1.1 days (range 1-2) of implantation. Foley catheters were usually removed within 24 hours post operatively, but were retained for 4 days (range 3-5) where operative bladder perforation had occurred.

**Results:** 68% of patients were pad free (dry) at the last follow up. Patient improvement based on global assessment (PGI score) and VAS was noted at each time interval and is described in Figure 3 and 4 respectively. The results are shown in the tables below.

11 patients had previously undergone external beam radiotherapy prior to implantation of their balloons. 4 (36.3%) were dry following adjustment. 2 of 11 (18.2%) were improved, 5/11 (45.5%) were unchanged from before their initial ProACT surgery at last follow up. Three of these patients required removal of single balloons due to erosion. 80% of these occurred within 6 months post op. with the remaining 20% occurring at 12 months. The volume in the balloons at time of erosion was equally distributed between 1.5mls and 7mls and was not statistically significant based on a 95% confidence interval.

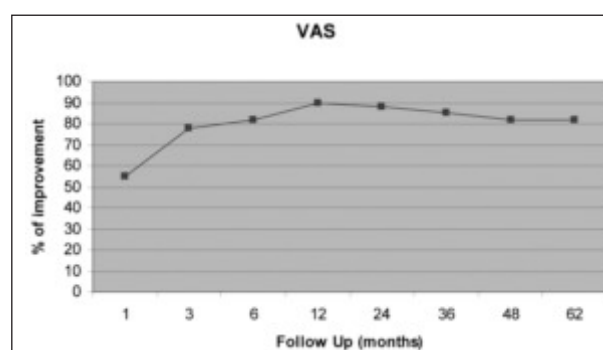


Fig. 1. - Pad. Count

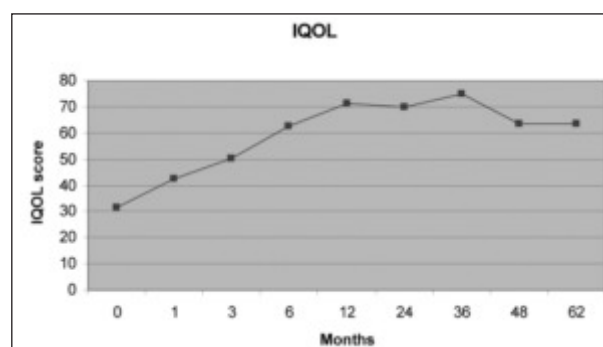


Fig. 2. - Quality of Life

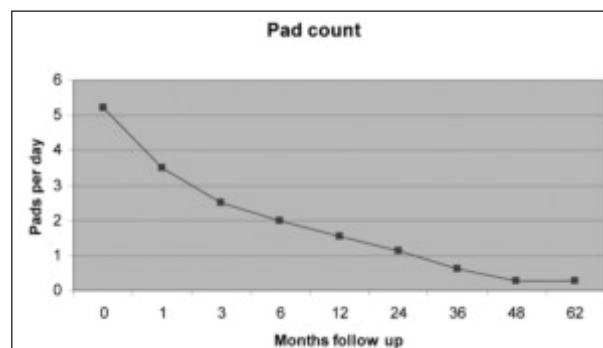


Fig. 3. - Visual Analogue Score

References are available from the author on request.

*Discussion:* The preliminary results appear to demonstrate that the implantation of the ProACT may offer relief of symptoms in men with SUI resulting from different causes. The main complication in this group was early erosion which occurred almost exclusively within this group. Reassuringly however, resolution was easy, with uncomplicated removal of the device in an outpatient setting without further sequelae. Conservative balloon inflation and adjustment should be adhered to in post radiotherapy patients. The ability to post operatively titrate was of great benefit, and as shown by the numbers of adjustments performed was a well utilised feature.

### **FlowSecure Artificial Urinary Sphincter: clinical experience, management and results. (28)**

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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 urethral 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 were to confirm whether surgical technique, management of patients and results were reproducible.

*Patients, materials and methods:* The FlowSecure AUS is a one piece pre-filled silicone device comprising a (1) pressure regulating balloon, (2) a stress relief reservoir for conditional occlusion, (3) a single wrap-around cuff adjustable in the range 4-7 cm and (4) a control pump with a self sealing port for injection of additional fluid to adjust pressure. 17 patients were implanted with the new AUS from October 2006 to date at our institution. Bulbar urethra cuffs were implanted in 16 male patients with stress incontinence secondary to radical prostatectomy (14), retropubic prostatectomy for BPH (1) and orthotopic ileal bladder (1). 5 patients had failed previous surgery for incontinence and 3 patients had previous history of pelvic radiotherapy. One Spina Bifida female patient was also implanted in the bladder neck.

*Results:* Mean operative time was 57 minutes (39-97). There were no intra-operative complications, though one AUS was punctured when suturing the cuff and needed intra-operative replacement. At implantation, a mean volume of 9.3 cc (6-10.2) was required to be withdrawn from the system in order to leave the device depressurised during the immediate post-operative period. Urethral catheter was removed 2.5 days (1-4) post implantation and mean inpatient hospital stay was 4 days (3-7). Post-operative complications included scrotal oedema/haematoma in 6 patients and pump malposition in 1 patient who needed surgical revision and intra-operative repositioning. Initial device pressurisation was performed 2 weeks post-implantation and subsequent pressurisations were performed at weekly intervals if needed. A mean total volume of 6 cc (3-6) was necessary to inject in 3 (2-4) subsequent weekly punctures in order to reduce daily use of 6-8 pads before the AUS was implanted to 0-1 pads once the pressurisation process concluded.

*Interpretation of results:* The FlowSecure AUS can be used for bulbar urethra and bladder neck. The surgical technique is easy to learn and associated with little handling, reducing risk of infection and potential assembly errors. The association of a pressure regulating balloon and a stress relief reservoir allows the cuff occluding pressure to be set at a low range, reducing risk for atrophy and erosion. The latter is especially relevant in patients needing intermittent catheterisation. The system can be individually adjusted to clinical needs in order to achieve satisfactory continence rates. Surgical procedure, management and results are reproducible.

*Concluding message:* Though short term results look promising, long term results are needed to confirm that the FlowSecure device is an alternative to the AMS-800 AUS.

### **ATOMS – A new device for male incontinence. (29)**

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*Background:* We present a new self-anchoring adjustable transobturator male sling and the surgical procedure for the treatment of stress urinary incontinence in men with initial results of the first 10 patients.

*Methods:* All of the patients were evaluated with urodynamic study, pad test, cystoscopy and had a written informed consent. 6 patients had totally incontinence (condom catheter, > 10 pads/day), 4 patients had mild incontinence (pad usage 4 – 7). 4 Patient had a radical laparoscopic, 2 Patients had a radical retropubic and 2 had a radical perineal Prostatectomy. 1 Patient of the perineal group had a bone anchored male sling in situ. 2 Patient had a laser enucleation of the prostate and a TUR-P. 2 Patients were after secondary irradiation. All patients were placed in lithotomic position and the operation was performed in general anesthesia. The implant was placed through a perineal approach with an inside-out technique and the port was placed on the left symphysis region. All patients had a catheter for 2 days postoperatively. Adjustment was made 2-3 weeks after placement.

*Results:* All patients received the implant without intraoperative complication. One patient received the implant with an outside-in technique because of his anatomical physiognomy. One patient received a bone anchored male sling removal and an ATOMS implantation simultaneously without complication. In the follow up period of 1 to 5 month there were no wound infections. 3 patients reported perineal pain > 3 weeks. One patient showed a port rotation. 3 patients with grade II incontinence are dry (0 pads), 4 Patient with grade III incontinence use a safety pad/day, 1 patient with grade II (instable bladder after irradiation) and 2 patients with grade III incontinence uses 2 pads/day. Filling volume of the device to reach dryness ranged from 13ml to 24ml.

*Conclusion:* The ATOMS Implant is a promising new device for the treatment of stress urinary incontinence in men. It is simply adjustable at any time without surgical procedure by filling or deflating the cushion and it is not a mechanical device. Further studies are necessary to evaluate the efficacy and safety of this system in the different grades of incontinence.

### **Male Remeex system. (30)**

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Urinary incontinence after prostatectomy is a frustrating and bothersome problem for patients, with a significant negative impact on quality of life. The rate of urinary incontinence 12 months after radical prostatectomy ranges from 5% to 30%. The treatment of persistent stress urinary incontinence is mainly based on surgery. The best results are achieved by implanting an artificial urinary sphincter, but with significant complication and revision rates. Recently several techniques have been described that use a male sling. Different materials and fixations are being used, either with a composite of synthetic materials, human fascia, or porcine dermis, fixing methods with bone anchors.

The male Reemex system is an adjustable suburethral sling that permits effective regulation of the suburethral pressure at any time during the patient's life. The possibility of control is always an advantage in incontinence surgery but is especially important in male SUI because of the narrow error margin between urinary retention and leakage persistency. Remeex is implanted by perineal approach. A soprapubic incision will receive the varitensor and the needles with the sling's suture, by a perineal approach. A vertical incision is made at the perineum and the urethra surrounded by bulbocavernous muscle is carefully dissected in order to found the angle between the bulbocavernous and ischiocavernous muscles. At this point, the urogenital diaphragmatic fascia is sharply penetrated and the hole is enlarged with scissors to permit the introduction of the index finger. Digital ascending dissection of the retropubic space is then performed trying to reach the highest possible position in order to diminish to a minimum the space between the finger tip and the anterior rectus fascia. A 60 degree modified Stamey needle is then pushed down from the retropubic until it reaches the finger tip. At this moment, the needle is passed down to the perineal area through the Retzius space guided by our finger to avoid urethral or bladder

perforation. The same manoeuvre is performed at the other side. A cystourethroscopy is then performed to ensure bladder integrity. If there is no perforation, the traction thread tips are passed through the needle hole and the needles pushed from the perineal field to the suprapubic area, where the tips of the traction threads are pulled up until the polypropylene sling mesh is in full contact with the bulbocavernosus muscle without asserting pressure. The sling is then fixed and fully extended by placing four reabsorbable stitches. The traction thread tips are introduced into the *varitensor*, and wound into it by rotating the manipulator clockwise until the *varitensor* rests over the abdominal rectus fascia. The operation ends by closing the abdominal wound, leaving the external manipulator connected to the *varitensor* and protruding through the centre of the abdominal incision. At mean follow-up of 32 months the success rate is 65%. Remeex implant seems to be effective with high patient satisfaction although long-term results are needed.

## JOINT MEETING WITH SIUD & AIUG

### CURRENT APPROACH TO MANAGEMENT OF URINARY INCONTINENCE

#### Adult consequences of paediatric urological problems. (31)

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There is scarce but slowly increasing literature on long-term outcome of congenital malformations in adults, and consequences into communities' health care. This is an unresolved problem for doctors, medical care organizations and the society. Throughout the world, increased dramatic survival of newborns and children with major congenital anomalies, in general, produced a new generation of persons, who have problems due to the continuing effects of their illness. Adolescent Medicine is a growing area, and departments for many disciplines exist, where specific pathologies are treated, combined with all the problems of adolescents. Specialists dealing with continence care obviously focus on those congenital anomalies that involve lower urinary and intestinal tracts, and perineal structures. Most of those conditions are rare in the population as a whole, but there is a need to take care of adult consequences of them. For conditions which have no equivalent in adult life seems inappropriate to pass care from paediatric to the local adult care, as may be done for diabetology or rheumatology. Thus, an adult urologist or gynaecologist or coloproctologist cannot be expected to look after patients born with, for example, exstrophy, posterior urethral valve or anorectal anomaly, when he is likely to have seen only one or few in his entire carrier.

**Kidney Function.** Damage to the kidneys occurs in foetal life in many of the urological, and also genital, malformations. Even if renal failure treatment is a task of nephrologists, urologists and gynaecologists who take care of the patients have to follow-up renal function, as well; and renal follow-up is an integral part of adolescent care. Patients who reach adolescence with a glomerular filtration rate of less than 40ml/min/1.73 m<sup>2</sup> have a substantial chance of developing end renal failure within 16 years (Neild GH, BMC Nephrol, 2004). Decisions on further surgical corrections should be made, taking in account renal failure, most often arising at puberty, with consequent polyuria, and possible necessity for kidney transplant.

**Bladder Function and Augmented Bladder.** The function of the bladder may have, particularly in the young, profound effect on renal function. This is evident in several boys born with posterior urethral valve and in almost all born with neural tube defects. In valve boys the main long-term consequences occur in utero, before valve resection, dealing with bladder dysfunction. In adulthood the pattern is of chronic retention, often with high pressure (De Gennaro M, BJU 1998). Very few problems improve in adolescents and adults and most deteriorate. Better management of the bladder reduces the incidence of renal failure, and control of its dysfunctions nowadays allows comparable graft survival compared with patients with normal bladders (Nguyen HT, BJU Int, 1999). All urinary reservoirs made of intestine have long-term problems: hyperchloremic acidosis occurs in up to 14% and many more may have metabolic acidosis; reservoirs stones occur in 12-15%, having as risk factors infection, retained mucus and catheterization. Perforation is rare but possible

and a most severe complication. Cancer is an important long-term risk, especially at anastomosis between urothelium and intestine, combined with the risk for cancer that bladder exstrophy has itself in long-term. Maximum neoplasm incidence had been found in classical ureterosigmoidostomy, up to 33% at 35 years, but under flexible sigmoidoscopy surveillance, it had been reduced to 10% at 35 years (Smeuders N, BJU Int, 2001). Even after having excluded reservoirs with feces, there is still a risk of neoplasia, calculated in 1.6% at 10 years (Soergel TM, J Urol, 2004) and flexible cystoscopy is advisable, annually, from the 10th year.

**Sexual Function and Fertility.** When a baby is born with a severe anomaly, it is hard to imagine how, in a 15 years adolescent, the interest with sex will be as great as in others. The problem in females with exstrophies or vaginal and urogenital sinus anomalies, is entirely anatomical, with at least 50% incidence of uterine prolapse in exstrophies Woodhouse CRJ, J urol, 2001). Infertility is the major issue in male born with genital abnormalities. The problem lies in the delivery of sperm to the vagina; even once corrected erectile deformities, and allowing penetration altogether, shortness of the penis may interfere with delivery the semen close enough to the cervix. Furthermore, ejaculation can be incompletely sustained by poor spongiosus muscle.

**Pelvic Floor and Genito-Urethral Surgery.** All congenital malformations including genitalia and pelvic floor, even after the most successful anatomical correction, and if continence has been achieved, have a residual pathological functional condition. The pathological embryology itself, the attempts of the surgeon to reconstruct such a complex entity as the perineum, are the causes of early and late dysfunction. Pathophysiology of the pelvic floor of adults born with congenital pelvic floor anomalies is completely unknown, yet. But recent surgical techniques and a modern surgical approach is more and more prone to respect pelvic floor anatomy, than in the past. Urodynamic studies and long-term functional follow-up may help in this respect.

#### The scientific basis of the overactive bladder. (32)

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Insight into mechanisms underlying the onset of detrusor over activity have for some time focused on changes in the behaviour of the smooth muscle of the bladder wall (myogenic hypothesis) and alterations in the central reflex activity controlling lower urinary tract function (neurogenic hypothesis). More recent developments have highlighted crucial aspects of both peripheral and central contributions to both normal and overactive bladder function. At a peripheral level, the urothelium is now recognised to be substantially more complex functionally than a mere barrier to urine. Its behaviour is affected by bladder distension and it releases active compounds that affect behaviour of subjacent nerves. It can also influence smooth muscle contractility. There are also interstitial cells suburothelially and within the detrusor muscle itself which are capable of stimulating the muscle and affecting nerve function. The interaction between these cell types may be crucial to generation of sensory activity and control of bladder behaviour. From this has emerged the integrative hypothesis, which states that the overall level of excitation within the regulatory structures at a peripheral level determines behaviour. Within the central nervous system, reflexes within the spinal cord and brain stem remain incompletely understood. However, functional imaging studies have given some insight into the role of the higher centres during urgency sensations and when attempting to resist voiding. These new developments point towards a very complex multifactorial basis for overactive bladder symptoms and hierarchical control of normal lower urinary tract function.

#### A prospective randomised controlled study comparing vaginal prolapse repair with and without Tension free Vaginal Tape (TVT) in women with severe pelvic organ prolapse and occult stress incontinence. (33)

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**Hypothesis / aims of study:** To compare the use of TVT™ retro-pubic sling or not in the treatment of occult urinary stress incontinence (OSI) at the time of prolapse repair.

**Study design, materials and methods:** A prospective, randomi-

zed controlled trial was conducted of women with OSI defined as symptomatically continent women with urodynamically demonstrable stress incontinence with (or without) reduction of prolapse (> Stage 2 on POPQ examination). Ethics committee approval at the Mercy Hospital for Women and Monash Medical Centre was obtained, the rules in the declaration of Helsinki were followed and informed consent was obtained prior to entry in the study. The pre- and 6 month post-operative protocol included: complete urogynaecological history, physical examination, multi channel urodynamics testing, 1-hour pad test and a three day bladder diary. The UDI 6 SF, IIQ7 SF, PISQ and visual analogue score (VAS) were used for subjective assessment of quality of life (QOL) and treatment success. The type of surgery performed was determined by the site of the prolapse and its most appropriate route of correction. The primary endpoint assessment was the need for subsequent anti incontinence surgery. Follow-up was at 6 weeks and 6 months.

**Results:** From Feb 2004 to Feb 2007 sixty nine women were eligible to participate and 52 were enrolled with randomization of 27 to no sling and 25 to TVT sling procedure which was performed concurrently with the prolapse repair. No differences in demographic or clinical characteristics of either group were detected. Type of surgery was similar in no TVT and TVT group. In particular anterior vaginal colporrhaphy (midline fascial repair without bladder neck plication) (5 vs 3) and anterior and posterior repair (12 vs 14) were the same in both groups. There was one (1) TVT sling inserted after 6 months following prolapse surgery in the group of women with prolapse surgery and no sling procedure and none in the prolapse and TVT group. The postoperative urodynamic study demonstrated urodynamic stress incontinence (USI) at 6 months in nine (9) of the non TVT and one (1) in the TVT group ( $p = 0.002$ ). The 1 hour pad weigh data showed no difference in the median score between the two groups at 6 months. Subjective assessment with VAS at 6 months (cure = VAS > 80) showed a median score of 90 in TVT vs 95 in the non TVT group ( $p=0.81$ ). The QOL questionnaires showed no difference between the groups at follow-up. Within both groups there was no difference in IIQ 7 SF with difference score mean of 1 [range; 0-6] and in the UDI 6 SF with a difference score mean of 0 [range; (-1) - 3]. Sexual function was assessed by PISQ and more than half of this patient group either declined to answer the PISQ or were not sexually active. In the patients with available data, the PISQ scores were not significantly different between the 2 groups.

Complications reported in the TVT/non TVT groups were: haemorrhage (defined as blood loss > 500ml) with 1 (4%) vs 2 (7.%) (however no blood transfusion was required in any patient), voiding difficulty postoperatively with urethral catheterisation in 1 (4%) vs 1 (3.7%) or intermittent clean self catheterisation in 2 (8%) vs 0 (0%) for 6 - 10 days post surgery.

**Interpretation of results:** In this study only one woman of 27 had clinically significant SI requiring a TVT insertion after six months in the non TVT group, despite the diagnosis of USI in eight other women in that group. 18 of the 27 women with occult USI in the no TVT group had no USI on repeat urodynamic testing following vaginal repair of the prolapse. These short-term results indicate that a clinician would have to insert 26 TVT slings unnecessarily to prevent 1 woman needing a sling postoperatively. Longterm follow up will be needed to confirm whether this trend continues. A potentially confounding factor (anterior vaginal repair) has been eliminated as the same number of anterior repairs were performed in both groups. There is a lack of correlation post operatively between the UD result and subjective results such as the symptom of stress incontinence and VAS. This might be due to the high sensitivity of the urodynamic testing demonstrating leakage at capacity of 500 ml. There is no difference in QOL and sexual satisfaction scores between the two groups. There was no significant haemorrhage attributable to the sling procedure. There was a significantly higher rate of temporary voiding difficulty in the TVT group requiring either indwelling or intermittent self catheterisation for less than 10 days. None required further surgery.

**Concluding message:** Our study shows that based on 6 month follow up, the routine insertion of a suburethral sling where occult stress urinary incontinence has been demonstrated prior to prolapse repair performed by the vaginal route cannot be recommended. Longer term follow up will be performed to determine if symptomatic stress incontinence develops in the no sling group

## Incontinence and urinary tract infections. (34)

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Urinary tract infections (UTIs) are clinically best stratified into uncomplicated and complicated UTIs. In complicated UTIs complicating factors within the upper or lower urinary tract are the major host factors responsible for the acquisition of UTIs. More than 50% of women experience at least one UTI episode during their life. Interestingly approximately 50% of women also experience at least one episode of incontinence during their life. There exists a significant positive correlation in healthy women between urinary incontinence and UTI and recurrent UTI. Up to date there is no clear pathophysiological basis, to explain this. One possibility could be the development of a complicating factor, such as cystocele and residual urine formation in female patients with incontinence due to pelvic floor insufficiency. On the other hand bacteria may alter their virulence factors in response to microenvironmental changes at the urethral meatus, which could take place in the case of uncontrolled urinary dribbling. Additional hormonal imbalance might lead to overgrowth of vaginal enterobacteria, increasing the likelihood of bacterial ascension.

In conclusion, urinary incontinence and UTI are significantly correlated. Most probably a complex pathophysiology exists, on the basis of which adequate treatment options need to be discussed.

## Is there any place for colposuspension? (35)

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The wide-spread acceptance of tension-free slings world wide apparently forced colposuspension onto the sidelines, even though still estimated to be the "gold standard" by Cochrane Collaboration or other scientific groups. In a Medline-search we found 547 publications on "colposuspension" within the last 10 years, only 157 between 2000 and 2005, many of these last ones describing the advantage of tension-free slings or describing complications of colposuspension.

Open retropubic colposuspension is a surgical treatment which involves lifting of the tissues near the bladder neck and proximal urethra in the area behind the anterior pubic bones to correct deficient urethral closure. The cornerstone of today's technique of colposuspension was laid by John.C.Burch in 1958, who first used the term "urethrovaginal fixation" and then later "urethrovaginal suspension"<sup>1,2</sup>. Colposuspension was first used by Turner-Warwick and Whiteside. Since then numerous modifications of this strategy, different terminologies and different suture materials have been published and proposed<sup>3</sup>.

With the development of the tension-free vaginal tape concept it seems that these slings have taken over completely and there is no indication for other procedures any more<sup>4</sup>.

The aim of colposuspension is a restoration of proper urethral function and maintenance of continence by positioning and well supporting the proximal urethra within the abdominal cavity. Downwards and backwards movements of the bladder neck during stress (hypermobility of the urethrovesical junction) are supposed to be the major cause of sphincter incompetence.

Since the early description of the Marshal/Marchetti/Krantz procedure<sup>5,6</sup> and the classical Burch<sup>1,2</sup>, the Cowan and Morgan modification<sup>7</sup>, the variations of Tanagho<sup>8</sup> or Turner-Warwick<sup>9</sup> many varied procedures have been described. In our experience with more than 250 reoperations after "Burch" in other institutions > 90% had been whatever suspensions, but, no "Burch". The many modifications and sub-modifications explain the wide-spread success and complication rates published, because very different procedures have been performed. A simple analysis of operating times demonstrates that surgeons and techniques must be very different: average operative times between 132 min (e.g. Paraiso et al. 2004) and 30 min in our institution (EP) must describe very different things.

The mechanism of colposuspension is bladder neck elevation and support, raising the pressure transmission ratio over 100% in the upper third of the urethra. In addition there is at least some functional outlet obstruction. It is sufficient to elevate the paravaginal tissue just to achieve some support for the bladder neck area; all attempts to reach Cooper's ligament area likely to induce voiding difficulties, de novo urge even not achieving better and longer lasting success rates.

In our hands indications for colposuspension include primary and secondary sphincter incompetence in the presence of good vaginal mobility and capacity, mainly with a paravaginal defect, where this technique allows to take care of the functional and the anatomical defect as well. In patients with low MUCP of < 20 cmH<sub>2</sub>O colposuspension is more likely to fail. In case of an overactive bladder (better urgency) caused by an anatomical defect (e.g. funneling of the bladder neck under stress or bladder neck insufficiency) a preoperative test by insertion of a pessary (imitating the effect of colposuspension) might be helpful and demonstrate an indication for surgery.

Cochrane evaluated 33 trials involving a total of 2403 women. Overall cure rates were 68,9 to 88,0% with a few studies demonstrating lower failure rates than with conservative treatment and anterior colporrhaphy, needle suspension and Marshall Marchetti Krantz procedure. The benefit was maintained over time (RR of failure 0,51; 95% CI 0,34 to 0,76 before the first year, RR 0,43; 95% CI 0,32 to 0,57 at one to five years, RR 0,49; 95% CI 0,32 to 0,75 in periods beyond 5 years)

Correct indication, use of open anatomical spaces and reducing extent of procedure is able to reduce complications of colposuspension. Systematic control of complications is rare, most of them apparently being unpublished. In a review of the literature we discussed typical problems like bleeding, bladder injuries, ureteral kinking or injury, voiding dysfunction and infections with incidences between 0 and 21,2 %; this might be caused by different definitions of complications, techniques, patient material, lack of follow-up or just honesty (49). In a prospective randomised comparison of colposuspension and TVT direct perioperative complications were comparable (42).

Obstructed voiding and secondary recto-enterocele are the clinically relevant complications after colposuspension, apparently correlating with the extent of elevation, thus overcorrection. Broad and high elevation might result in functional obstruction and a wide opening of the posterior compartment (49 - 57).

We prefer a lateral fixation with only slight elevation of the bladder neck, similar to the Cowan and Morgan or Tanagho descriptions.

Colposuspension should be performed or supervised by trained instructors who must anticipate potential problems, especially in women with previous pelvic surgeries

The author started with colposuspension in 1978 after having seen the technique demonstrated so impressively by Stuart Stanton, Sir Richard Turner-Warwick, Emil Tanagho and others in the late 70es and early 80s. We have been able to more and more minimize the open colposuspension, exchanging experience and ideas continuously. We performed more than 4500 procedures in the last 30 years. With such a long period it was impossible to follow all these patients continuously, either the surgeons changing their clinical position or because of the great mobility of the patients thus being lost to follow-up. But over the years, major unselected subgroups have been followed, looking for short- and long-term complications as well as objective and subjective success rates and satisfaction of the patients.

The evidence available indicates that open colposuspension is still the most effective treatment modality for stress urinary incontinence especially in the long term. Within the first year of treatment, the overall continence rate is approximately 85-90%.

In competition with the tension-free vaginal tapes colposuspension will remain the first choice for all laparotomies necessitated by other pathologies, especially in cases with marked paravaginal defects and in women with unstable bladders caused by anatomical defect.

*References available from the author on request.*

### **The role of urodynamics before and after treatment of USI and POP. (36)**

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Clinically significant ( $\geq$  Grade III) Pelvic Organ Prolapse (POP) is associated with: USI in 51-69%, latent USI in 23-50%, BOO in 30-66%, bilateral ureteral obstruction in 2%, UUI in 16-26%. A thorough functional evaluation of the LUTD before surgical correction of POP is an essential prerequisite to: understand the anatomic and functional conditions of the specific patient, assist the surgeon in

decision making, obtain the informed consent, anticipate the functional outcome of surgery, prevent post-operative complications. Video-Urodynamics assisted by intra-pelvic repositioning of POP (usually by a vaginal pessary) is the gold-standard test under these circumstances. It can help in: documenting detrusor overactivity (although its sensitivity is only about 50%), documenting OCU, discriminating whether the cause of OCU is POP or other possibilities are involved, including detrusor-external sphincter incoordination, documenting latent (occult) USI, documenting detrusor acontractility with an exclusive use of abdominal straining during micturition.

### **How to choose the best sling. (37)**

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Urethral suspension with a sling supporting the urethra, usually indicated as mid-urethra sling (M.U.S.) is nowadays the treatment of choice for stress urinary incontinence with urethral hypermobility. The transobturator approach has replaced the retropubic one, as it has proven to warrant the same success rate with a reduction in complications and side effects.

Some elements must be taken into account when a surgeon has to choose a sling among the many ones manufactured and put on the market. I suggest that the questions to be considered are the following: Can I improve my results without any additional risk of complications or on the contrary can I reduce complications without a decrease in positive results? Or, with equal results, other elements play in favour of the new device (e.c. less pain, shorter operating time or lower price)? The type of the synthetic sling is of utmost importance and at the moment, following the Amid classification, all the slings belong to type 1, that represent the best option for MUS, as they are associated with the lowest rate of complications. Biological sling are interesting, as they offer the lowest percentage of erosions, but their efficacy at a long term follow-up is not yet well established.

A new approach with minimally invasive slings has been introduced since 2005 and a number of products are actually available: TVTsecure, Needleless device, Miniarc, etc. They allow the surgeon to suspend the urethra with a shorter tunnel toward the obturator foramen or, only for TVT-s, also with a retropubic way. The time requested is less, probably there is a reduced risk of damaging the vessels and the bladder. Despite of these considerations, many surgeons believe that a more skill is needed to placing the sling in the right position, without compressing the urethra or leaving the device too loose. The efficacy and the complications of these new devices must be fully evaluated.

### **Long term efficacy of transurethral injections of bulking agents: a retrospective long term study. (38)**

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*Introduction:* The purpose of this study was to assess the reliability of the paradigms/concepts: 1) the median duration of success of bulking treatment for urodynamic stress urinary incontinence (with or without urethral hypermobility) by bulking agents is short and 2) positive outcome of bulking treatment necessitate repeated injections.

*Materials and Methods:* A retrospective study was performed from January 1999 and September 2006 evaluating outcomes of 230 women who had undergone transurethral bulking injections with Contigen and Macroplastique to treat urodynamic stress incontinence. A telephonic interview was performed using PGI-I and I-PSS (8<sup>th</sup> question, bother score) questionnaires; a further question was asked: "would you reserve the same treatment for a relative or a friend?". 190 women were interviewed of whom 183 answered the questionnaires, 180 of whom were considered reliable.

*Results:* Subjective postoperative incontinence outcome was positive in 103 (57,2 %) women: in 18,7 % of women was verbally reported as dry, in 66,8 % as improved, a slight improvement was reported in 14,5 % of cases. A total of 77 women (42,7 %) were not improved. A single injection treatment was performed in 98 (54,4 %) women. In this single group the 60,2 % of women reported outcome as dry or improved, 39,8 % as not improved. More than one treatment (up to three) were performed in 82 (45,6 %) women

and outcome in this group was dry or improved in 53,6 % of cases, not improved in 46,4 %.

**Conclusion:** The reliability of the two paradigms/concepts was not assessed by the present study: 1) it is not true that the median duration of success of bulking treatment of stress incontinence by bulking agents is short: at 2 – 9 years follow-up 57% of positive results were reported; 2) it is not true that positive outcome of bulking treatment for urodynamic stress incontinence necessitate repeated injections: 54,4 % of the women in the group of 103 with positive outcome, received a single injection of bulking agents.

The present study seems to invalidate the previous assessed concepts/paradigms about bulking treatment for urodynamic stress incontinence

### The management of recurrent Stress Urinary Incontinence after Burch colposuspension. (39)

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**Background:** The management of recurrent stress urinary incontinence is a distressing problem. We aimed to notify our experience with the recurrent cases after Burch colposuspension.

**Methods:** There were 262 cases who have undergone Burch colposuspension for the primary treatment of stress urinary incontinence. The cure rate was 84%. There were 42 failures (16%). The recurrent cases were treated in the light of literature with midurethral sling surgery, periurethral injection, anticholinergic drug therapy and biofeedback therapy.

**Results:** The number of recurrent cases was 42. Ten cases were treated with tension free vaginal tape (TVT) / intravaginal slingoplasty (IVS) operations (group I), 13 cases were treated with transobturator tape (TOT) operation (group II), 19 cases refused another surgical intervention (group III). In group I, 5 patients were cured 5 patients were a failure. For the treatment of this failures 2 patients underwent transobturator tape (TOT) procedure (1 of these patients was cured, the other one reported that her stress urinary incontinence complaint had declined dramatically, therefore she was accepted as a partial recovery), 1 patient underwent periurethral injection (however, the patient was still leaking and she started biofeedback therapy), 2 patients still leaking after the midurethral sling surgery and these patients refused another intervention and started to anticholinergic drug therapy. In group II, 8 patients were cured, 5 patients were a failure (3 of these patients started anticholinergic drug therapy concomitant with biofeedback therapy, whereas 2 patients refused any other intervention. In group III, 12 patients started anticholinergic drug therapy (3 of them were happy with the drug, 7 patients had good effects of the drug and 2 patients discontinued anticholinergic drug therapy because of side effects), 7 patients refused any intervention.

**Conclusion:** The management of recurrent cases after Burch colposuspension should be tailored individually. Midurethral slings (particularly TOT) seems to be a better option, not only ease of operations but also their relatively high cure rate. The number of patients who refused another intervention after the Burch colposuspension was comparatively high. This could be due to the long period of recovery after Burch colposuspension.

### The changing role of urodynamics in urinary incontinence. (40)

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“Urodynamics” should be regarded as a “way of thinking”, rather than merely as a list of functional tests. Lower Urinary Tract Symptoms – LUTS can take origin from dysfunction occurring in both the storage and the voiding phase of the bladder function. A number of different LUTS, arising from dysfunction in the two bladder phases, often coexist, thus representing the “two faces of the moon”. A pressure/flow study, possibly including perineal surface EMG, can provide comprehensive information about bladder and pelvic floor function, during the full storage/voiding cycle. The dichotomic categorisation of Stress Urinary Incontinence (SUI) as being due either to Urethral Hypermobility or to Urethral Intrinsic Sphincter Deficiency appears more and more too much simplistic. There is a growing clinical impression that some degree of ISD may exist in many patients who were thought to have only hyper-

mobility as a cause of their SUI. This conceptual shift toward a continuum interpretation is mostly based upon the concept of Valsalva Leak Point Pressure (VLPP). VLPP studies, especially if integrated with fluoroscopy in videourodynamics, may also help in searching the presence of occult SUI in patients with Pelvic Organ Prolapse (POP). The changing role of Urodynamics, therefore, is mainly paced by our ability to thinking functionally, or, in other words, to thinking urodynamically.

## COMPLICATIONS OF PELVIC SURGERY WITH PROSTHESES

### Voiding dysfunction after anti-incontinence surgery (41)

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**Introduction:** Voiding dysfunction after pelvic surgery may be caused by anatomic or functional disturbances. The causes may be related to outlet obstruction or failure to store. Failure to store can be caused by detrusor overactivity resulting from denervation supersensitivity. Failure to empty, mainly bladder outlet obstruction, is related to increased tension resulting in urethral compression. Sutures too medial, close to the urethra, can cause urethral deviation or periurethral scarring. In addition, if sutures or tapes are tied too tightly, overcorrection and “hypersuspension” of the bladder neck and urethra may result. The clinical manifestation is a low and intermittent flow during micturition, hesitancy, slow stream and high post void residual.

**Anti-incontinence surgery and voiding dysfunction:** Immediate postoperative urinary retention is the most common type of voiding dysfunction after any anti-incontinence procedure (Table 1)

TABLE 1.

Authors	N	No. patients with retention	No. With resolution
Karram <sup>1</sup>	350	17 (4.9)	11
Hung <sup>2</sup>	23	2 (8.7)	0
Tavian <sup>3</sup>	200	14 (7)	0
deTayrac <sup>4</sup>	31	8 (25.8)	8
Levin <sup>5</sup>	313	8 (2.5)	7
Aboussaly <sup>6</sup>	241	47 (19.5)	37
Paick <sup>7</sup>	247	38 (13.9)	33

In most of these patients, urinary retention (partial or complete) is transient, secondary to postoperative edema of the bladder neck and urethra, and resolves with catheter drainage. The estimates probability of temporary urinary retention lasting longer than 4 weeks is 5% for retropubic and transvaginal suspension and 8% for sling procedures<sup>8</sup>.

Storage symptoms, including frequency, urgency and urge incontinence are also common after incontinence surgery, in the immediate post-operative period. In patients who are emptying well, a trial of anticholinergic drugs can be used, while if patients are not emptying well, intermittent catheterization should be considered. Sometimes, however, it is only time that will cure this problem. Storage symptoms occurs in 75% of women, while only 61% refer obstructive symptoms and 55% experienced de novo urge. Urinary retention as the sole symptom was uncommon, occurring only in 24% of cases<sup>9</sup>. Postoperative voiding and storage symptom most resolved within the first 4 weeks.

In an extensive literature review to determine the incidence of voiding dysfunction after incontinence procedure, persistent voiding dysfunction (longer than 4 weeks) has been reported to occur in 5% to 20% after Marshall-Marchetti-Krantz procedure, 4% to 22% after Burch colposuspension, 5% to 7% after needle suspension, 4 to 10% after pubovaginal sling and 2% to 4% after TVT procedure<sup>10</sup>.

**Evaluation of voiding dysfunction:** An accurate history and assessment of storage and voiding symptoms, and a positional voiding are the first step for the evaluation. The physical examina-

tion includes signs of the hyperelevated bladder neck and urethra, persistent or worsening of the pelvic organ prolapse and erosion of the mesh in the vaginal wall. Post-void residual volume (PRV) should also rule out. From a functional point of view, there are no absolute urodynamic criteria defining the obstruction in women, despite various proposed cut-off values. Chassagne et al. proposed a cut-off value of 15 ml/sec flow with a combined detrusor pressure at least 20 cmH<sub>2</sub>O. Blaivas and Groutz classified obstruction with a detrusor pressure more than 20 cmH<sub>2</sub>O, despite no flow or inability to void with a catheter in place. Cystoscopy can show scarring, narrowing, occlusion, kinking or deviation of the urethra. Moreover, the urethral and the bladder should be carefully inspected for eroded sutures, sling material or the presence of a fistula. A standing cystogram in the anterior-posterior, oblique and lateral position can assess the degree prolapse and the displacement and distortion of bladder neck and urethra. A voiding cystourethrogram can assess the bladder, bladder neck and urethra during voiding to determine narrowing, kinking or deviation.

**Surgical procedures:** Important factors for decision making include the type of sling, the temporal relationship from surgical procedure and the onset of symptoms, the material used and the patient desire. A three-month waiting period arose from data on autologous fascial slings that loosened with time. An other important aspect is the tissue reaction after a short period even though the actual trend is to perform urethrolysis as soon as 4 weeks to impede any further fibrous reaction. A midline sling section is indicated in the short term period after midurethral sling in case of severe urinary retention. When the procedure has been carried out previously (6 months or more) or if different procedures (MMK, colposuspension, etc.) have been carried out, a complete urethrolysis should be performed.

**Synthetic midurethral sling loosening or lysis:** After infiltration with local anaesthetic, the previous incision is opened and the sling is found by direct inspection or palpation. An angle clamp is placed around the tape. During the early postoperative period (up to about 10 days), the tape must be pulled down or loosened. After longer period, it is usually necessary to cut the tape. Simply cutting or loosening or loosening a midurethral synthetic sling has yielded excellent results: Klutke et al reported resolution of obstruction in all 17 of their patients, and recurrent SUI in 1 patient<sup>11</sup>. Rardin et al. found that impaired bladder emptying resolved in 100% of 23 patients, with 61% remaining continent, 26% having partial recurrence, and 13% having complete recurrence<sup>12</sup>.

**Transvaginal pubovaginal sling incision:** Intervention for obstruction caused by pubovaginal sling is usually done after a longer period of time than with midurethral synthetic sling. The dissection is usually more extensive and general or regional anaesthesia is required. The first-line treatment is a simple sling incision<sup>13</sup>. Transvaginal incision of the pubovaginal sling alone may effectively eliminate obstruction with similar results to a formal urethrolysis, limiting morbidity, potential injury to soft tissue or nerve, and fibrosis from surgical dissection. If the sling cannot be clearly cut, formal urethrolysis should be performed.

**Transvaginal urethrolysis:** Bilateral urethrolysis is indicated when bladder neck and proximal urethra are fixed in high retro-pubic position. Transvaginal urethrolysis was originally described by Leach and Raz, as a primary operation (rather than retro-pubic urethrolysis) because it is easier, less morbid with quicker recovery times and highly effective<sup>14</sup>. Carey et al reported the use of Martius labial fat pad flap in association with transvaginal urethrolysis with success of 87% of patients<sup>15</sup>. The Martius flap may decrease the risk of recurrent fibrosis and provide some urethral support. The use of Martius flap should be reserved for selected case such as repeat urethrolysis and extensive fibrosis. If there is a remnant rigidity of the bladder neck area, a suprameatal urethrolysis is mandatory just to mobilize completely all the urethra.

If a vaginal approach is not feasible due to the patient's anatomy or if surgeon prefers, urethrolysis can be performed via a retro-pubic approach. The technique was firstly described by Webster and Kreder that reported excellent results with a sharply incision of all adhesion of prior cystourethropexy and a complete mobilization of the anterior vaginal wall<sup>16</sup>. The procedure is completed by and obturator shelf repair to prevent rotational descent and placing an omental pedicle to fill the retro-pubic dead space and prevent further scarring. In selected cases (e.g. extensive mobilization or SUI co-existing with obstruction) it may be desirable to resupport the urethral

at the time of urethrolysis. It may increase the risk of persistent obstruction so it is best to deal with recurrent SUI at a later time. It is also possible to treated recurrent SUI with transurethral collagen injection: Goldman et al reported a 66% response rate to collagen in women with recurrent SUI after transvaginal urethrolysis<sup>17</sup>. The literature reported outcomes give a success rate ranging from 65-93% with an incidence of de novo stress incontinence from 0 to 19%<sup>18, 19</sup>. The long-term outcomes show the appearance of mild bladder myopathy probably related to chronic neurogenic dysfunction. In patients who fail to void satisfactorily after urethrolysis, repeat urodynamics does not give conclusive information about the cause of the failure. Explanations include poor contractility or intrinsic damage to the urethral innervation from surgery.

**Conclusion:** Bladder outlet obstruction after pelvic surgery is a complex condition. The long-term outcome is not as good as expected even though should be a tool in the hand in the urogynecologists to improve as much as possibly the QoL of such a patients that cannot be managed otherwise.

*References available from the author on request.*

### Voiding evaluation after stress urinary incontinence surgery. (42)

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Numerous reports in the international bibliography inform voiding disorders after stress urinary incontinence surgery, such as: - urinary tract infections (10% - 64% not antibiotic prophylaxis and 0% - 15% with antibiotic), de novo urge or overactive bladder 8% - 27%, post void residual volume (15.8% - only 3.5% symptomatic), voiding dysfunction 5% - 20%.

The presence of voiding dysfunction not necessarily indicates abnormal post void residual volume but may increase the long-term morbidity through increase risk of infection, detrusor overactivity and subjective voiding difficulties. There is still no agreement about the appropriate assessment and management of post surgical urinary dysfunctions. The frequency of its presentation vary according to the used method for its study in the different centers and the preoperative predicted factors remain with low limiting accurate prediction of early voiding dysfunction.

Urinary infection, de novo detrusor overactivity, urinary retention and voiding dysfunction modify the outcomes of surgical treatment of stress urinary incontinence. After surgery the voiding dysfunction is evaluated by: 1 - QoL Questionnaires (subjectives), 2 - Electronic Uroflowmetry, 3 - Uroflow Monograms (Liverpool), 3.1 Voided volume at Mx flow, 3.2 Voided volume at average flow rates, 4 - Mon Electronic Uroflowmetry

Early voiding dysfunction occurred in 5.8% of post operative women. Pre operative pressure flow rate < 15 ml/seg (p:0,04) and general anesthesia (p: 0,02) were the only positive predicted factors (Duckett J R).

Sander evaluates the voiding function in patients that subjectively and objectively cured or improved SUI: 95% (n:38) at 3 years of follow up, 63% subjectively felt an altered voiding function.

We analyzed 80 patients who underwent vaginal surgery of SUI and anterior vaginal wall prolapse. G1: 20 TVT (age: x: 52.5), G2: 20 TOT (age x: 50.6), G3: 20 (age x: 60.1) anterior repair, G4: 20 (age x: 50.2) normal control group. All of them completed QoL Questionnaires, Stress Test, Electronic Urodynamic Studies, Liverpool monograms, free non electronic flowmetry. All of them did not have post voiding residual urine.

Abnormal findings (<12ml/seg):

G1: preoperative 3/20 (15%), postoperative 5/20 (25%), total 8/20 (40%).

G2: preoperative 7/20 (35%), postoperative 2/20 (10%), total 9/20 (45%)

G3: preoperative 7/20 (35%), postoperative 5/20 (25%), total 12/20 (60%)

G4: all patients > 15 ml/seg.

Normal group versus TVT (P:0.04), normal vs. TOT: p: 0.05, normal vs. AR: p:0.002

When we compared non electronic flowmetry with electronic uroflowmetry there were no significant differences between the two studies.

**Conclusions:** Until now measurement of urine flow with electronic uroflowmetry through maximum and average urine flow

rate and voided volume is a non invasive screening test for voiding difficulty. The shape of the flow curve depend on: detrusor contractibility; abdominal straining; bladder outlet (Dunn J. S. et al). There is no consensus about the cut off point of the lower limit considered normal so the measures proposed are arbitrary. In our study we consider as lower limit <12ml/seg. The use of monograms allows improving the diagnosis of voiding difficulties (sensitivity 81%, specificity 92%) (Haylen B et al.). Basically uroflowmetry is a screening test and does not give by itself a diagnosis of causes. In cases of normal flowmetry complementary studies for diagnosis are necessary (pressure/flow studies, etc.). The presence of urethral catheter during uroflowmetry may alter the result of urine flow rates (Ryall RL). Non electronic uroflowmetry combined with postvoid residual volume measurement is an appropriate screening test for voiding difficulties. If this is abnormal, electronic urodynamics studies should be done. The prevalence of voiding dysfunction after TVT, TOT and anterior repair is higher than the normally considered; the impact on QoL and health should be further studied with new studies.

*References available from the author on request.*

### **Surgical footprints: the role of the vaginal surgeon. (43)**

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*It is better to know some of the questions than all the answers (James Thurber)*

The role of the pelvic organ reconstructive surgeon is to erase the footprints mainly left behind by previous obstetric experiences- be it by the mechanical damage caused by the birthing process or by the, up to now not described, role that the obstetrician plays in this processes. The footprints of the aging process and collagen changes add to the challenges facing the pelvic organ reconstructive surgeon.

In the surgery done by the surgeon a new set of footprints can be laid down: these are not always to the advantage of the patient: this lecture is about those. The focus will be on the vaginal approach to surgery, with special reference to surgery of the anterior compartment. The different options available in corrective surgery will be highlighted.

The plight of the young patient and the patient who had suboptimal results after previous pelvic reconstructive surgery will show which type of primary surgery should be the preferential footprint. Stumbling blocks can be changed into stepping stones, if the surgical choice for the primary operation is correct.

Practical pointers for the vaginal surgeon will be the use of a *colposuite* setup in theatre. With the use of a camera in the theatre light and strategically placed video screens for viewing by the assistants and surgeon, as well as the use of a magnified picture on screen, surgery is easier to assist and safer. With this concept the surgical footprint is improved. By using an auditing system the vaginal surgeon can keep a close watch on his/hers surgical footprinting.

### **Neurological risks of pelvic floor vaginal surgery. (44)**

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The risk benefit ratio of prolapse surgery must be weighted. Classical and historical techniques have been progressively replaced by vaginal or abdominal «fixations» and later by prosthesis uses. Precise evaluation of new techniques is ongoing but several studies have already highlighted the risk of recurrence in other compartments or of pain. Traditional explanation is that a non-anatomic axe of the vagina could permit abnormal forces to create new prolapses. Another explanation could be that muscles (and nerve) responsible for the protection against prolapse can be damaged by previous anti-prolapse surgeries. We wanted to evaluate the risk of nerve injuries in the most frequent surgeries done in our country: sacrospinous ligament fixation (SSLF), posterior IVS, transobturator surgery for stress urinary incontinence (TOI), mainly in the in out procedure incontinence and TO surgery for prolapse (TOP).

Sacrospinous ligament fixation carries a rate of anterior vaginal wall prolapse varying from 10% up to 92%. Why not try to explain these new cystoceles by denervation and subsequent atrophy of the levator ani muscle due to an injury to the levator ani nerve (NLA)? Our dissections have confirmed that this nerve is always present on the superior aspect of the pelvic floor, above the sacrospinous

ligament. When a stitch is put about 2 cm medial from the ischial spine to avoid the pudendal pedicle, it is exactly where the NLA crosses the ligament. Intractable pain can appear after SSLF and can be the consequence of an entrapment of the pudendal pedicle. Furthermore, sciatic nerve injury has also been described after SSLF. De novo anal incontinence has also been described as urinary incontinence.

In IVS procedure, the ischiorectal fossa (IRF) is transfixated with a trocar attached to a tape, and advanced just before the SSL. It then perforates the iliococcygeus muscle just before the SSL. The inferior rectal pedicle is at risk of injury in the IRF. At the level the trocar perforates the muscle, there is an almost constant nervous branch innervating the anterior quadrants of the sphincter ani, at risk of damage. There have been no studies published, evaluating the neurophysiological consequences of this operation on the anal sphincter physiology and function.

There are 2 mainly types of TOI: the original out-in procedure and the in-out. Anatomical studies have demonstrated that the paths of these two techniques are different. Neurological risk are essentially the damage of the posterior branch of the obturator nerve. This branch is always at a minimum of 2 cm in the out-in procedure. In the reverse technique (in-out), not only the distance is smaller but the nerve can be sectioned by the trocar.

New techniques of prolapse repair with meshes are emerging. The arms of these meshes can be left without any fixation or passed through muscles and ligament. One path is through the inferior (in gynecologic position) part (angle) of the obturator foramen. The dorsal nerve of the clitoris often cut this angle as it detaches from the pudendal nerve immediately after the SSL and travels superior to the Alcock canal. The long-term significance of these potential injuries is not identified.

*Conclusion:* As prolapse and incontinence are essentially functional problems, complications should be reduced at the lower possible level. To achieve this goal, three dimensional anatomy of the pelvic floor and significant surgical landmarks should be well understood as important structures (mainly nerves) can be damaged.

### **Complications of biological implants. (45)**

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Surgical implants are designed to attach to the body wall by soft tissue ingrowth. When considering tissue augmentation, it is intuitive to select an inert permanent material, such as synthetic mesh (e.g., polypropylene; polyester). However, the host immune surveillance always mounts a foreign body inflammatory reaction, encapsulating the mesh in a fibrous envelope. Subsequent healing response is determined by two main factors: pore size/accessibility and device motion at the implantation site. Net result can be either beneficial or morbid, depending on circumstances. On one hand, adding synthetic mesh to a healing wound certainly increases tensile strength of the connective tissue scaffold. This is especially true of macroporous monofilament meshes (*Amid class I*), which generally incorporate by vascular and connective tissue ingrowth. On the other hand, tissue flexibility is reduced by the cicatrizing effects of the foreign body reaction, and by the fact that mesh itself is inelastic. In fact, even macroporous mesh implants typically contract by ~25% during the healing phase, creating a wound that is harder & stiffer than natural scar tissue. In some instances, continued severe inflammatory reaction can lead to erosion, deforming contracture or chronic wound pain. These adverse reactions are especially associated with microporous and multifilament meshes (*Amid classes II and III*), which always remain encapsulated in mini-seromas. Unfortunately, such adverse reactions also complicate a small proportion of *Amid class I* mesh implants.

Searching for a less morbid bolster, biomaterials scientists turned to biological implants. A "first generation" of biological implants was created in the early 1990's, by tanning various cadaveric and animal tissues with glutaraldehyde or hexamethylene diisocyanate to delay or permanently retard collagen turnover. But "leatherizing" these biological materials failed to produce the "natural" scaffolds that manufacturers sought. Because chemically cross-linked scaffolds are not colonized by host cells, the healing response to implantation of first generation biomesch is limited to the graft surface - producing fibrous encapsulation with mini-seroma formation. This type of healing response mirrors the relatively weak graft-



to-tissue bonding seen with Amid classes II and III synthetic mesh. Hence, first generation biological implants are also prone to chronic wound pain and graft erosion. However, the major deficiency of first generation biomesh is that any denatured collagen – whether of endogenous or exogenous origin – is seen by the host's immune system as “dead tissue”. Hence, there is an intense biodegradation reaction within the mini-seromas. Several authors have described this potential for support failure, secondary to graft autolysis. FitzGerald (*Int Urogynecol J* 2004; 15: 238-42) reported that 45 of 67 (87%) Tutoplast® sacrocolpopexies failed, as did 14 of 35 (52%) of Tutoplast® slings. In 16 cases coming to abdominal re-exploration, 15 women had absent or inadequate graft material. Gandhi (*Am J Obstet Gynecol* 2005; 192: 1649-54) found that an adjunct patch graft of Tutoplast® (Coloplast Corp, Minneapolis, MN) did not reduce the risk of recurrent stage II cystocele. Similarly, in a prospective series of rectocele repair, using a bridging graft of Pelvicol® (CR Bard, Murray Hill, NJ), Altman (*Obstet Gynecol* 2006; 107: 59-65) had a 41% failure rate at 3 years due to autolysis of the implanted biomaterial. Fenestration (e.g., Pelvisoft®; C.R. Bard) partially alleviates the situation by allowing deposition of fibrovascular tissue within the pores. Even so, the efficiency of tissue incorporation is poor and first generation biological implants are at a distinct theoretic disadvantage compared to either Amid class I alloplastics or a second generation biomesh.

More recently, a “second generation” of xenografts has been developed, using a manufacturing process that preserves the tertiary organization of both structural proteins and matrix molecules. Cellular antigens are extracted by hypotonic washing, followed by ethylene oxide sterilization (to destroy any foreign DNA or RNA without damaging the collagen or glycoprotein molecules). Net result is an acellular but intact protein scaffold that appears viable to the host immune response. Specialized cells and blood vessels readily re-populate the spaces vacated by the animal fibroblasts and endothelial cells under the direction of still viable chemo-attractants, binding molecules and other animal growth factors. Constructive remodelling transforms the biomesh into a permanent new layer of host tissue, which is homeostatically renewable. Minimally altered biomesh has been prepared from such tissues as porcine small intestinal submucosa (Surgisis®: Cook), porcine dermis (InterXene®: AMS), fetal calf skin (Xenform®: Boston Scientific), and human cadaveric skin (Alloderm®: Boston Scientific). Because these tissue-inductive implants are engineered to resorb within 3-5 months, the morbidity associated with placing a permanent foreign body in the wound is thus avoided. There is virtually no potential for mesh-related morbidity (provided that the xenograft is not placed in a fat layer).

### Incontinence after mesh. (46)

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All types of mesh are increasingly used in the surgical management of pelvic organ prolapse. While the use of mesh for sacrocolpopexy has been well documented, this is not the case for vaginal mesh repairs. Stress-continent women undergoing sacrocolpopexy randomized to receive a Burch colposuspension or not showed an advantage for the prophylactic colposuspension (CARE trial). Studies reporting continence status following mesh repair have ranged between 0 and 11% for repairs without mesh-kits. Most of these studies utilize polypropylene mesh with variable sites of attachment. When specifically looking at studies utilizing mesh-kits (Perigee/Apogee, AMS and Prolift, Gynecare) de novo stress incontinence occurs between 0 and 9% and persistent incontinence as high as 13%. Most studies are retrospective and have short follow-ups. In conclusion the use of mesh in the surgical management of POP does not appear to adversely affect continence, nor prevent the correction of incontinence when concomitantly addressed at the time of POP repair.

### Alloplastic slings - Are they really the solution? (47)

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Ulf Ulmsten and Peter Petros developed the concept that stress incontinence results from the failure of the pubourethral ligaments in the mid-urethra (1990,1993).

This led to the “integral theory for the management of female

stress incontinence” which is based on the model that continence is maintained at the mid-urethra and not at the bladder neck. The aim of the tape is to reinforce the “functional” pubourethral ligaments and hence secure proper fixation of the mid-urethra to the pubic bone, allowing simultaneous reinforcement of the suburethral hammock and its connections to the pubococcygeus muscles.

There has been a worldwide immediate acceptance of this concept and to date > 2 million alloplastic slings have been implanted around the world, more than 50 different materials, trocars and modifications are offered by the companies.

In contrast to the wide-spread acceptance there are only few reliable prospective randomized studies comparing established techniques (e.g. colposuspension) with the alloplastic slings. While established products like the original TVT (Gynecare), IVS (Tyco) or Sparc (AMS) offer randomised studies most of the imitations and copies, that might have important differences in structure (monofilaments, multifilaments, silicone coated, extruded crosslinked polypropylene, etc.), pore size, elasticity and biological properties lack of any reliable studies and data. Only about 5% of the patients were operated on in controlled clinical studies and complications are reported as case reports, the problems always having been produced by another surgeon (of course!).

Economy based medicine is reigning in many parts of the world, competition between departments is a bad indication for surgery (Petri and Koelbl, 2004).

In 2001 Delorme et al. described the transobturator passage of a polypropylene tape from the area of the inner thigh through the obturator membrane and fossa to the suburethral area. The rationale was to reduce the rate of bladder perforation and bowel and great vessel injury with the TVT operation.

The author, after 35 years in the field, always has wondered why strategies with up to 98% success rates still have to be modified or even changed. If there are really more than 90% cured, why change? “Never change a winning team!”

We have discussed complications and possible reasons for them elsewhere (Petri et al. 2006). Apparently complications are more frequent than reported (Deng et al. 2007).

There is a proven correlation between the experience of the surgeon and complication rates (Kuuvu and Nilsson et al., 2002), but it might not only be a technical problem, but also a question of indication. In our own department up to now we have re-operated on 400 women together with innumerable patients with conservative approaches and phone consultations or guidance for patients or colleagues. Apparently 46% underwent a technically wrong procedure, most of them either with a sling position at the bladder neck or a sling not being tension-free at all. This is not a problem of the “tension-free” procedure as such, but of the surgeon. If partial resection of 5-10 mm of the suburethral tape segment is enough to solve the problem (as the paraurethral fixation apparently is sufficient to maintain continence) it is a technical fault. Unfortunately only few gynaecologists stay with the “cook book”. Modifying the location of placement (apparently having no idea of the shortness of an incontinent urethra, remembering the old traditional slings at the bladder neck), disregarding the changes in pressure transmission in general or regional anaesthesia (cook-book is in local!), disregarding the position on the operating table (lithotomy position is a problem because of the paralaxis of the pelvis) will end up in positioning of the tape under tension.

Nearly 40% of our patients referred for complications apparently were no good candidates for a TVT. Situations of complete disruption of the vagina from its pelvic side wall attachment (paravaginal defect) seem rather to be an indication for colposuspension rather than for a distal, very localized sling. Even though continence might be achieved, functional obstruction by compression of the mobile vagina, residual, obstructive voiding up to OAB might be the sequelae. With more than 600 anti-incontinence and prolapse procedures per year we thoroughly believe that paravaginal defect with complete detachment of the full length of the vagina from the pelvic sidewall still is an excellent indication for a colposuspension.

As in recent years up to 70% of our patients referred had recurrences with up to 18 previous procedures, where complete revision with (at least) partial resection of alloplastic materials was necessary, we still have more “open” procedures than “minimal invasive slings”. With the increasing number of referrals of complications our own indication for these procedures has become more

and more strict. It might be mentioned that this attitude applies to the use of meshes in prolapse surgery as well; experienced groups from other countries stated, that even though success rates can be improved a little by the use of meshes, the rate of serious complications led them to the harsh conclusion to completely abandon their use (Milani et al. 2005).

Because of the open questions concerning mid- and long-term complications and success rates we would not see an indication for an alloplastic sling in young women still wanting to deliver – one could even discuss a medico-ethical contraindication.

The surgeon should be very careful in women with extreme overweight not only because of technical difficulties, but because of the increased risk of penetration/perforation due to the high pressures in the small pelvis. There should be a thorough selection of the sling material asking for the needed elasticity and experience with the properties of the trocar and the sling.

No single procedure has a 100% cure rate – the complex anatomical and functional failure of pelvic floor function cannot be restored. Even staying with the “cook-book” will not prevent occasional penetrations of bladder and urethra, intra- and postoperative bleeding, obstructive micturition and de-novo OAB.

Correct selection of the patients by functional and morphological tests should be mandatory – patient wish for the “new minimal invasive procedure” is limited by concomitant pathology recommending another procedure, e.g. extensive paravaginal defect or preexisting overactive bladder without anatomical explanation.

Without no doubt the concept of the tension-free tape by Ulmsten and Petros has been a revolution in incontinence surgery for the benefit of our patients. But with the complex pathophysiology and the many factors contributing to the failure of the continence mechanism there cannot be one solution for all problems.

We would like to plea for more honesty and evidence-based strategies, rather than tradition and “good experience”. Prospective randomised studies are mandatory in order to treat our patients the best way possible, prevent complications and failures, and, hence legal problems.

In our hands alloplastic slings “TVT-type” in intrinsic sphincter incompetence with central pelvic floor defect or without additional pathology and ISD.

Broad paravaginal defects, total prolapse and laparotomy for other gynaecological reasons are candidates for a colposuspension (Petri 2001).

*References are available from the author on request.*

### Sexual dysfunction after mesh surgery. (48)

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The effect of pelvic organ prolapse (POP) on sexual function is variable and POP repair may change sexual function. Before repair, the most bothersome barrier to sexual function is vaginal bulging, while postoperatively it is vaginal pain. De novo dyspareunia is a risk of many prolapse repairs, particularly when performed trans-

vaginally. The increasingly use of synthetic mesh reinforcement to improve the anatomical results has led to specific complications (local intolerance, delayed or incomplete healing, mesh shrinkage, loco-regional sepsis, etc) liable to induce vaginal pain and dyspareunia.

*Sexuality after prolapse surgery: general remarks.* When focusing on published data, we can make several observations: the low proportion of women sexually active before surgery is a limiting factor; the wide range of associated procedures during surgery results in a major bias and make debatable any conclusion on “responsibility”; there is no correlation between the length of the vagina after surgery and the quality of sexual function (except, obviously, if unreasonable and unacceptable modifications of the vaginal dimensions because of technical error); [1-4] reported cases of symptomatic shortening or contraction of the vagina are rare; generally, the proportion of women who are sexually active is only slightly affected by surgery, even though a small constant percentage of women becoming sexually inactive is commonly reported after surgery: anxiety, fear of recurrence or a pretext to withdraw from something which they considered simply a conjugal obligation, the reasons are many, but with no direct link to the intervention itself; concurrent hysterectomy, subject to respect of the elementary rules of good practice, does not alter sexuality; [5] the optimal period for the sexual evaluation is between 6 months and 1 year after surgery (sufficiently distant from the intervention to allow recommencement of sexual activity, but not too distant to avoid interference by other inter-current elements); postoperative sexual outcome must also all be considered in comparison to results reported in studies performed on the general population.

The Pelvic Organ Prolapse / Urinary Incontinence Sexual Questionnaire (PISQ) was introduced in 2001 by Rogers [6] as the first validated self-administered and condition-specific questionnaire for women with POP or UI. The short form (PISQ 12) [7] has gained general acceptance and should be widely used in publications to make easier comparisons between the different surgical procedures.

*Sexual outcome after transvaginal mesh repair.* Mesh augmentation in pelvic floor reconstruction surgery is increasing in popularity and frequency of use. The majority of published papers reports on the anatomical success rates with only few of them focusing on sexual function and quality of live. If mesh exposure, sometimes implicated in sexual dysfunction, has generally been well studied, implant shrinkage, the consequences of which can be more deleterious, has been less often evaluated and sometimes totally neglected. Relevant literature is reported in table 1 (biological implant) and 2 (synthetic implant). Few studies have compared sexuality after vaginal surgery with or without prosthetic implant: the comparative studies reporting sexual outcome are reported in the table 3.

A recent paper from Jia et al [8] focused on de novo dyspareunia as an indicator of safety of transvaginal mesh repair. At this time of our incomplete knowledge further prospective studies are needed to assess more specifically sexual consequences of POP repair using augmenting material.

TABLE 1. – *Sexual outcome after transvaginal biological implant*

Authors Year	Study tools	Surgery	PRE-OP		POST-OP		
			n	SA	n	SA	
David-Montefiore (2005) [9]	Case series VAS	anterior and posterior Pelvic implant	47	18	mean sexual discomfort score: 3.2 +/- 3.5 (range 0 – 8)	mean sexual discomfort score: 0.8 +/- 1 (range 0 – 2) 1 case of mild dyspareunia after posterior perineorrhaphy	
Altman (2006) [10]	Prospective VAS	Post Pelvicol implant	29	15	superficial dyspareunia : 1,3+/-1,2 abdominal dyspareunia : 1,8+/-2,0 Discomfort at intercourse : 2,0+/-1,8	superficial dyspareunia : 1,7+/-2,3 abdominal dyspareunia : 1,1+/-0,7 Discomfort at intercourse : 1,6+/-2,1	
Doumerc (2006) [11]	Prospective	anterior pelvicol implant +/- post Pelvicol implant	132			107	de novo dyspareunia: 6% at 1 year
Rouach (2007) [12]	Retrospective BISF-W	Ant Pelvicol implant	50	10			none of the 10 preoperative SA patients reported postoperative discomfort

TABLE 2. – Sexual outcome after transvaginal synthetic mesh repair

authors year	Study Questionnaire	Surgery	PRE-OP			POST-OP		
			n	SA	dyspareunia	n	SA	dyspareunia
Ansquer 2004 <sup>[13]</sup>	prospective Non validated Questionnaire	anterior mesh repair	30	16	?	30	14	sex improved : 21% sex unchanged : 43% sex worsened : (dyspareunia) : 36%
Dwyer (2004) <sup>[14]</sup>	Retrospective Non validated Questionnaire	Anterior and/or posterior Atrium mesh repair	97	67 (69%)	25 (37%)	77	66 (86%)	7 (11%) de novo : 3 patients
Milani (2005) <sup>[15]</sup>	Prospective observational Non validated Questionnaire	Anterior mesh repair	32	17 (53%)	6 (18%)	32	17 (53%)	12 (38%)
		posterior mesh repair	31	17 (55%)	2 (6%)	31	13 (43%)	21 (69%)
De Tayrac (2006) <sup>[16]</sup>	Suivi de cohorte PISQ 12	posterior mesh repair (Gynemesh)	26	?	?	25	13	de novo = 7,7%
De Tayrac (2007) <sup>[17]</sup>	Prospective multicentric PFDI PFIQ Non validated sexual Questionnaire	Anterior and/or posterior mesh repair (Ugytex)	143	88	10 (11,4%)	99	88	11 de novo: 10 patients (12,8%)
Gauruder- Burmester (2007) <sup>[18]</sup>	Rétrospective Validated Questionnaire	Apogee and/or Perigee	120	80 (67%)	15	120	?	0
Lim 2007 <sup>[19]</sup>	Suivi de cohorte Non validated Questionnaire	Post Vypro 2 mesh repair	78	?	20	53	30	de novo dyspareunia = 27%
Jo (2007) <sup>[20]</sup>	Suivi de cohorte Non validated Questionnaire	Anterior Gynemesh mesh repair	38	14	dyspareunie: 2 patientes	35	?	les 2 patientes dyspa- reuniques en pré-op ont une sexualité normale Dyspareunia : 0
Amrute (2007) <sup>[21]</sup>	Retrospective Charts review + entretien téléphonique	Total polypropylène mesh repair	76	?	?	76	21	dyspareunia : 2
Cervigni (2008) <sup>[22]</sup>	Suivi longitudinal de cohorte P QoL	Anterior mesh repair (Marlex tension free)	218	?	dyspareunia: 46 patients	218	?	dyspareunia : 39 patients De novo dyspareunia = 21 patients

TABLE 3. – Comparative studies “mesh” versus “no mesh”: sexual outcome

author	surgery	tools	Pre-operative			Post-operative		
			n	SA	Dyspareunia	n	SA	Dyspareunia
Paraiso 2006 <sup>[23]</sup> RCT post repair	Post colporrhaphy	PISQ12	37	17 (46%)	PISQ: 29 +/- 8 usually/always: 30%	33	19 (61%)	PISQ: 36 +/- 5 usually/always: 20%
	Site specific		37	18 (46%)	PISQ: 31 +/- 8 usually/always: 9%	33	21 (63%)	PISQ: 36 +/- 7 usually/always: 14%
	Collagen graft augmentation		31	17 (53%)	PISQ: 33 +/- 8 usually/always: 0%	28	16 (57%)	PISQ: 37 +/- 5 usually/always: 6%
Meschia 2007 <sup>[24]</sup> RCT Ant repair	Fascial plication	Non validated VAS	106	74	11 (15%)	103	48	5 (10%)
	Pelvicol		100	65	12 (18%)	98	47	7 (15%)
Novi 2007 <sup>[25]</sup> Comparison of Cohorts Post repair	Pelvicol repair	PISQ 31	50	50 §	PISQ : 81,4=/-7,3 <sup>a</sup> dyspareunia = 20 (40%) <sup>c</sup>	50	50 ?	PISQ : 101,3+/- 6,4 <sup>b</sup> dyspareunia = 4 (8%) <sup>c</sup>
	Post fascial plication		50	50 §	PISQ : 83,6+/-8,2 <sup>a</sup> dyspareunia = 18 (36%) <sup>d</sup>	50	50 ?	PISQ : 89,7+/-7,1 <sup>b</sup> Dyspareunia = 5 (10%) <sup>d</sup>
Nguyen 2008 <sup>[26]</sup> RCT Ant repair	anterior colporrhaphy	PISQ12	38	28 (74%)	always or usually: 21%	37	26 (70%)	always or usually: 13% de novo: 16%
	Anterior polypropylene mesh repair		37	27 (73%)	always or usually: 22%	37	23 (58%)	always or usually: 13% de novo: 9%
Sivaslioglu 2008 <sup>[27]</sup> RCT Ant repair	Site specific surgery	validated QoL questionnaire	45	?	?	42	?	no dyspareunia

References are available from the author on request.

**Alternatives to mesh in prolapse surgery. (49)**

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History of gynecologic surgery accounts different approaches to the cure of prolapse. Prosthetic surgery nowadays represents the most common surgical treatment of female genital prolapse. Minimally invasive surgery is advocated as an effective, quick and safe approach when compared to traditional surgery. But the use of meshes has been associated to a series of iatrogenic complications that often required a second surgery and currently available data don't reflect evidence in terms of efficacy. So far, fascial surgery has preserved its rule in the urogynecological scenario. Vaginal vault suspension is a landmark in the treatment of pelvic floor disorders: uterosacral (Shull technique) and iliococcygeus colposuspensions are procedures whose aim is to restore the apical attachment of vagina and are particularly indicated for the treatment of high grade prolapse. Posterior and anterior repair can include the site specific correction of fascial defects and the rectovaginal septum reconstruction is based on the identification and surgical separation of connective tissue used as a collagen-flap in the posterior vaginal wall synthesis. In conclusion there are several surgical techniques that combine a good anatomical and functional result with avoidance of prosthetic material and its implications.

**IPFDS SYMPOSIUM****PELVIC PAIN SYNDROME****The painful bladder syndrome/interstitial cystitis. (50)**

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**Introduction:** Painful bladder syndrome/Interstitial Cystitis (PBS/IC) is a heterogeneous disorders characterized by pelvic pain, urinary urgency e frequency, in absence of urinary tract infection? Recent data suggest that IC may be far more common than previously thought, even though the diagnosis of IC is largely one of exclusion, and the clinical presentation mimics those of other more common disorders. A typical patient may see almost five-seven physicians before the correct diagnosis is made after a period of 3-5 years. Although many physicians consider IC a relative rare disease for which no effective treatment is available, recent studies have demonstrated that IC can be treated successfully.<sup>1,2</sup>

**Epidemiology:** Chronic Pelvic Pain (CPP) is not only one of the more prevalent gynecologic condition affecting over 9 million women in the USA, but also one of the more difficult to treat.<sup>3</sup> Currently there is no standardized internationally accepted definition for CPP and recently two large multicenter study demonstrated that over 80% of patients with CPP had evidence of bladder-origin pain due to bladder epithelial damage or IC4.<sup>4,5</sup>

IC is largely a disorder of adults; its onset is often between 30 and 70 years of age<sup>6</sup> with the median age at onset of 43 years.<sup>6,7</sup> The disorder is also more common in women who account for up to 90% of cases.<sup>8</sup> IC is sometimes referred to as a "syndrome" because it overlaps significantly with prostatitis or other confusable diseases.

Epidemiological studies show a wide prevalence ranging from 18.6/100.000 women to 67/100.000<sup>9-10</sup>. One central problem in assessing the epidemiology of IC is the definition of the disorder. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in 1988 published strict diagnostic criteria for research purposes. However this definition excludes all but advanced cases of IC lacking 60% of clinical cases.<sup>11</sup> In fact, using different methods, recent data suggest that the true prevalence of IC may be ten fold higher than previous estimates.<sup>9-12</sup>

**Etiology and pathogenesis:** Although the cause of IC is not known, several theories have been proposed. These hypotheses include:

**Epithelial dysfunction:** One of the main hypotheses is that IC is caused by a defect in the urothelial surface lining the bladder. The urothelial surface is coated by bladder surface mucin composed of Glycosaminoglycan (GAG).<sup>13</sup> This component is hydrophilic and protect the urothelium from potentially harmful agents (bacteria, proteins, ions). In such patients GAG layer is deficient allowing irritancy in the urine to leak through the urothelium and cause inflammation and irritation<sup>14</sup>.

**Mast cell activation:** Numerous investigators have identified increased numbers of mast cells (MC) in the bladder of IC patients and in the muscularis and submucosa.<sup>15</sup> The association with increased numbers of MC is stronger when IC is more advanced, as in patients with Hunner's ulcers (ulcerative IC).<sup>16</sup> MC allocated close to the intrinsic nerves of the bladder wall, and MC activation may affect nerve function.<sup>17</sup> A cut-off of more than 25/mm<sup>2</sup> is considered synonymous of mastocytosis.

**Neurogenic inflammation:** Neurogenic inflammation (NI) is considered an other important pathophysiologic mechanism of IC. The sensory nerves of the bladder become activated and for a phenomenon of "up regulation" there is a stronger activation in the central nervous system<sup>18</sup>. Possible causes of sensory nerve activation include stimulation or injury of peripheral nerves by potassium or toxic substances in the urine. In this sense, there is cascade of events: increased level of substance P in the urine, MC activation, C fibers activation and nociceptive neurotransmitter release. Possible causative factors triggering this cascade include: stress, hormonal changes (menstrual cycle and menopause).<sup>17</sup>

**Autoimmunity:** Autoimmunity is an other possible component of the disease process. Many of the symptoms of IC are like those of many autoimmune diseases such as systemic erythematosus lupus, rheumatoid arthritis.<sup>19</sup>

**Diagnosis:** The ability to diagnosis an early or mild disease depends on the awareness of the physician. Despite the lack of an inclusive clinical evaluation, the NIDDK definition is internationally recognized a valid albeit too restrictive clinical tool. The diagnostic method should: identify the symptoms of pain, urgency and frequency ruling out other confusable diseases using questionnaires for a specific evaluation (Pain Urgency Frequency Symptom Scale – PUF – and O'Leary/Sant Questionnaire)

A careful history and physical examination should be carried out to ascertain duration of the symptoms and sexual behavior. The pelvic examination may reveal a tender bladder or other painful sites or vulvodinia. Potassium sensitivity test (PST) is based on the underline dysfunctional urothelium that allow potassium ions to cross into the bladder wall depolarizing nerves and muscles and causing symptoms of pain and urgency.<sup>20</sup> Using the PST, Parsons et al. reported 85% positive for IC.<sup>21</sup> Cystoscopy is required to rule out the presence of either glomerulations or classic Hunner ulcers. The procedure should be carried out with hydrodistension according to NIDDK criteria to confirm the diagnosis of IC22. Urodynamic evaluation is not strictly indicated if there are not specific voiding dysfunction (intermittent flow, severe dysuria, etc).

**Approach to treatment:** The goal of treatment is to reduce or eliminate the symptoms of IC and consequently improved the Quality of Life. Because IC is a chronic disease, patient should be informed regarding the trend of disease with flares and remissions. Because of the heterogeneity of the disease, successful treatment may require several attempts with different agents or combination of agents. The therapeutic strategy includes: correct epithelial dysfunction, inhibit neural hyperactivity, control allergies, modulate symptoms of pain.

Dietary modification are also important the urinary metabolite of some foods may cross the damaged urothelium, further irritating the bladder and perpetuating the inflammatory state. For instance, tomato, orange juice or pizza can elicit a flare of symptoms and should be avoid. Bladder retraining protocols are also recommended to improve the urgency/frequency syndrome and to increase bladder capacity.<sup>23</sup>

**Medical Therapy: protection of the mucosal surface:** a number of agents have been used to improve the integrity of the mucosal surface. These include oral and intravesical Pentosanpolysulfate Sodium (PPS)<sup>24</sup> intravesical subcutaneous Heparin,<sup>25</sup> intravesical Hyaluronic Acid,<sup>26</sup> Chondroitin Sulfate.<sup>27</sup> The treatment should continue for a period no less than six months. **Mast-cell inhibition:** Histamine is the major mediator released by activated mast-cell. Anti-histamines are commonly used in the treatment of IC: Hydroxyzine an H1-receptor antagonist as been extensively used in IC patients with reported reduction score in 40% of cases<sup>28</sup>. The H2 –receptor antagonist Cimetidine produces some symptoms relieve even though as not been tested in randomized controlled trials.<sup>27</sup> **Pain modulation:** Various agents are been used to modulate the perception of pain in IC. Tricyclic antidepressants (Amitriptyline) have pain –reducing effects.<sup>28-29</sup> In a randomized study improvement in overall symptoms was significantly greater in the treatment group

with reduction in pain and urgency ( $p < 0.001$ ).<sup>30</sup> The Dimethylsulfoxide (DMSO) has been used as an intravesical therapy. Its multiple effects include anti-inflammatory and analgesic effects, muscle relaxation, mast-cell inhibition, and collagen dissolution. Patients treated with DMSO showed a 50 to 70 % reduction of symptoms and the combination with other agents as hydrocortisone, heparin and sodium bicarbonate improve the response.<sup>31</sup> One side effect is a garlic-like breath odor than can last up to 2 days. *Immunologic modulation:* Bacillus Calmette-Guerin (BCG) is used as an intravesical agent in IC<sup>32</sup> weekly instillation in IC patients showed an initial response of 60% even though a later study failed to show any significant response in comparison with DMSO.<sup>33</sup> Cyclosporine an immunosuppressant used in organ transplantation was tested in a recent trial with positive response with significantly reduction of symptoms and a number of voiding compared with baseline.<sup>34</sup> *Multimodal therapy:* To manage the multiple pathologic features a multimodal approach is prefer in the severe no responder patients. One common approach is a combined treatment with heparinoid, pain control drug (amyltriptiline) and control allergies with an antihistamine. In pats who do not respond to oral therapy intravesical treatment with, Heparin or PPS. *Surgical procedures:* The surgical approach is only indicated in very selected cases in end stage of the diseases and this include partial or total cystectomy and urinary diversion. More recently neuromodulation has been proposed with promising results.<sup>35</sup>

*Conclusions:* IC is one of the more debilitating chronic pelvic diseases in women. Patients suffer for the consequences of this misdiagnosed and underdiagnosed syndrome. This is due in part to the complexity and multifactorial aspects of the pathology and on the other hand for the low attention made from the Scientific Community. Great improvement have been made in this area in the last ten years and hopefully IC patients will have positive expectations in the near future.

References available from the author on request.

### Vulvodinia. (51)

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The International Society for the Study of Vulvovaginal Diseases defined vulvodinia as »chronic vulvar discomfort or pain, characterized by burning, stinging, irritation or rawness of female genitalia« The term *vulvodinia* derived from "vulva" and the Greek word "odynia" meaning pain. In clinical sense vulvodinia is a syndrome of unexplained vulvar pain, accompanied by physical disabilities, limitation of daily activities, sexual dysfunction and psychological distress. If untreated, chronic pain can lead to low self-esteem, anxiety, depression, reduced quality of life.

Vulvodinia is frequently misdiagnosed. In a general gynecologic practice population, the prevalence of this condition may be between 10 and 15 percent. Before the 1980s, very little was written about vulvodinia. Later renewed interest was generated with the publication of articles by Friedrich, Lynch and McKay. The incidence and prevalence has not been well studied. Systematic epidemiologic, etiologic and therapeutic studies of vulvodinia should be undertaken.

The cause of vulvodinia still remains unknown and it is the result of multiple factors. Various theories suggest infection (viral, fungal, or bacterial); an allergic response to environmental irritants; an autoimmune response to the body's own chemistry; irritation, dysfunction of the muscles that support the bladder, uterus, and rectum (called the "pelvic floor muscles"); or irritation of the nerves that innervate the vulva. There is no evidence that vulvodinia is a sexually transmitted disease. Several subtypes of vulvodinia have been recognized. Recognition of the distinct subsets of vulvodinia is a pre-requisite for successful therapeutic outcome. Vulvar vestibulitis syndrome, cyclic vulvovaginitis, and dysesthetic vulvodinia are the most common subtypes. Other frequently misdiagnosed vulvar or vaginal conditions which can also cause vulvodinia are vulvar papillomatosis, cytolytic vaginosis, lactobacillosis, and desquamative inflammatory vaginitis. Many vulvar dermatoses can cause acute or chronic vulvar itching or pain, and are a frequent cause of differential diagnostic problems.

The treatment of vulvodinia requires great patience both on the part of the doctor and of the patient. Most often symptoms improve, but it can take months of treatment. In some cases simple

medical treatments relieve symptoms. When long term treatment is necessary, a psychotherapist specializing in sex therapy and sexual pain management can help minimize the impact the pain has on a woman's life. Tenderness in vulvar area can lead to spasm of the pelvic muscles, which in turn can aggravate the pain. For many women a multidisciplinary approach is more effective than any single treatment. There are many therapeutic modalities to treat vulvodinia: local anesthetics, injections, nerve blockades, topical creams, discontinuation of all topical medications, douches, soaps, etc. that can cause irritation, oral medications, physical therapy, pelvic floor therapy, laser treatment and surgery.

In conclusion vulvodinia is a complex multifactorial underdiagnosed clinical syndrome. Systematic epidemiologic, etiologic, and therapeutic studies of vulvodinia should be undertaken. Some case reports from our Department are going to be analysed.

### Chronic Pelvic Pain Syndrome: a practical clinical approach. (52)

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Chronic Pelvic Pain Syndrome (CPPS) is an ominous condition characterised by pain in the pelvis, perineum and/or external genitalia and/or contiguous areas of the body lasting for more than six months. Possible contiguous areas where the pain can radiate are the lower back, the groin, the supra-pubic area, the sacrum and coccyx, and the upper thighs.

The common patho-physiologic condition inducing the symptoms is an involuntary hypertonic condition of the pelvic floor muscles (levator ani). Sometimes the typical symptoms and signs of Interstitial Cystitis/Painful Bladder Syndrome (ICPBS) are associated. Rarely the true Pudendal Nerve Entrapment (PNE) syndrome is the main problem.

The clinical presentation is rather heterogeneous, regarding both the intensity, frequency and location of pain and the several associated symptoms. These include lower urinary tract (LUTS), gastro-intestinal (GI) and sexual and psycho-social symptoms. The involvement of these organs and systems is related to the fact that the urethra and the rectus (and also the vagina in the female) cross the levator ani through the respective hiatus and therefore their walls can be squeezed by an hyperactive pelvic floor. If IC/PBS is not the main problem, the pelvic pain is not related with the micturition cycle, whereas in IC/PBS the pain increases with bladder filling and tends to substantially decrease soon after voiding.

*Diagnosis:* Ideally, individuals with CPPS should be treated in specialised centers where either a single doctor expert in Perineology or a multidisciplinary team including urologist, gynaecologist colo-rectal surgeon, neurologist, physical therapist, physiatrist, anaesthesiologist.

A very detailed history and a focused physical examination are mandatory and, almost always, diagnostic. However, the first step should be to rule out specific, non-idiopathic, disorders of the pelvic organs which may be the sole cause of the pain (large endometriosis, painful proctologic conditions, like complicated haemorrhoids and anal fissures, interstitial cystitis/painful bladder syndrome, Tarlov cysts, bladder or rectal tumours, herniated disk, herpes zoster or genitalis infections, etc). Pelvic ultrasounds and/or spinal or pelvic MRI, cystoscopy, urine cytology, rectoscopy are mainly employed at this stage of assessment.

Physical Examination should be gentle and aimed at assessing the existence of provoked pain on touching the external genitalia (vulvodinia and vestibulodynia is a common concomitant feature) and the pelvic floor which can be hypertonic and painful under digital compression in several points (trigger points) (Fig. 1).

If LUTS are prominent a Bladder Diary is mandatory. Uroflowmetry can show a fluctuating or intermittent pattern of the curve, the residual urine should be checked. Video-Urodynamics with EMG can detect a detrusor-external sphincter incoordination and complications including vesico-ureteral reflux. To confirm or rule out IC/PBS specific diagnostic procedures including cystoscopy, bladder distension and biopsy under sedation may be useful. If PNE is suspected, various neurophysiological tests are also useful, including EMG, Sacral Latency Test (SLT), Pudendal Nerve Terminal Motor Latency (PNTML) and the very accurate Current Perception Thresholds (CPT) with dedicated equipment (Fig. 2).

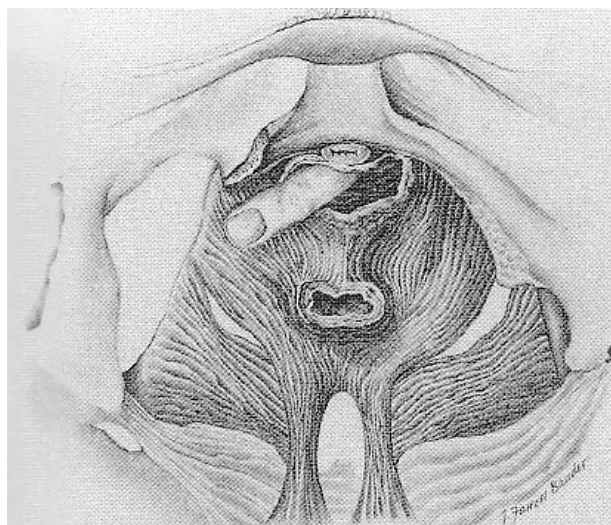


Fig. 1.

**Treatments:** Several treatment modalities are available, which are to be combined simultaneously or sequentially:

- counseling, behaviour therapy and lifestyle interventions, anti-stress measures, pharmacotherapy, FANS, opioids, anti-convulsants, alpha-blockers, tricyclic antidepressants, muscle-relaxants, physical therapy, pelvic floor rehabilitation;

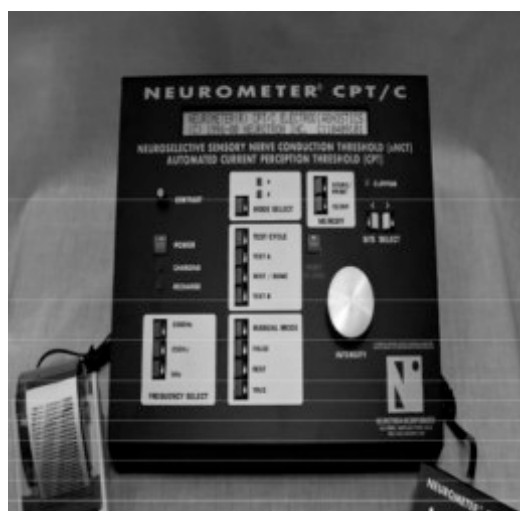


Fig. 2.

- manual therapy (Thiele massage, trigger point release), electrical stimulation (interferential currents, TENS, posterior tibial nerve stimulation), acupuncture, botulinum toxin injections in the pelvic floor muscles, sacral neuromodulation, Pudendal Nerve decompression surgery (if indicated), specific measures for interstitial cystitis (if indicated).

### Controversies in the treatment of interstitial cystitis (53)

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In much of the literature regarding interstitial cystitis there is either no consensus or the answer is unknown. The controversy regarding the possible name change to bladder pain syndrome as suggested by ESSIC is one example of this.

Interstitial cystitis / painful bladder syndrome is an extremely difficult condition in which to follow results of therapy. The disease tends to fluctuate in severity and up to 50% of patients experience temporary remissions unrelated to therapy for an average duration of 8 months. Most therapies for IC have been associated with very promising initial results followed by either no or much

reduced benefit when analysed in a randomised placebo controlled double blind trial. This type of trial minimizes the problems of bias and regression to the mean which occurs as a result of recruitment of more symptomatic cases to a therapeutic trial. It is crucial to take into account the placebo effect which can be of the order of 30%. There may be limited evidence available for some treatments which are in widespread clinical use because there is no pharmaceutical company incentive to conduct such studies.

The ICI 2004 and 2008 have made recommendations based on the available published literature which may differ from unpublished clinical practice. Grades of recommendation range from A (highest) to D (lowest), and levels of evidence from 1 (highest) to 4 (lowest).

**Conservative treatment:** behavioural modification (level 3), physical therapy (level 2), stress reduction (level 4) and dietary manipulation (level 4) all received a grade C recommendation.

**Oral medications:** **Antidepressants:** Amitriptyline: Level 2 evidence, grade B recommendation. There has been 1 RCT trial and a number of non-controlled studies. The theoretical mechanisms of amitriptyline include: central and peripheral anticholinergic action, sedative action, blocking H1-histaminergic receptors, analgesic action (inhibiting re-uptake of serotonin and noradrenaline). Desipramine and doxepin received level 3 evidence and grade C recommendation. **Antihistamines:** Hydroxyzine: Level 1b evidence, grade D recommendation. Blocks neuronal activation of mast cells, is anticholinergic, angiolytic and analgesic. Good therapeutic effects by non-controlled studies, but NIDDK study, 2003 showed no significant benefit. **Immunosuppressants:** Cyclosporine: Level 3 evidence, grade C recommendation. 3 uncontrolled studies, 1 study comparing cyclosporine with PPS. Cyclosporine improves pain and frequency, but potentially serious side effects, only be considered in severe, intractable patients. IPD-1151T: Suppresses helper T-cells producing IL-4 and 5. 1 uncontrolled study, but a large-scale placebo-controlled study underway. Pentosan Polysulfate Sodium (PPS): There have been 5 randomized controlled trials with mixed results. ICI Committee awarded PPS level 1 evidence but grade D recommendation (conflicting level 1 evidence).

**Intravesical treatment:** DMSO (Dimethyl sulfoxide) 2 B; Heparin 3 C; Hyaluronic acid 4 D; Chondroitin sulfate 4 D; Pentosan polysulfate sodium 4 D; Capsaicin, Resiniferatoxin 1 D; Bacillus Calmette-Guerin (BCG) 1 D; Oxybutynin 4 D; Lidocaine 2 C; Botulinum toxin 4 D.

**Sacral Neuromodulation** in IC patients is still investigational procedure. Its therapeutic effects have not yet been fully confirmed. Strict patient selection and detailed discussion with the patient, are necessary.

**Bladder distension** has been used for many years not only as a diagnostic tool but also for the treatment of IC patients. However most studies are retrospective and uncontrolled and evidence is conflicting. Level of evidence 3, grade C.

**Principles of Management.** Without a known common etiology and pathogenesis for IC, the patient heterogeneity and range of co-morbidities makes it likely that for many treatment modalities there will inevitably be only a proportion of responders. For the nonresponders a step wise progression through the range of other available options occurs.

**Recommendations** by the committee included the following: treatment decisions should be based as far as possible on placebo-controlled RCTs; treatment should be guided by patient-driven outcomes; start with the least invasive treatments; approach surgical therapies with caution; add or subtract treatments on the basis of results in individual patients; consider more extensive evaluation and more invasive therapies in patients who have failed oral and intravesical treatments; unproven therapies should be given within the framework of clinical trials; irreversible surgery should be a last resort, with rare exceptions. The treatment algorithm was presented by Professor Nordling; 1st line treatment: conservative therapy, patient education, dietary modification, nonprescription analgesics, pelvic floor relaxation, address treatment of pain; 2nd line treatment: consider: oral therapies, intravesical therapies, physical therapy, address treatment of pain; 3rd line treatment: consider: cystoscopy under anaesthesia with bladder distension, fulguration of Hunner's lesion, address treatment of pain; 4th line treatment: consider in context of clinical trial: neuromodulation, botulinum toxin intramural, pharmacologic management, address treatment of pain. Consider: diversion with or without cystectomy, substitution cystoplasty.

### Trigger points and electromyographic biofeedback in managing pelvic pain. (54)

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Pelvic floor disorders are a cluster of pain, incontinence and sexual disorders that arise mainly out of dysfunctional muscle states and structural changes rather than malfunction of specific pelvic organs. Surface electromyography (SEMG) as the primary modality for assessment of muscle function can assist in the diagnosis and treatment of pelvic disorders. Muscle resting tone correlates with disorders due to either hypoactive muscle tone (associated with weakness) or muscle hyperactivity (associated with irritability and pain). Unexplained vulvar pain in the form of vulvodynia and interstitial cystitis (more recently referred to as painful bladder syndrome) are two disorders associated with overly active pelvic muscle, muscle shortening, myofascial trigger points and referred pain causing dyspareunia, urgency and frequency, nocturia, suprapubic pressure and bladder pain. Normalisation of muscle function leads to resolution of symptoms. The presentation will focus on evidence highlighting the role of pelvic floor muscles and discuss conservative strategies for their management.

### PODIUM PRESENTATIONS SURGICAL TECHNIQUE

#### Tension free colpo-utero-suspension with low elasticity sling. (55)

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**Background:** Genital prolapse is a multifactorial disease with different etiologic factors that determines continuous mechanical strain on the endopelvic fascia with progressive neuromuscular damage. Alterations of the amplitude and/or the position of the angle of flexion of the vaginal hammock, determine a loss of the normal anatomical and functional relationships of the pelvic organs. We suggest a tension-free, minimally invasive technique using low elasticity slings through the vagino-perineal route for the reconstruction of the support system of the pelvic organs.

**Materials and methods:** 81 patients with genital prolapse underwent tension-free colpo-hysterosuspension with low-elasticity slings. The technique has two phases. During the anterior phase, a sling is passed bilaterally through the obturator fossa with a out-in direction, on the tendinous arch 2 cm from its insertion on the pubic bone and then fixed on the anterior part of the uterine cervix at the insertion of the lateral cervical ligaments. The posterior phase is a sovracoccigeal miopexy, which consist in passing a sling through the sacrospinous ligament and coccigeous muscle and through coccigeous muscle and piriform muscle through the ischio-rectal fossa. This sling is then fixed at the cervix at the insertion of the utero-sacral ligaments.

**Results:** Preoperative Pop-Q stage 3 in 42 cases and stage 4 in 39 cases. At the last follow-up control, postoperative Pop-Q score staged 0 in 55 patients and 1 in 23 patients. Only three patients showed a stage 3 Pop-Q score. The intraoperative complication rate was 12%, with 4 cases of bladder perforation and 6 cases vaginal lacerations. Post-operative complication rate was 28%, most of the cases being represented by urinary infections (8) and pelvic/inguinal pain (8). Only one case of vaginal erosion was observed.

**Conclusions:** Tension-free, mini-invasive procedure using low elasticity for the conservative treatment of functional genital prolapse is feasible and effective on a long term basis with limited perioperative complications.

#### UST (Urethra Surrounding Tape) – a minimally invasive operation for stress incontinence. (56)

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**Purpose:** The intention of this original paper is to provide information about a new minimally invasive operative method for the treatment of female stress incontinence.

**Materials and Methods:** In 2004, 43 patients between 34 and 81 years of age underwent a UST (Urethra Surrounding Tape) operation after preoperative clinical, urodynamic and radiological assessment. The following criteria were investigated and formed the basis

for inclusion: a preoperatively positive stress test and the subjective suffering of the patients irrespective of the degree of stress incontinence, as long as there was no massive descent of the anterior vaginal wall. A mesh of 1,5 x 2,6cm is sutured in the mid third of the urethra in such a way that a moderate impression of the dorsal urethra surface results through the mini-sling. This impression releases the urethrovesical reflex. After about a year the patients underwent a clinical and urodynamic follow-up examination. The measured results of the 43 patients operated in 2004 were evaluated.

**Results:** On the basis of the clinical tests a continence rate of 97,7% was achieved. According to subjective assessment 83,7% declared themselves completely cured and 14% clearly improved, while in 2,3% there was no improvement at all. The depression quotient showed a significant amelioration from 0,67 to 0,47. Furthermore, a decrease of the retrovesical angle  $\beta$  and the inclination angle  $\alpha$  was found which corresponds to a flattening of the funnel in the bladder base plate. The urethra resting pressure results varied considerably. The average duration of an operation was 25 minutes. There were no peri- or postoperative complications. In only one patient the mesh jutted out below the orificium urethrae externum requiring the protrusion to be cut off horizontally, after which intact vaginal skin was formed.

**Conclusion:** Clearly reproducible operative steps, precisely predictable results and a complete lack of peri- and postoperative complications justify the classification as a minimally invasive operative technique.

#### Tissue Fixation System- 3 year results. (57)

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**Introduction:** The TFS (Tissue Fixation System) is a new universal "minisling" tool. It can be used as a midurethral sling, posterior sling, and as a substitute for large mesh through its ability to reinforce major suspensory ligaments such as ATFP, cardinal, uterosacral and perineal body. The bioengineering principle applied is akin to a domestic ceiling construction. The tape (beam) reinforces weakened fascia at critical points. Because the TFS tightens lax ligaments and fascia, it intra-operatively exposes other damaged sites which may need repair.

**3 year data:** Posterior TFS sling for prolapse- 3 year review (Petros & Richardson): 39 patients >2nd degree prolapse. Cure 86%; improvement: 6%. Midurethral sling for Stress Incontinence – 3 year review: 31 patients. Cure: 80%; >70% cure in 2 patients (6.5%).

**Other data:** RCT of TFS with TOT for GSI at 30 months follow-up (Sivaslioglu) 80 patients. The TFS had a slightly greater cure rate, 90% vs 84%, no post-op retention (zero vs 2) or groin pain (zero vs 12), and a shorter operating time (5 mins vs 12 mins.).

TFS midurethral sling for GSI and ISD performed under LA in an outpatient setting (Yuki Sekiguchi) 37 patients, 15 with ISD OPD surgery discharged within 8 hours. 3 patients discharged with indwelling catheter but passed urine at 48 hours. Review 6 months: 91% cure rate at 6 months. The 3 failed cases responded to a repeat TFS.

3 zone TFS repair (Abendstein et al) 154 site specific TFS operations in 81 patients. 12 month review. Symptom improvement: fecal incontinence (n=33), 88%, stress incontinence (n=43), 89%, urgency and nocturia (n=50), 80%.

#### PVDF as implant-material in pelvic floor surgery. (58)

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The experiences with different mesh-implants showed the advantages of mesh-supported versus conventional methods applied in pelvic floor surgery. Despite this improvement, the recurrence rate about 10-15% arises the potential for optimised implants. The requirements of an optimised implant are compiled and the appropriate developments are executed. The validation of the development is resulted with the help of new measurement methods and analysing processes and is to be tested in clinical use. 4 new textiles implants were developed based on the material requirements (less inflammation and fibroses, less cell-turnover, less shrinkage, nonabsorbable polymer with standardised features, no Polyester,

no Silicon, no bio-material) and on the structural requirements (no sharp edges, large pores (>1 mm, no film), little elasticity (< 10%), high form stability, minimum width of 1 cm): One sling for the treatment of female urinary stress incontinence (anterior sling), the treatment of moderate Cystocele (median sling) and the treatment of vaginal blind pouch prolapse (posterior sling). Three special shaped meshes for the treatment of a rectocele / enterocele, the treatment of a cystocele and for the Sacrocolpopexy after vaginal blind pouch prolapse or uterus prolapse. All the structures are based on a newly designed warp knitted structure and are made out of polyvinylidene fluoride (PVDF)-monofilament. Remarkably less inflammation and fibrotic foreign body reaction is the result of excellent biocompatibility of PVDF in comparison to conventional Polypropylene. The PVDF-implants indicate significantly less shrinkage. 249 new PVDF structures are operated in KMG Hospital Güstrow and HANSE-Hospital Wismar and Pelvic Floor Centre of Munich since begin of 2006 (124 anterior slings, 11 median slings, 42 posterior slings, 72 prolapse meshes). An extrusion into the vaginal wall has been observed in only three cases. All cases were treated conservatively. The procedures achieved the favoured treatment success and no further complications were observed. With an extrusion rate of 1.2 % and satisfying success rates significant improvement has been achieved by application of structural optimised PVDF-implants.

## IPFDS SYMPOSIUM

### HOLISTIC CONCEPTS OF PELVIC FLOOR DYSFUNCTION – FROM DELIVERY TO DYSFUNCTION

#### Pelvic floor rehabilitation. (59)

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The ICS defines urinary incontinence (UI) as the complaint of any involuntary leakage of urine. In France the prevalence of urinary incontinence in women of working age is 23 % and the majority of them is suffering from stress urinary incontinence (SUI). SUI is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing. It results from specific damage to the muscles, fascial structure, and nerves of the pelvic floor. A commonly accepted etiologic factor is perinatal damage, as well as pregnancy itself, hereditary factors, strenuous physical activity, chronic cough, obesity and aging. So many studies are published about PFME, VC, ES, Biofeedback and Neotonus. The goal of the lecture is to define which one is the most appropriate to treat Female Urinary Incontinence. Physiotherapy for SUI is a widely accepted mode of conservative treatment that involves Pelvic Floor Muscle Exercises (PFME), with or without biofeedback, electrostimulation, and weighted vaginal cones and balls. The purpose of pelvic-floor re-education is to increase the strength and functional activity of the pelvic floor muscles, which may reduce the problems of SUI. As conservative treatment seems to have no side effects, it should be considered as the first choice of treatment of SUI. There have been few randomized controlled trials involving comparison of various types of therapy. Some studies have been implemented in which mostly two combinations of treatment modes have been evaluated. However, the repetitive voluntary contractions of the pelvic floor musculature (sometimes called Kegel exercises) have formed the basis of physiotherapy treatment for SUI and are currently recommended as a first line treatment. Cardozo<sup>1</sup> concludes, in a group of 97 patients completing a 14 week program of PFME Rehabilitation, that displacement of bladder neck on Valsalva (rotation excursion) was reduced after treatment suggesting increased levator stiffness. Parkkinen et al<sup>2</sup>, in a prospective long term study (5 years), comparing two groups, one with individual therapy (PFME, Vaginal ball, Biofeedback and Electrostimulation (ES)) and another with Home-Based Pelvic Floor Training, conclude that home based PFME and VB proved to be equally effective as once-a-week supervised therapy, and the 5 year follow-up results demonstrate a successful response in the treatment of female SUI. According the prospective study of Bo<sup>3</sup> in 107 patients comparing PFME, ES, Vaginal Cones and lack of treatment, it is concluded that training to increase the strength of pelvic floor muscle is supe-

rior to ES and Vaginal Cones in treatment of Female SUI. Adverse effects are reported with electrostimulation but not with exercises, patients tolerance with ES and VC is low and Pelvic Floor exercise should be the first approach.

*References are available from the Authors on request.*

#### Pelvic floor and functional bowel disorders. (60)

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Functional disorders of the lower gastrointestinal tract often affect, and interact with, physiology and other disorders of the pelvic floor. The clinical relevance of functional bowel and anorectal disorders is due to their high prevalence and the not always easy differential diagnosis with conditions originating from the bladder and the gynaecological apparatus.

Functional pelvic pain related to physiologic events, such as eating, defecation and passage of flatus, is regarded associated with Irritable Bowel Syndrome (IBS) or Functional Constipation. Recurrent functional pain referred to the anorectal area and unrelated to physiological events can be associated with Proctalgia Fugax or Levator Ani Syndrome.

Chronic pelvic pain is a frequent distressing complaint that may derive from the pelvic floor or one or more pelvic organs. Patient with IBS refer gynaecologic, urinary and anorectal symptoms more frequently than expected in the general population. Detrusor instability, Interstitial Cystitis dyspareunia, dysmenorrhea, are several folds more frequent in IBS patients than in a control population (Whorwell et al. 1986; Alagiri et al 1997).

IBS and Interstitial Cystitis (IC) share the following features: female prevalence, worsening with menstrual cycle and stress, pain on visceral filling, reduced visceral compliance, lowered sensitivity threshold, low grade epithelial and subepithelial inflammation. In addition both conditions are associated with similar extra-pelvic conditions: fibromyalgia, chronic fatigue syndrome, psychological disorders, stressful events (Alagiri et al 1997; Van de Merwe 1999). IBS and IC appear to have an identical neuroinflammatory pathogenesis sharing the activation of mast cells by several and different stimuli as pivotal mechanism.

#### Fecal incontinence (61)

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Actually the treatment of the Fecal Incontinence (FI) has satisfactory indications already if it is not a severe degree. In fact we know a lot of kind of indication to traditional medical, conservative, rehabilitative, surgical therapies in case of correct diagnosis of mild to moderate FI.

Nevertheless the rate of successful results decreases in the middle and long follow-up also in the described cases. The problem, in all the international literature, is higher in case of severe FI.

All the authors, justifying the unsatisfying long-term results, relate to the complexity of anatomical and physiological structure of the ano-rectal canal and pelvic floor.

It is important to show the results following a traditional conservative treatment of a moderate FI: we suggest, for example, diet, bulking and pharmacological supports as is described in all the gastroenterological schools. After a variable period of subjective satisfactory result we observe in an important % of cases a systematic request of stronger suggestions that we have and give many times changing products and increasing doses, etc.

This is possible because a conservative treatment gives to us the opportunity to change, to repeat and, at least, to suggest also an invasive, surgical treatment.

In case the long-term result of a conservative or rehabilitative treatment will be not higher than the 50% we save many other opportunities, in the other hand, in case of invasive treatment, the same unsatisfactory result doesn't leave to us any other kind of suggestion and we will have a 50% of problematic patients.

In the recent literature are described the results following conservative procedures random to rehabilitative procedures in the tempt of validating these in all the degrees of FI, so that mini invasive procedures are proposed better than more invasive procedures.

In this presentation we describe all the surgical procedures used for F.I. treatment like Bulking Agents, SNM, Stimulated Gracileplastic, AAS, Tibial Nerve Stimulation, Sling, their results and follow-up.



**Complex pelvic problems - a multidisciplinary perspective. (62)**

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The philosophical concept of "Complex thinking" has been applied in many fields of human knowledge. However in human biology this concept has been still little investigated. We believe that the multidisciplinary approach to Pelvic Floor Dysfunction could be considered an interesting theoretical field of application of this philosophical concept.

Let's rest thinking... this will help us to understand the distance between our auspices and the actual experience in everyday clinical practice.

**WHO initiatives in Central Asia - are we learning from the past. (63)**

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The way in which past obstetric history contributes to subsequent pelvic floor dysfunction has been debated for decades. It is – probably correctly – thought that some of the epidemic rise in caesarean sections is caused by women choosing to protect their pelvic floor. But what of a country where caesarean section rates are less than 2%? How does a country with good access to medical care in labour develop a system where such a strange state of affairs can exist? What can we learn from this?

**PODIUM PRESENTATIONS  
SURGICAL TECHNIQUE****Anterior paravaginal repair using Gynemesh. (64)**

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**Introduction:** Pelvic organ prolapse is a frequent cause of physical & psychological distress. Traditional cystocele repair has high failure rates as attenuated tissues are utilized & paravaginal defects remain uncorrected. Mesh repair aims to overcome these deficiencies but has been associated with varying success & morbidity.

**Objectives:** To determine the efficacy and safety of vaginal mesh repair using polypropylene monofilament mesh (Gynemesh) to repair paravaginal defects in patients with symptomatic cystocele.

**Patients & Methods:** Retrospective study of all patients with symptomatic cystocele treated at Hamilton, New Zealand during 2004-08. Patients were assessed using POP-Q scores  $\pm$  urodynamics as appropriate. An individually tailored tension-free Gynemesh was fixed to the sacrospinous ligament, arcuate line & suburethrally using PDS sutures. Postoperative pain assessments were done using VAS. Patients were followed up at 1, 6 and 12 months. Efficacy of repair, morbidity and impact on quality of life were recorded and analyzed.

**Results & discussion:** Of the 118 women, 4 presented with proidentia, 25 with stage 2 and 89 with stage 3 prolapse. 15 patients had Urinary stress incontinence in addition to prolapse, and 38 had a previous surgery (34 with previous hysterectomy, 14 with previous repair, 10 with both).

The median follow-up was 18 months; 112 patients felt improvement in symptoms and quality of life, 16 patients had transient micturition problems (12-USI, 2-urinary retention, 1-urgency) and were managed conservatively in all but 1 (needed Monarc sling). One wound infection and 3 mesh exposures were noted and these required excision of the exposed mesh. There were no clinical recurrences of prolapse. Complications have decreased with increasing experience with use of the technique.

**Conclusion:** Paravaginal mesh repair is a safe, simple surgery, and provides excellent anatomic results with few complications.

**Vaginal prolapse and stool outlet obstruction, a combined approach with 1 year follow up. (65)**

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The stool outlet obstruction with incomplete or complete rectum prolapse in combination with a vaginal vault prolapse is a severe form of pelvic floor insufficiency. The combination of a laparo-

scopic resection-rectopexy with a vaginal vault Mesh colposuspension is a possible way to correct this defect in an interdisciplinary way between surgeons and gynaecologists. The safety of the combination is evaluated in 18 patients.

**Results:** In 16 of 18 cases no complication were observed. One rectum perforation during preparation was sutured laparoscopically, one hemorrhage was fixed during surgery. The mean hospitalization was 11.4 days (8-20). The urethral Foley catheter was removed at 4.3 days (2-10). Short term mild temperature rising over 38°C take place in 28% and disappears under antibiotics after a few days. Two urinary tract infections were seen. After 1 year, 7 of 12 patients were satisfied. One suffers from painful intercourse and 1 gets a recurrent stool outlet obstruction. Anatomical correction of the prolapse was successful in 11/12 patients, only 1 asymptomatic POPQ-II descensus was observed.

**Conclusion:** The combination of the laparoscopic resection-rectopexy with a vaginal vault mesh colposuspension might be safe. The close contact between Mesh and anastomosis might induce no higher insufficiencies. The long term outcome must be evaluated.

**Techniques for avoiding incontinence after prolapse surgery. (66)**

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Genital prolapse is usually associated with functional alterations, in particular urinary : voiding dysfunction, urgency, retention and stress urinary incontinence (SUI). A relationship between the seriousness of the prolapse and urinary alterations is not clear. For example SUI diminishes as the prolapse increases. This problematic association between prolapse and incontinence remains widely discussed, especially occult incontinence in woman affected with urogenital prolapse. All recent studies which have involved surgery for prolapse and at the same time surgery for occult incontinence with T.V.T. conclude that surgical performance of both is quite effective in the prevention of post surgical incontinence. A disadvantage of this combined procedure could be an elevated risk of voiding dysfunction, in particular urinary obstruction and retention. In some studies this risk has been seen at 27%. On the other hand no voiding dysfunction has been seen in woman who were operated on only for prolapse. Nowadays there isn't sufficient data regarding surgical association between prolapse and occult incontinence with T.O.T. techniques. Our experience proves that this kind of association is successful in the prevention of post surgical incontinence but without any voiding dysfunction. This may be due to the fact that a tape placed through the obturator space is less tense than the tape placed in the retropubic way. In our experience the results are very positive even when the T.O.T. technique for occult incontinence is associated with prosthetic surgery for prolapse.

**A randomized controlled study to compare tension free vaginal tape (TVT) and Monarc trans-obturator tape in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (ISD). (67)**

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**Objective:** To compare TVT™ retropubic and Monarc™ trans-obturator sling in the treatment of women with urodynamic stress incontinence (USI) and intrinsic sphincter deficiency (ISD).

**Materials and Methods:** A prospective, randomized controlled trial was conducted of women with USI and ISD, defined as maximum urethral closure pressure < 20cm H<sub>2</sub>O and/or ALLP < 60 cm H<sub>2</sub>O. The pre- and post-operative protocol included: complete uroynaecological history, physical examination, multi channel urodynamics testing, 24-hour pad test and a three day bladder diary. UDI 6 SF, IIQ7 SF and visual analog score (VAS) were used for subjective assessment of quality of life (QOL) and treatment success. Follow-up was at 6 weeks and 6 months.

**Results:** From Feb 2004 to Feb 2007 181 women were eligible to participate in this study and 162 were enrolled with 80 randomized to TVT and 82 to Monarc.sling. Additional surgery to correct prolapse was performed in 49 women (21(26.2%) TVT / 28 (33.3%) Monarc). No differences in demographic or clinical characteristics of either group were detected. Primary endpoint assessment revealed that seven (7) repeat sling procedures (TVT) were required for recurrent SI in the Monarc group compared with none

(0) in the TVT group ( $p=0.004$ ). Postoperative urodynamic study demonstrated USI in 23 (28%) of the Monarc and in 13 (16.25%) of the TVT group ( $p=0.09$ ). However, subjective assessment with VAS at 6 months follow-up (cure = VAS > 80) showed 77.5 % in TVT vs 79.5 % in the Monarc group ( $p=0.81$ ). 24 hour pad weigh data showed very large baseline variation but no difference between the groups at 6 months ( $p=0.53$ ). Additionally, the QOL questionnaires showed no difference between the groups at follow-up, but for both groups there was an overall improvement in IIQ 7 SF from baseline of a median score of 6 [range; 2 -12] and in the UDI 6 SF median score of 6.5 [range; 4-9]. Complications in TVT / Monarc groups such as haemorrhage (defined as blood loss > 200ml) was (3 (3.75%) vs 7 (8.5%), voiding difficulty prior to discharge (7 /8.75%) vs 3 /3.7%), long term voiding difficulty requiring clean intermittent self catheterisation (2 /2.5%) vs 1/1.2%) were similar. Other complications in TVT/Monarc group were bladder perforation (6/7.5%) vs 0), vaginal perforation (0 vs 4/4.8%) and division of tape for voiding difficulty (3/3.7% vs 2 /2.4%).

**Conclusion:** These data demonstrate that TVT is objectively superior to Monarc sling for the treatment of USI with ISD, though subjective outcomes were not different. Further follow-up will be performed after 12 and 24 months.

### TVT vs. TVT-O for primary stress urinary incontinence: a prospective, randomized trial. (68)

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**Hypothesis/aims of study:** We compared objective and subjective outcomes and perioperative factors (complications) of TVT with those of TVT-O as treatment for primary stress urinary incontinence in a prospective randomized noninferiority trial. The hypothesis was that TVT-O is not inferior to TVT for curing female stress incontinence.

**Study design, materials and methods:** We conducted a randomized, controlled, multicenter noninferiority trial of patients undergoing a midurethral tape procedure for primary stress urinary incontinence. All patients gave informed written consent. Patients undergoing concomitant hysterectomy or procedures to correct prolapse were excluded; minor concomitant procedures were allowed. Patients were randomized to retropubic or transobturator TVT (TVT vs. TVT-O). The primary outcome measure was objective cure of stress incontinence (negative cough stress test at bladder filling of 300 ml). Secondary outcome measures were overall and condition-specific quality of life data (King's Incontinence Questionnaire; Short Form 12 (SF-12); Euro QoL5; Patient Global Impression of Severity and Improvement, PGI-S, PGI-I). Perioperative complications were recorded and data were obtained for cost and cost utility analyses. We assumed an 80% cure rate with TVT and that a 10% difference in cure between procedures would be clinically important. The hypothesis was that there is no more than a 10% difference in cure rate between the methods. To detect this level of difference with 80% power required 198 patients in each arm.

**Results:** A total of 564 patients were randomized at 25 participating centers (both general and regional hospitals and university departments). At 3 months a negative cough stress test was documented in 174/204 (85%) of patients after TVT compared with 157/188 (84%) after TVT-O. The rate of patients not using pads was 72% after TVT vs. 63% after TVT-O. There were 9 bladder perforations (3.3%) and 1 bowel perforation with TVT. The bladder perforations healed without sequelae; the bowel (transverse colon) perforation was repaired by laparotomy 48 hours after the TVT procedure and the patient subsequently did well. There were no bladder or bowel perforations with the TVT-O operation. There were 4 cases of increased bleeding with the TVT-O operation compared with 2 for TVT-O. Quality of life and health economic data are being analyzed.

**Conclusions:** At 3 months continence rates after TVT were not significantly inferior to those after TVT. Bladder perforations were more common with the retropubic approach. (ClinicalTrials.gov number NCT00441454).

### Brazilian experience with the posterior intravaginal slingplasty: functional results and complications. (69)

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This is an observational study of 47 patients treated with infracoccygeal sacropexy with IVS Tunneller™ device either for pro-

lapse or for functional symptoms presented in the posterior fornix syndrome described by Petros in his Integral theory.

We treated 57 non-selected patients with apical and/or posterior vaginal prolapse grade II or more, based on POP Q (ICS classification), who had urinary, fecal and local symptoms with infracoccygeal sacropexy (posterior vaginal slingplasty) using IVS Tunneller™ (Tyco healthcare, USA) a polypropylene multifilamentar tape, with pores varying from 10 to 75 micra.

All patients had a complete symptoms evaluation, prolapse examination (POP Q as defined by ICS, 1996) and urodynamic study prior to the operation.

They were evaluated after surgery with a symptom questionnaire at 1, 6, 12 months, then every year after that. And were also evaluated through a physical exam classifying them in the POP Q. Although we had a great improvement of irritative urinary symptoms, we will not consider them here, because almost half of the patients showed a concomitant sub-urethral sling for urinary stress or mixed incontinence, at the same time as the posterior IVS.

The average age was 61 years, parity 4.4, follow-up 25 months. In Tab.1 the results.

TABLE 1.

	Pre	Post	p
<b>Anatomy-POP Q (ICS, 1996)</b>			
Posterior > 2	97%	4.3%	<0.05
Apical > 2	22%	3%	<0.05
Perineal body	75%	3%	<0.05
<b>Local and sexual symptoms</b>			
Dyspareunia	33%	9%	<0.05
Vaginal Laxity	41%	6%	<0.05
Vaginal lump	66%	2%	<0.05
Vaginal flatus	21%	2%	<0.05
Perineal pain	18%	9%	<0.05
<b>Intestinal function</b>			
Difficult defecation	34%	2%	<0.05
Anal Incontinence	30%	2%	<0.05

We had 2 patients with vaginal erosion of the tape, one of them was solved by cutting the tape at the doctor's office, and the other one had to undergo surgery, due to a vaginal cyst as a complication of the posterior repair, with no further complications or new symptoms. One patient complained of an unspecific pain, a severe dyspareunia, two years after the procedure, with no sign of extrusion or erosion. However, at that time the patient felt that the pain got worse when we did a finger palpation of the place where we put the posterior IVS. This patient went to surgery and we took all the tape off. Now the patient is feeling well, with no prolapse recurrence. She had a Grade II prolapse. We had good cure rates in our series, and lower rates of complications with the multifilament tape, conflicting with the literature. We are following these patients to see if this results and complications will continued at the same rate with time.

### TVT Secur – a novel anti-incontinence procedure. (70)

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The TVT procedure has become very popular ever since it was first described by Ulmsten in 1996. Common complications in previously performed surgeries for the treatment of stress urinary incontinence, such as intra-operative blood loss, pelvic and abdominal organ injury, post-operative de novo detrusor instability, dyspareunia and urethral erosion, are rare in the TVT era. Prospective randomized multi-center studies, comparing TVT to the former gold standard Burch colposuspension, demonstrated similar therapeutic impact for both. However, TVT was associated with a higher intra-operative complication rate while colposuspension was associated with a higher post-operative complication rate and a longer recovery period. The previously reported TVT-related complications included bladder penetration, intra-operative bleeding, post-opera-

tive infection and vessel and bowel injuries. Since surgical procedures are more likely to cure stress urinary incontinence rather than non-surgical procedures, Delorme and de Leval adapted the TVT-Obturator procedure to avoid the aforementioned complications. The reported data regarding efficacy of the TVT-Obturator in terms of cure as well as intra-operative and early post-operative complication rates is encouraging. Therapeutic failure, intra-operative bleeding, post-operative infection and voiding difficulties also seem to occur less with the TVT-Obturator than previously reported for TVT. However, the TVT-Obturator is not free of operative complications: thigh-pain is reported to interfere with patient satisfaction, operative infections and post-operative bladder outlet obstructions still occur as well as occasional operative hemorrhage. The TVT-SECUR was designed to minimize the operative procedure as much as possible in order to reduce those undesired complications. This new device is composed of an 8 cm long laser cut polypropylene mesh and is introduced to the internal obturator muscle by a metallic inserter, while no exit skin cuts are needed. This approach imitates the sub-mid-urethral support provided with the TVT-Obturator. The TVT-SECUR procedure appears to be potentially easier to perform and relatively trouble-free for both surgeons and patients and might not require urethral catheterization or diagnostic cystoscopy during surgery. Paying respect to the procedural specific surgical steps might shorten the TVT-SECUR learning curve.

### ISD Update. (71)

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The factors necessary for the urethra to remain closed at rest and during increased abdominal pressure have been well characterized: - functional striated sphincter controlled by pudendal innervation, - well vascularized urethral mucosa and sub mucosa, - properly aligned and functioning intrinsic smooth muscle, - intact vaginal support.

One of the most difficult tasks to address in patients with stress urinary incontinence is to establish the amount of intrinsic sphincter deficiency that is causing incontinence. The concept of failure of the urethra in functioning as sphincter mechanism is not new. In fact Giordano in 1907 first recognized that the urinary incontinence could be caused by failing of the internal sphincter mechanism. This concept was also suspected by Green and co-authors. They described in a paper published in *Am J Obstet Gynecol*, in 1953 "patients in whom multiple retropubic operations failed and the failure was due to a deficient sphincter mechanism characterized by an open vesical neck and proximal urethra at rest, with minimal or no urethral descent during stress."

The first definition of intrinsic urethral insufficiency or deficiency (ISD) has been proposed by McGuire et al in the paper: "The value of urodynamic testing in stress urinary incontinence (*J Urol* 124:256, 1980). ISD was defined as the inability of the urethra to function as a sphincter either at rest or in response to minimal stress activity. These findings led Blaivas et al to propose a classification of stress urinary incontinence in two big categories: incontinence due to lack of sufficient support of the bladder base and the urethra can lead to increased movement (hypermobility), and the group of patient where incontinence is due to weakness in the urethral sphincter.

The typical ISD patient was characterized by a low urethral closure pressure at urodynamic examination, stovepipe appearance on cystoscopy and an opening or funneling of the urethra and bladder neck at rest on cystography.

Further research showed that the presence of ISD was not that easily found and treated as thought. In fact open bladder neck may or may not produce stress urinary incontinence, depending on compensatory mechanisms as presented by Ostergard et.al. in the article "Predicting intrinsic urethral sphincter dysfunction in women with stress urinary incontinence" (*Obstet Gynecol*. 1994; 84: 188). Additionally Cardozo demonstrated radiologically that 50% of normal climacteric continent women might have an incompetent bladder neck at coughing. According to Kayigil et al in the paper "High rate of ISD in patients with hypermobility" ISD has to be considered in an incontinent patient. More recently Ghonaim (*Int Urogyn J* 2002 13:99) was able to subdivide the ISD using videourodynamics:

ISD A Subtle/Urodynamic: loss of functional urethral closure,

common in elderly females; urethral hypermobility is common; only diagnosed by VideoUrodynamic (low MUCP < 10cm H<sub>2</sub>O, ALPP < 120); the hypermobility can mask the underlying ISD. (32%);

ISD-B Beak shaped open bladder neck: may show mild degree of mobility with stress (54%) (MUCP < 10, ALPP < 90)

ISD-C Pipestem urethra: fixed in position, severe incontinence, suggestive history (e.g. pelvic surgery or radiation etc) (14%) (MUCP < 10, ALPP < 70).

The authors concluded that intrinsic urethral sphincter deficiency (ISD) is a clinical entity that should be suspected in women with stress urinary incontinence as it poses a significant risk factor for repair failure.

Regarding the treatment of ISD, according to Shaw et al. (*NeuroUrol Urodyn* 1990;9:503) creating an adequate intrinsic urethral resistance might be more important in the correction of urethral hypermobility especially in patients with moderate and severe intrinsic sphincter deficiency. Patients with ISD have also a high incidence of postoperative urinary retention or dysuria and long term clean intermittent catheterisation could be necessary. (Leach, *J Urol* 1996; 158:875). The simple increasing of the tenting of a mid urethral tape is not probably the proper answer for ISD. Several recent reports appeared on tape erosion into urethra and vagina. A few cases of intravesical erosion were also reported (Madjar, *Urology* 59:601, 2002; Pit, *J.Urol* 176:647, 2002 Wolkmer, *J Urol* 169:570, 2003, Boubilil, *Curr Opin Obstet Gynecol* 14:515,2002). According to Tsivian (*J Urol* 171, 762, 2004) one possible scenario is that the pressure necrosis cause a gradual penetration of the tape into the urethra or bladder.

The EAU *Female Urology Update on ISD* in 2005 recommendations were the following: for *severe* forms of ISD the evaluation is easy and particularly in previous operated patients conventional therapies are probably not recommended. For *moderate* forms cure rates are probably reduced and validated evaluation and comparative studies are still needed. For *mild* forms no modification of prognosis and management are requested.

## INCONTINENCE UPDATE

### Stress urinary incontinence (SUI).

#### Pathophysiology: current knowledge. (72)

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Although the level of comprehension of the pathophysiology of female Stress Urinary Incontinence (SUI) has dramatically improved in the last decade, the inter-relationships existing among the different causative factors are still not fully understood.

Urethral mobility, intrinsic urethral sphincter function, the action of pelvic floor muscles, and its interaction with pelvic organs, all seem to play a role in ensuring continence and in determining SUI. A few theories have addressed each of these factors, and a number of surgical procedures have been proposed, based on each of these theories. The more recent interpretation of pathophysiology of SUI tend to look at urethral hypermobility and urethral Intrinsic Sphincter Deficiency (ISD) as a continuum, rather than in a dichotomic manner.

#### Biological slings - the latest data. (73)

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*Introduction:* The use of materials has become more common in urogynaecologic surgery over the past three decades. The sling approach has been around since 1907 and has consistently had high success rates, with cure rates of up to 91%. The downside until recently, however, had been that suburethral sling for SUI caused more postoperative complications, including voiding dysfunction retention, and sling erosion. In 1996 the introduction of TVT procedure revolutionized the treatment of SUI, opening up a variety of pubovaginal sling option, including synthetic and natural graft materials, including the transobturator sling approach. The tension placed on suburethral sling varies considerably among surgeon and plays a direct role in postoperative rates of retention and erosion (Iglesia, Fenner, and Brubaker).

*Synthetic slings:* Synthetic sling have been used for many years in the treatment of stress incontinence and have shown approxi-

mately comparable success rates in the order of 70%. However, concerns regarding the long-term safety of synthetic materials have arisen because of the risk of urethral erosion and infections (Table 1 e 2). Silicone sling material was withdrawn from the market due to severe erosion problems, and the polyester sling material was recalled in January 1999. The number of wound infections and erosions seen with Teflon is high, and it is therefore recommended that patients should be warned of this complication rate and told that graft removal may be necessary<sup>1</sup>. Erosion is also seen with Gore-Tex<sup>®</sup>, and the high rejection rate dictates that caution be exercised when using Gore-Tex<sup>®</sup> in stress incontinence.

TABLE 1. – Clinical trials evaluating synthetic biomaterials in pubo-vaginal sling procedure for surgical treatment of SUI.

Material	Success rate (%)	Complications
Polytetrafluoroethylene (PTFE; Teflon <sup>®</sup> )	61	Wound infection (40%) <sup>1</sup>
Expanded PTFE (Gore-Tex <sup>®</sup> )	72	Erosion/retention (15%) <sup>5</sup>
Expanded PTFE (Gore-Tex <sup>®</sup> )	87	Erosion (4%) <sup>6</sup>
Expanded PTFE (Gore-Tex <sup>®</sup> )	65	Rejection (around 30%) <sup>7</sup>
Vicryl	95	Erosion/infection <sup>9</sup>
Prolene	87	De novo instability (6%) <sup>10</sup>

TABLE 2. – Pubo vaginal synthetic sling: results.

AA	n. pts	Followup mts	% rate	Valutatio subj/obj	% complications and voiding dysfunction	material
Kersey (1988)	100	6-60	78%	Subj	-	mersilene
Young (1995)	83	16	95,2%	Subj	-	mersilene
Young /2001)	127	12,6	95,3/94%	Subj/obj	3%	mersilene
Stanton (1985)	22	12	95,5%	Subj	31%	silastic
Chin (1995)	88	3	92,6/89%	Subj	2%	Silastic
Kondo (1999)	54	6-42	92,6/89%	Subj/obj	2%	silastic
Weinberger (1996)	108/62	38	72,5-61%	Subj/obj	33%	Go-retex
Norris (1996)	122	24,4	88%	Subj	32%	Go-retex
Morgan (1995)	88	49,7	85,2%	Subj	7%	Marlex
Amaye-Obu (1999)	70/45	12-144	88,9-69%	Subj/obj	-	Marlex
Nilsson (2001)	90	60	85%	Subj	-	Prolene/TVT
Villet (2002)	124	19-54	88,7%	Subj	-	Prolene/TVT
Adile (2002)	87	24	88,6%	Subj/obj	3%	Prolene/TVT

Biological slings may be made from the patient's own fascia lata or rectus fascia (autograft), from human donor tissue (allograft) or from animal tissue (xenograft). Allograft are solvent-dehydrated or freeze-dried and may be gamma-irradiated. Autologous fascia sling are the most established of these opinions. The safety and short-term efficacy of the insertion of biological slings for SUI in women is adequate to support the use of this procedure. Data on the long-term efficacy of the insertion of biological slings for stress urinary incontinence in women are limited to autologous sling. Biological slings may be made from the patient's own fascial tissue (autograft), from human donor tissue (allograft) or from animal tissue (xenograft). Suburethral sling procedure involve making an incision in the lower abdomen and one in the anterior vaginal wall. An instrument is tunnelled between the incision to introduce the sling and position it around the bladder neck where it forms a supportive hammock. There are three main methods of positioning the sling, depending on its length. A full-length sling passes through the retropubic space, underneath the urethra to other side, and is fixed by sutures to the anterior abdominal wall. Shorter sling are attached by suspending sutures at each end of the sling to the anterior abdominal wall. Alternatively, bone screws may be used to secure the sutures into the pubic bones. Once the sling is in position, a cystoscopy may be performed to check that there has been no bladder perforation.

TABLE 3. – Autologous fascia lata results

AA	n. pts	Followup mts	% rate	Subj/obj Evaluation	Complications Voiding dysfunction
Ridley (1966)	+36	+6	83,3%	Subj	-
Beck (1988)	170	24	92,4%	Subj	-
Breen (1997)	60	6-42	90%	Subj	0
Berman (1997)	14	10-22	71,4%	Subj	-

One randomised controlled trial reported that 82% (56/68) of women were cured of stress urinary incontinence after biological sling procedure, compared with 88% (53/60) of women having a vaginal tape procedure (not statistically significant). The patient satisfaction rates were also similar for the two groups (tab 5-6).

Two non-randomised controlled trials compared cadaveric fascia lata sling with autograft slings. These reported similar cure rates of 71% (45/63) and 74% (77/104) for the allograft groups and 77% (55/71) and 73% (22/30) for autograft group (tab 7-8) One for these studies reported that 89% (93/104) of women having allograft sling were satisfied and would undergo the procedure again, compared with 90% (27/30) of women having autograft sling. A case series

TABLE 4. – Autologous rectum abdominal fascia results

AA	n.pts	Followup mts	% rate	Subj/obj Evaluation	Complications Voiding dysfunction
Mc Guire (1978)	52	10-72 (27,6)	96,2%	Subj	-
Blaivas (1991)	67	12-96(42)	82,1%	Subj	-
Swierzewsky (1994)	108	60-107 (84)	82%	Subj	36%
Ghoniem (1998)	80	30	85%	Subj	8%
Chaikin (1998)	251	12-180 (37)	72,9%	Subj	8,7%
Cross (1998)	114	6-42 (22)	92,5%	Obj	8%
Barrington (1998)	73	24	95,9%	Subj/Obj	6%
Morgan (200)	247	22-68 (51)	88%	Subj	7%
Borup (2002)	32	60	93,8%	Subj	-

of 198 women with autologous fascia slings reported an overall success rate of 72% (142/197) after a median follow-up of 6 years (Hawkins 2002).

TABLE 5. – Randomised controlled trial: biological sling vs TVT for IUS treatment Abdel-Fattah (2004)

Material	n.pts	Mean age	Followup Months	Cure rates
Biological sling	74/142 52%	53 (range 34-75)	34	Dry 82% (56/68)
Porcine dermal collagen				Improved 10% ( 7/68)
				Failed 7% ( 5/68)
Synthetic sling	68/142 48%	54 (range 32-83)	36	Dry 88% (53/60)
Vaginal tape				Improved 5% ( 3/60)
				Failed 7% ( 4/60)

TABLE 6. – Randomised controlled trial: biological sling vs TVT: complications Abdel-Fattah (2004)

Complications	Biological sling Porcine dermal collagen	Synthetic sling Vaginal tape
Haemorrhage	4,1% (3/74)	2,9% (2/68)
Infection	0%	1,5% (1/68)
Severe pain	1,4% (1/74)	0%
Release of sling	6,8% (5/74)	2,9% ( 2/68)
Urethral dilatation	2,7% (2/74)	1,5% (1/68)
Postoperative urinary urgency	17,6% (12/68)	15,0% (9/60)
Postoperative voiding difficulties	5,9% (4/68)	8,4% (5/60)
Postoperative dyspareunia	0%	3,3% (2/60)

TABLE 7. – Non-randomised controlled study compared cadaveric fascia lata vs autograft sling Brown (2000).

Material	n.pts	Mean age	Followup Months	Cure rates
Cadaveric fascia lata sling	121/167 (52%)	62	12	Dry 74% (77/104)
				Improved 19% (20/104)
				Failed 7% ( 7/104)
Autologous fascia lata sling	46/167 (46%)	62	44	Dry 73% (22/30)
				Improved 27% ( 8/30)
				Failed 0% (0/30)

TABLE 8. – Non-randomised controlled study compared cadaveric fascia lata vs autograft sling: complications Brown (2000).

Complications	Cadaveric fascia lata sling	Autologous fascia lata sling
Sovrapubic abscess	2% (2/104)	0% (0/30)
Prolonged urinary retention	0%	10% (3/30)
Severe pain	0% (0/104)	0%
Lower extremity neuropaty	1% (1/104)	0% (0/30)
Suprapubic haemathoma	1% (1/104)	0% (0/30)
Cerebrovascular accident	0% (0/104)	3% (1/30)

Another case series reported that 85% (75/88) of the patient followed up for longer than 5 years where continent. The two most commonly reported complication were urge incontinence, which affected between 3% (5/152) and 50% (5/10) of women, and voiding difficulties or urinary retention, affecting between 3% (4/134) and 94% (232/247) of women. Two studies reported severe or persistent pain in 1% (1/74) and 4% (5/134) of women other complications included infection, release of sling, pelvic haematoma, haemorrhage and urethral dilatation.

**Conclusions:** The potential adverse effects include urethral obstruction and retention, bladder perforation haemorrhage, infection and urgency. There is also an additional potential risk of infection associated with the use of cadaveric tissue. A variety of types of biological slings are available, including allogenic, xenogenic or autogenic grafts; and that outcomes may vary according to the type of graft used and also of methods are used for the implantation of slings.

*References available from the author on request.*

### Options after sling failure. (74)

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Transvaginal midurethral sling procedures have become increasingly popular in the past decade and currently become the gold standard to treat urodynamic stress incontinence (USI). Since the initial description of tension-free vaginal tape (TVT) by Ulmsten in 1996 other delivery methods of a midurethral sling have been introduced. For recurrent incontinence after a previous anti-incontinence surgery a sling is an option. Prior to the introduction of midurethral slings a pubovaginal sling would have been the most logical choice, however, now there are other options. There are few reports specifically looking at the use of midurethral slings to treat recurrent USI following other midurethral slings. One series showed complete resolution of stress incontinence with TVT in five patients following failed TOT. A case report reported resolution of the USI after three TVT slings. TVT slings have been shown to be effective in patients with ISD. Studies show similar continence outcomes among the TVT, Monarc TOT and TVT-O. TVT has been reported to have better outcomes than TOT in patients with ISD in some studies. A new sling that allows for postoperative adjustment is the Remeex system. At short-term follow-up 1 year it has been shown to have approximately 90% cure rate and is effective in patients with ISD. Other options following failed midurethral slings include pubovaginal sling, urethral bulking and MMK. The choice of procedure should take into account co-morbidities, urodynamic findings, status of the lower urinary tract and status of the anterior compartment as well as expectations and activity level.

### Drug treatment for stress urinary incontinence. (75)

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Stress urinary incontinence is one of the most important gynecologic health care problems worldwide. In general, it affects about 30% of women and has a high cost attributed to pads, diapers and treatment measures. Although behavioral and surgical therapies are the commonest treatment for this condition, recently, pharmacotherapy is becoming an important alternative. The goal of drug treatment for stress urinary incontinence is to suppress parasympathetic activity and enhance sympathetic and somatic activity in the lower urinary tract. Many drugs have been used with this purpose; the best results are obtained with selective serotonin reuptake inhibitors (especially duloxetine and venlafaxine). Selective serotonin reuptake inhibitors have good initial results in the treatment for stress urinary incontinence but there is no evidence to recommend them as a first-line therapy. Long term efficacy, patient preference, clinical conditions and adverse effects should be considered when drug treatment is offered for the treatment of stress urinary incontinence.

### Coital incontinence. (76)

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Coital urinary incontinence is a common (10-24%) symptom affecting sexually active women with pelvic floor dysfunctions. Although frequently under-reported, it can have a devastating impact on female sexuality and quality of life. It is traditionally divided into two forms: 1) incontinence at penetration, and 2) incontinence during orgasm. For the first time in 1988, Hilton tried to identify the underlying pathophysiological mechanism associated to coital urinary

incontinence. Data from his prospective study showed that incontinence at penetration is mainly related to urodynamic stress incontinence, whereas incontinence during orgasm is more often associated with detrusor overactivity. These findings have not been questioned for more than 10 years, until Moran retrospectively reported that both forms of coital incontinence were caused by urethral sphincter deficiency. Since pathophysiological features of incontinence during orgasm are controversial and have not been properly understood, its treatment is inevitably poorly defined nor standardized. Very few studies are available in the literature about the outcome of treatment for coital urinary incontinence. Regarding surgical therapy for urodynamic stress incontinence, the available data are difficult to evaluate because the authors did not distinguish between different forms of coital incontinence. Only two papers (one assessing the Burch colposuspension and the other the TVT procedure) considered the efficacy of surgical treatment exclusively in women affected by incontinence at penetration showing the highest cure rates, indirectly confirming the involvement of urethral sphincter incompetence in this condition. In 2005 Sand et al. were the first to evaluate the impact on sexual function of treatment with antimuscarinics in women with overactive bladder: of the 569 patients affected by urinary incontinence during intercourse at baseline, only 23% were cured whereas 438 (77%) did not respond to the treatment. However, these authors did not distinguish between incontinence at orgasm or at penetration and no urodynamic evaluation was performed. The low cure rate reported could therefore be the result of possible inappropriate treatment.

We have recently published a study including selected women with concomitant incontinence at orgasm and the urodynamic diagnosis of DO before prescribing Tolterodine 4mg ER once daily with a success rate of 60%. Despite being satisfactory, this cure rate is significantly lower than that observed in the control group (women with DO, without coital incontinence). To explain these findings we can speculate that incontinence at orgasm may be a marker of a more severe form of DO or a late onset symptom of a long-lasting untreated DO, making its management more difficult. These hypotheses could be the basis for further research in this field.

### Slings for incontinence: what does the data say. (77)

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The primary goal in the surgical treatment of stress urinary incontinence (SUI) is the restoration of continence utilizing a method, which minimizes both short-term and long-term morbidity. With more than 150 different surgical procedures having been proposed for the correction of SUI, much research is ongoing to determine the most efficacious and cost-effective way of treating the condition. Since the first reports from Ulmsten and co-workers, tension-free vaginal tape (TVT), the first polypropylene midurethral sling put on the market, has become one of the most commonly performed procedure worldwide due to the ease of performance and high success rates and, to date, several hundred thousand TVT procedures have been performed. Since then, several devices have been introduced on the market with the aim to make the midurethral sling procedures even less invasive reducing the complications rate described with the TVT. Therefore the transobturator approach (TOT) was developed as an alternative technique to minimize the risk of bladder and vascular injuries during the retropublic passage of the needle. The transobturator procedures can be performed either with the outside-in technique or with the inside-out approach resulting in similar success rates and complications. To date different RCT's have been performed comparing the retropublic and the transobturator procedures with results showing similar cure rates but lesser complications with the transobturator approach. The recently marketed single incision sling procedures have been proposed for the treatment of SUI as a day-case techniques minimizing the impact of surgery on women's life. Data on medium and long term efficacy of these procedures are still unavailable even if preliminary results suggest a lesser continence rate when compared with the traditional retropublic or transobturator techniques.

## PROLAPSE UPDATE

### Pathological investigations on alloplastic materials. (78)

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Alloplastic materials and textile structures are required for the treatment of incontinence and prolapse syndromes to increasing extents. However, most surgeons are aware of serious complica-

tions such as recurrences, erosions, infections and chronic pain syndromes after implantation of these materials.

The study presented reports results of pathological studies of the last 15 years on different kinds of textile structures used for hernia, prolapse and incontinence repair. Up to now nearly 1000 mesh explants were completely investigated, including 834 meshes used for hernia repair and 120 meshes used for prolapse and incontinence repair.

The review defines specific features of different mesh modifications and their advantages or disadvantages for biocompatibility. The investigation gives a deep insight how textile structures are incorporated and describes how the structure influences long-term biocompatibility.

Incontinence and prolapse repair reveal specific complications in particular formations of erosions and local infections. Up to 90% of all mesh explants indicated defects of the vaginal mucosa. In nearly all cases the mesh showed a pronounced fibrotic reaction of the interface and in the area of the erosion the mesh revealed larger folds penetrating the mucosa. Since 98% of these mesh explants indicate heavyweight and small porous constructions the use of next generation lightweight and large porous mesh modifications in incontinence and prolapse repair could be favorable. Lightweight and large porous textile structures have proven an advanced biocompatibility with a significantly decreased foreign body reaction and connective tissue formation after long-term implantation. After our experiences in hernia repair textile structures with decreased foreign body reaction and connective tissue formation show a significant increased patients comfort due to a lasting tenderness and flexibility of the implant, which also should be of significant importance in incontinence and prolapse repair.

### Elitrocele and vaginal vault prolapse. (79)

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Prolapse of the vaginal vault and enterocele are the most challenging conditions encountered by pelvic surgeons. Vaginal vault prolapse is reported to occur in about 20% of all women with pelvic organ prolapse. The condition occurs as a loss of apical support which is a result of detachment or excessive stretching of the uterosacral-cardinal ligament complex (level I support). An enterocele is a herniation of peritoneum and its contents at the level of the vaginal apex and results from the detachment of the pubocervical fascia or the rectovaginal septum from the vaginal apex.

A careful and thorough clinical examination using speculum blades and a bimanual examination in the standing position are required in order to identify the presence of a vault prolapse or an enterocele. Very often these situations are misdiagnosed as simple cystoceles or rectoceles.

Although obliterative procedures (LeFort, total colectomy) are still considered a surgical option in the management of vault prolapse, the goal of reconstructive procedures is to restore anatomy and function in all pelvic compartments. The vault should be suspended at the level of the ischial spines and the normal vaginal depth and axis should be preserved, with the upper two thirds of the vagina lying over the levator plate. Care should be taken to reapproximate the pubocervical fascia and the rectovaginal septum to the vaginal apex and reconstruct any other defects present.

The suspension of the vaginal vault can be performed transvaginally with McCall Culdoplasty, uterosacral ligament suspension, levator myorrhaphy, sacrospinous fixation or iliococcygeous suspension. Recently the use of vaginal meshes synthetic or biologic have been proposed. The infracoccygeal sacropexy (posterior IVS) and the use surgical kits (Prolift, Avaulta, Apogee, etc) give promising results but their long term effectiveness is still under study.

Abdominal colpopexy to the sacral promontory using a graft is a well studied procedure and considered by many investigators as the 'gold standard' procedure of vaginal vault prolapse, as it is associated with lower failure rates and less dyspareunia compared to vaginal procedures (sacrospinous fixation). However, the abdominal approach is associated with longer operating times, longer time to recovery and is more expensive. The procedure is performed in many centers by laparoscopy and robotic techniques giving comparable results with the abdominal approach.

### Partially absorbable mesh – a new beginning. (80)

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*Background:* Implantation of polypropylene mesh for pelvic

organ prolapse treatment is a promising new technique leading to lower recurrence rates. Nevertheless they are hampered by erosion rates of up to 20% especially after implantation in the anterior compartment causing discomfort for the patient. A new mesh made of thin polypropylene threads covered with absorbable material might decrease erosion rates after surgical transobturatoric mesh implantation for cystocele treatment.

**Methods:** A prospective randomized multicenter trial was initiated to compare a standard polypropylene mesh (SERATOM® E PP, Serag Wiessner KG, Naila, Germany) with a partially absorbable mesh (SERATOM® E PA) for transobturatoric surgical treatment of cystoceles. The primary endpoint of this trial is the erosion rate after one year. A number of 200 participants were calculated to detect a difference of 10% in erosion rates between both meshes.

**Results:** In a first interim analysis of 109 patients 10 erosions were observed after three months follow up. Seven erosions were observed in patients with standard polypropylene meshes and three in patients with partially absorbable meshes. Two cystocele and two vaginal vault prolapses recurrences (all Grade 2, one with each kind of mesh, respectively) were observed. Recruitment of the study finished after inclusion of 200 patients in July 2008.

**Conclusion:** Preliminary data of this prospective randomized trial suggest a reduction of vaginal erosions after transobturatoric implantation of a partially absorbable mesh in comparison to a polypropylene standard mesh. Data will be available in more detail in October 2008 when most of the patients finished three month follow up, mature data will be published in October 2009. *The study was founded by Serag Wiessner KG, Naila, Germany.*

### Vaginal approach for pelvic prolapse surgery, with implants: OCTOPUS CONCEPT(anatomic and surgical approach of the prosthesis arms). (81)

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Patients were operated by vaginal route using a specially designed prosthetic mesh "Octopus" for anterior and posterior repair. Octopus is a low-weight and highly porous polypropylene monofilaments mesh (ABISS s.a.s France). The aim of octopus is to reproduce and reinforce the pelvic floor fascia. We hope the numerous arms give a good dividing up of the suspension and decrease the risk in shrinking. There are two kind of prosthesis:

- The *anterior 6-armed Octopus* is to support the bladder and the cervix or uterus. The 2 anterior arms are anterior transobturator (A.T.O.), the 2 medium arms are posterior transobturator (P.T.O) and the 2 posterior arms (T.S.S) are through the uterosacral ligaments, laterally to the cervix and posteriorly through the sacrosacral ligaments.

- The *posterior Octopus* is to cure the middle rectocele. It is fixed by 4 arms: 2 superior arms (T.S.S) through the SSL and 2 inferior arms (P.R) through the puborectal muscles. The anatomic study describes the courses of the different arms and the surgical risk of these courses. The clinical study is an assessment of the arm morbidity based on two groups of patients. A.T.O, T.S.S, P.R arms have the same course in the two series. P.T.O has a transversal course in S1 and crosses the pudendal area. P.T.O is posterior and lateral in the S2 (outside the area of the pudendal nerve).

S1 : 2002/2005 (2 surgeons)  
(205 patients - Prospective)  
- A.T.O = 346 : 0 complication  
- P.T.O = 346 : 5 shrinkage (dyspareunia) /2 erosion/ 2 pudendal pains.

- T.S.S = 410 : 3 serious rectal dysfunction  
- P.R = 370 : 0 complication

S2 : 2005/2008 (1 surgeon)  
(84 patients - Prospective)  
- A.T.O = 162 : 0 complication  
- P.T.O = 162 : 0 complication  
- T.S.S = 168 : 1 Shrinkage (dyspareunia)  
- P.R = 68 : 0 complication

In S1 & S2 there is no shrinkage with the meshes. Maybe the main reason is due to the hanging of the prosthesis with several arms.

**Conclusion:** the morbidity with the A.T.O., T.S.S., P.R. is very low. Too much tension on the T.S.S. increases the risk of rectal dysfunction and shrinkage. The morbidity with P.T.O. remains very low if the arm course is very lateral, away from the pudendal area and the vaginal vault.

### Site-specific prolapse surgery. I. Reliability and durability of native tissue paravaginal repair. (82)

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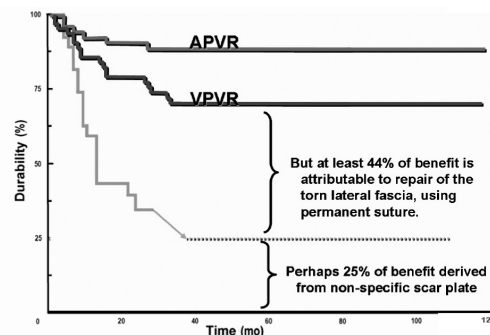
**Background:** The anterior vaginal wall is a fascial diaphragm, tautly strung between the pericervical ring and the urogenital diaphragm, and attached laterally to the two fascial white lines. The pubocervical fascia functions like a trampoline, giving all direction support to the proximal urethra and bladder base. It was traditionally believed that the central fascia of this suspensory hammock attenuates after childbirth, thus forming the bulge of a cysto-urethrocoele. In reality, healthy fascia is like canvas. It does not stretch, but will tear at pre-determined points. As a matter of engineering principle, these pre-determined points of weakness lie where the lines of force concentrate: namely along the peripheral margins, not within the central hammock. Rotatory cystocele formation has three elements: an apical defect, a lateral defect on at least one side and a fulcrum about which rotation can occur. Correcting this pattern of connective tissue damage in accordance with biomechanical principles mandates 'site-specific' repair of the causative fascial avulsions, either with permanent suture or by placement of a mesh bolster.

**Objective:** To compare *native tissue* abdominal (APVR) and vaginal paravaginal repair (VPVR), and to investigate whether surgical outcome was independent of operative route.

**Methods:** Retrospective review of 111 consecutive rotatory cystocele repairs, from a pelvic floor referral practice between 1997\_2007. Women were prospectively evaluated by symptom severity inventories, standardized physical exam and urodynamic testing if indicated. Treatment was by surgeon assignment, 52 women having APVR and 59 having VPVR. Main outcome measures were 'same site' prolapse recurrence; worsened or *de novo* urgency, voiding dysfunction or dyspareunia; and major peri-operative complications. Initial anatomic and functional reliability of cystocele repair were evaluated by chi-squared test. Repair durability over the succeeding ten years was gauged by Kaplan-Meier survival analysis, logistic regression and Cox proportional hazards models.

**Results:** At six month follow-up exam, APVR showed a trend towards greater dependability [48 of 52 (92%) versus 48 of 59 (81%);  $\chi^2 = 2.84$ , p-value = 0.09]. Over the succeeding 10 years, abdominal repair proved 19% more durable than native tissue VPVR [46 of 52 (88.5%) versus 41 of 59 (69.5%); logrank test  $\chi^2 = 5.472$ , p-value = 0.02]. Functional outcomes were broadly equivalent, with excellent resolution of bulge discomfort (89% vs 82%), improved stress (83% vs 69%) and urge (63% vs 43%) incontinence rates and a 50% decrease in overall dyspareunia. Peri-operative complication rate was 5.4%.

**Conclusions:** (1) Kaplan-Meier curves reached an absolute plateau within 40 months, denoting that paravaginal repair by either route was reliably curative of cystocele. (2) The abdominal approach had a 19% relative advantage, reflecting the fact that APVR sutures are placed into stronger tissues and close the fascial defects with less suture-line tension. (3) Although traditional anterior colporrhaphy does not repair the actual sites of anatomic damage, plication repairs are sometimes durable, presumably through the formation of a non-specific scar plate beneath the vesical neck and bladder base. Quantifying the reparative value of 'site-specific' repair therefore requires correction for such non-specific scarring. Long-term efficacy of anterior colporrhaphy was estimated from the literature and from the observed outcomes of prior cystocele repairs in our study population. Even after correction, at least 35-54% of the long-term success from native tissue VPVR was clearly



attributable to 'site-specific' re-suture of the causative defects in the endopelvic fascia. (4) Whether a 69.5% success rate from native tissue VPVR truly justifies the additional surgical effort involved in paravaginal repair, instead of anterior colporrhaphy (as a palliative treatment) or mesh augmented PVR (as a more robust curative procedure) is perhaps debatable.

### **MRI identification of focal vaginal support defects. (83)**

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Accurate imaging of vaginal support structures by surface phased-array MRI is currently considered an unsurpassed diagnostic tool which has become an essential part of preoperative assessment in patients presenting with pelvic prolapse syndromes.

Despite considerable variation among centers, the procedure is quite easy to perform and relatively easy to interpret. With no need for vaginal, bladder or rectal distension in order to avoid distortion of basal image anatomy, the examination includes the systematic combination of axial, coronal and sagittal T2-weighted high-resolution sequences. In particular, axial images are essential depicting each level of vaginal support structures. According to De Lancey, the term vaginal wall include the vaginal mucosa, submucosa and muscularis while the term endopelvic fascia is used to denote those tissues between the vaginal muscularis and adjacent organs or the pelvic walls.

In the axial plane, evaluation is focused on (1) the cervico-vaginal junction (level I); (2) bladder base (level II); and (3) proximal and middle urethra (level III).

At level I, the uterine cervix is visualized together with a portion of the paracolpium and parametrium, the coccygeus muscle and sacrospinous ligament complex.

At level II, the relationship between the layered appearance of the vagina and its surrounding tissue is seen as follows: the hyperintense submucosa is visible surrounded by the lower intensity muscularis of the vaginal wall. Outside this layer, the pelvic vessels and endopelvic fascia attach the vagina to the inner surfaces of the iliococcygeal muscle. The shape and configuration of the vagina in this region is flat when the rectum is empty.

At level III, the vagina assumes a concave forward configuration as it wraps around the proximal urethra, while it shows a W-shaped contour in the region of the middle urethra where the posterior vaginal wall is fused laterally to the pubovisceral parts of the levator ani muscle (pubococcygeus muscle) and is attached on either side of the rectum resulting in a posterior sulcus. More distally, at the level of the perineal body, the vagina assumes a U-shaped contour.

Focal defects of the vagina support system seen on MR imaging include the following: (1) vaginal canal opening; (2) abnormal shape and orientation; (3) distortion/dislocation toward the affected side; and (4) detachment of lateral sulcus(i) from the endopelvic fascia. In addition, the presence of an increased uro-genital hiatus size and abnormal findings of levator ani muscle (i.e., attenuation, asymmetry, discontinuity, detachment, fat infiltration etc) should be noted.

Site specific characterization of anatomical defects occurring in the vaginal support system helps planning the optimal surgical repair in singular cases.

### **Transperineal rectocele repair with APOGEE: A case series. (84)**

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Rectocele is a herniation of the anterior rectal wall protruding into the posterior vagina. Although the true prevalence of rectocele is not known, it is a leading cause of obstructed defecation with a surprisingly high prevalence (76%) reported in female patients. However, rectocele remains a poorly defined and poorly treated disease entity. The controversy concerning the anatomic importance (or even the existence) of the rectovaginal septum and extension of Denonvilliers fascia, the lack of appreciation of coincidental pelvic floor disorders and the small number of patients operated on in specialist centers have largely precluded the accumulation of an evidence base for the best form of surgical treatment. Until the 1980s, most gynecologists treated rectocele with posterior colporrhaphy without specific attention toward bowel dysfunction. Although vaginal bulging was largely eliminated, this approach resulted in a high incidence of postoperative sexual dysfunction

(19–41 percent), with up to one-third of patients still experiencing evacuatory difficulty. This study was designed to evaluate the outcome of transperineal rectocele repair using polypropylene mesh APOGEE.

**Patients and Methods:** One hundred consecutive females with predominant, symptomatic Stage II or Stage III rectocele underwent transperineal rectocele repair using APOGEE mesh and finished their one year follow-up. No additional interventions, including levatoroplasty or perineorrhaphy, were performed. The preoperative and postoperative symptom scores and stages of the posterior vaginal wall prolapse were recorded. The end points were reassessed at one year postoperatively.

**Results:** Preoperatively, 29 patients had Stage II and 71 patients had Stage III rectocele. The mean total symptom Score was 9.87 T 1.93, which was reduced to 1.62 T 0.59. Postoperatively (P < 0.0001) objective evaluation of anatomic repair revealed that 74 patients (89.2 percent) had anatomic cure. Surgical complications were seen in a total of seven patients (8.4 percent), including hemorrhage (3.6 percent) and wound infection (4.8 percent). Mesh erosion, mesh infection, or worsening of sexual function was not noted.

**Conclusions:** Transperineal repair of rectocele with APOGEE mesh is an efficient therapy for patients with rectocele. It is highly successful in eliminating symptoms of obstructed defecation, and it is free of significant complications.

### **Uterine preservation after Apogee and Perigee. (85)**

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Hysterectomy is the most frequently performed gynaecological operation after the cesarean section and urogenital prolapse is the most common reason for a hysterectomy. Unfortunately it is incorrect to think that the removal of a prolapsed uterus is the solution, and it's an incorrect belief that by removing a uterus one can arrive more easily to the fascial and ligamentous structures of the pelvic floor. It's rather obvious that a prolapsed uterus isn't the cause of a prolapse but the consequence. The uterus and its complex anchorage structures to the pelvic floor is a central fulcrum of the vaginal arc. The removal of this important element could lead to major changes in the forces that work in the pelvic floor and around the vagina. As a result you can have a high risk of vaginal wall prolapse. At this point must be considered that a hysterectomy can lead to diverse complications such as hemorrhage, bladder and ureteric injuries, urinary dysfunction, defecatory dysfunction and sexual dysfunction. In fact hysterectomy has a morbidity of about 7%. For all these various reasons it is desirable to utilize surgical techniques that promote urogenital prolapse correction without removing the uterus. However, all the surgical fascial reconstruction techniques haven't rendered positive results. It's for that reason that uterus is commonly removed. In the last 4 years, since new surgical prosthetic kits for prolapse reconstruction were put on the market, new interest has grown in uterine conservation. In this report we will present our experience in this type of surgical prosthetic conservation using the Perigee-Apogee device. This observational study follows 46 women who were operated on from 2005 to 2007 with an average follow-up period of 17 months. Presently the result of our clinical performance using prosthetic surgery for uterine preservation with this, and similar, devices aren't so promising. Infact there is very little difference between our findings and those of fascial reconstruction. After 17 months of observation we have noticed more than 30% relapse of central segment and 19% relapse of the anterior segment.

### **Complications of prostheses. (86)**

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We describe a simple description of complications related to synthetic implants used in the treatment of stress incontinence or prolapse by the vaginal route. We describe their symptoms and propose a strategy for prevention and treatment of these complications. We will describe successively:

Type 1: defect of vaginal healing (1A : exposure of vaginal implant, 1B : abnormal healing : polyps, synechiae)

Type 2: infection of the implant (2A : persistent vaginal exposition with apparent local infection, 2B : infection along the implant, 2C : skin erosion near issue of the prosthesis, contiguous infection and fistulae along the supportive implant, 2D : contact abscess, 2E : distant abscess, 2F : fistulae, 2G : acute infection: pelvic cellulitis).



Type 3: contraction of implant (*Grade 1*: palpation of supportive implant is painless, retraction moderate and asymptomatic, arm or body of the prosthesis is palpable but not thickened, *Grade 2*: retraction is moderate (less than about 30%) and/or without many symptoms, palpation may be sensitive, prosthesis globally moderately thickened without nodulae, *Grade 3*: important contraction (more than 50%) and/or painful palpation with localized thickening of the implant, 3A - important contraction, moderate symptomatology, 3B - important and symptomatic contraction, *Grade 4*: simple contact of implant is painful ++ even if contraction is not always palpable).

Type 4: erosions due to implant erosions: a) of vaginal fornix, b) urethral erosion, c) bladder, d) rectum, e) other distant).

This classification can only be temporary but distinguishes different types of complications too often mixed up in publications.

## AAVIS KEYNOTE SPEAKER: DR J. BECO

### How can we win the war against pudendal neuropathy? (87)

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**Background:** Pudendal neuropathy is one of the seven main defects encountered in Perineology. This defect can induce perineodynia but also gynaecological, urological and colo-proctologic symptoms. Despite growing evidence of its importance this diagnosis is still rarely made and effective treatments available more rarely used. The aim of this lecture is to improve the management of those patients who suffer from this quite frequent and very aggressive illness.

**Methods:** To win a war it is necessary to perfectly understand who your enemy is, how it looks like, how you can differentiate it from your other enemies and what are its weaknesses.

Strategy is of uppermost importance. Wrong ways and false friends must be avoided. Because it is a new enemy, changing its look like a chameleon, we must be very open mind and modest to win this war.

**Results:** Urge and stress urinary incontinences, urgencies, frequency, painful bladder, dysuria, abacterial prostatitis, sexual arousal syndrome, proctalgia fugax, painful ejaculation, impotence, pain while sitting, vulvodynia, anal incontinence, dyspareunia, dyschesia... can be induced by pudendal neuropathy. Don't forget to think "pudendal"!

Clinical examination is the first and most important part of the diagnosis. Besides the classical examination of the perineum, it is necessary to search at least for the 3 clinical signs of pudendal neuropathy, for an abnormal perineal descent (using a Perineocaliper®), for other neuralgias and for pelvic floor muscle trigger points.

EMG with PNTML, warm and cold detection thresholds, Doppler of the pudendal arteries, MRI of the ischio-rectal fossae and of the lombo-sacral spine, can be helpful to confirm the diagnosis.

The main steps of the treatment are life style changes, painkillers, physiotherapy (with trigger point treatment), pudendal nerve blocks, surgical pudendal nerve decompression and neuromodulation.

**Conclusion:** In front of a functional perineal trouble, be open mind; don't forget to think "pudendal"!

## FISTULAS AND FLAPS

### Complicated urinary fistula. (88)

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Successful management for complicated urinary fistula starts with sufficient diagnosis of location of the fistula (Ureter, bladder, urethra, rectum or combinations), the underlying causes and accompanied conditions (e.g. post radiotherapy, tumor recurrence, previous surgery, coloproctologic disease) and evaluation of the tissues surrounding the fistula tract. Small vesicovaginal fistulas with sound elastic surrounding tissue usually can be closed transvaginally: excision of the fistula tract, closing the bladder by inverting sutures, suturing the pubocervical fascia and the vaginal wall by everting running suture with the aim to approximate broad healthy wound planes without tension. If the wound edges cannot

be sutured without tension or if tissue defects are present, tissue transfer is necessary. Bladder flaps, interposition of bowel, omentum majus or peritoneal flaps can be helpful. By vaginal route a Martius-flap with skin-island can be interposed. Concomitant lacerations of ureter or rectum possibly need ureter reimplantation or rectal surgery. De-epithelizing and closure of the vagina partially or totally can be an option in old, sexually non active women. Supravescical derivation (Conduit, pouch) are options, if fistula closure is not possible.

### Anorectal fistulas and biological prostheses. (89)

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**Purpose:** In 2006 the anal fistula plug technique was introduced in the treatment of transsphincteric anal fistulas. Since the results were encouraging, the technique was adapted to the treatment of rectovaginal fistulas.

The surgical technique and the preliminary results were presented.

**Methods:** 15 patients with rectovaginal fistulas were included prospectively for the repair with biological meshes. Feasibility, complications and reinterventions were assessed.

**Results:** 15 patients with rectovaginal fistulas were treated with a biological mesh in a special surgical technique. No intraoperative or postoperative complications were observed. At a mean follow up of 7,9 months, 12 of 15 patients healed, in 3 of 15 cases a recurrence was observed.

**Conclusions:** The repair of rectovaginal fistulas with biological meshes ist a new procedure with good first results.

The long term recurrence rate must be awaited.

### Imaging of fistula-in-ano. (90)

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A variety of imaging techniques have been used to evaluate fistula-in-ano and perianal sepsis over the years. Preoperative identification of all loculate purulent areas and definition of the anatomy of the primary fistulous tract, secondary extensions, and the internal opening plays an important role in adequate planning of the operative approach in order to prevent recurrence after surgical treatment, and to minimize iatrogenic damage of anal sphincters. Over the last two decades, endoanal ultrasonography (EAUS) and magnetic resonance imaging (MRI) have been demonstrated to be very helpful diagnostic tools in accurately assessing fistulas characteristics. When considering the comparison between EAUS and MRI it is worthwhile focussing on exactly what it is that sonography does well. It is well-established that ultrasound generally best images structures that are close to the transducer surface, and the higher the frequency of the transducer, the more this condition will apply. In particular, using modern 16 MHz transducers, EAUS is particularly well-suited to identification of the internal opening, because it usually lies right at the probe surface. Anal endosonography facilitates quick and easy diagnosis of intersphincteric fistulas and abscesses because of the high spatial resolution of the technique. Transsphincteric fistulas are revealed by tracks that cross the external sphincter to reach the ischioanal fossa. The further they are from the anal canal, the less-well extensions are visualised by EAUS. This is because the depth of penetration of the ultrasound beam is limited, especially at higher frequencies. Also, EAUS has great difficulty to determine if a collection is supra- or infra-levator because the levator plates lies in the same plane as the ultrasound beam. Moreover EAUS cannot reliably distinguish infection from fibrosis since both appear hypoechoic. This causes particular difficulties in patients with recurrent disease since infected tracts and fibrotic scars are frequently combined. Injection of hydrogen peroxide into the external opening may help to clarify the course of patent tracts. The advent of high-resolution three-dimensional EAUS (3D-EAUS), constructed from a synthesis of standard 2D cross-sectional images, promise to improve the accuracy in preoperative fistula classification. When examining anal fistulas, the operator can trace the pathway of a tract by reviewing the entire series of ultrasound images reconstructed along all planes desired.

The success of MRI for pre-operative classification of fistula-in-ano is a direct result of its sensitivity for tracks and abscesses combined with high anatomic precision and ability to image in surgically relevant planes. The major advantage of MRI over EAUS is the facility with which it can image extensions (transsphincteric,

suprasphincteric, and extrasphincteric). Complex extensions are especially common in patients with recurrent fistulas or those who have Crohn's disease.

In the author's opinion, if imaging has to be restricted to one test, then MRI is the clear favourite. However, EAUS and MRI may provide complimentary information and no harm comes from performing both. Anal endosonography does have some clear advantages although these are related to the fact that it is relatively cheap and simple to perform rather than its technical performance. It is rapid and well-tolerated by patients and, unlike MRI, can be performed easily in the outpatient clinic or even on the ward since the machines are easily portable. It should also be borne in mind that EAUS is vastly superior to digital examination in clinic and is therefore well worth performing, especially if MRI is unavailable or if there is no specific expertise in its interpretation. Also, a major role of EAUS in fistula disease is to assess the degree of sphincter disruption in those patients who become anally incontinent following surgery.

### **Fistula - Anatomy and pathological correlation. (91)**

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Anal fistula is a common and often poorly understood pathology. Simply, it involves an abnormal communication between the anal epithelium and the external skin, usually presenting as acute sepsis. The nature of the acute presentation and the subsequent fistula correlate closely, especially for cryptogenic fistula and should allow the clinician to determine the exact nature of the fistula along with the path of any associated tracks within the perianal and ischioanal tissues. This lecture will explain the nature of the sepsis and its anatomicopathologic presentation and how with a basic understanding of anopelvic anatomy how the nature of the subsequent fistula may be determined without the routine need for complex imaging such as MRI. The basis behind the pathoetiology and classification of fistula will also be covered including the importance of suprasphincteric and extrasphincteric fistulae.

## **CONTROVERSIES IN OBSTRUCTIVE DEFAECATION**

### **Introduction to the STARR Technique. (92)**

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**Background:** Obstructed Defecation Syndrome (ODS) is a widespread pathology, with a significant impact on quality of life. Preliminary comparative studies on cadavers show that rectocele and internal prolapse of the rectum are characterised by: an anatomical alteration, the distal dislocation of the rectum; by a structural alteration, the thinning of the tunica muscularis, a damage that can also be seen echographically in patients. Radiological studies of the empty rectum of patients with ODS show a redundancy and lengthening of the distal rectum. A special defecographic technique demonstrates that this redundancy or prolapsing rectum can, in the dynamic phase, dilate and form a rectocele, opening the rectal lumen, be expelled externally, freeing the rectal lumen, invaginate internally, occluding the lumen. Extensive damage to the muscle wall of the rectum causes incapacity to create an adequate endoluminal pressure needed for defecation. In this case patients increase straining which causes: descent of the Douglas pouch or the formation of entero-sigmoidoceles; hyperdescent of the perineum. These two phenomena allow: extrinsic pressure on the rectum aiming adequate endoluminal pressure; longitudinal lengthening of the rectum with the consequence of prolapse-reduction. In a first phase these morphological modifications are rapidly reduced at the end of straining, hence they may be considered paraphysiological modifications functional for defecation; they can then become persistent anatomical alterations which anatomically and functionally alter the pelvis. In some patients with redundancy of the rectum, all the compensative mechanisms described above are insufficient to reduce the prolapse and to allow defecation; a rectoanal invagination occludes the lumen and faeces are stored in the rectal lumen and rectocele. Defecation then only can occur by external support: laxatives, enemas, digitations. The conclusion of the preliminary studies was that rectal redundancy or prolapsing rectum is an anatomical alteration, whose pathogenesis is uncertain, which can cause mechanical obstruction to defecation and indirectly determine other pelvic alterations.

**Rational Basis:** In 1996 Longo conceived that surgical resection of the prolapsed part of the rectum could constitute an efficacious treatment in case of mechanical obstructed defecation. The hypothesis was that the removal of the prolapsing rectum would prevent the formation of invagination, rectocele and external prolapse (if less than 3 cm) which are the causes of obstructed defecation. Furthermore, the ceasing of straining would be accompanied by the disappearance of all dynamic, morphological alterations (enterocele, deep Douglas, hyperdescending perineum) consequences of excessive straining.

**Technique:** In 1998 Longo standardized the technique of distal resection of the rectum via a transanal approach using two PPH01. Through this technique called STARR (Stapled Transanal Rectal Resection) a circumferential resection of the rectum is obtained in two steps: resection of the anterior rectal wall, which is pulled inside the stapler through 2-3 semi-circular sutures, protecting the posterior wall with a spatula; resection of the posterior wall by the same method.

**Materials and Methods:** From 1999 to 2002, out of 2872 patients with symptoms of ODS, 339 patients were selected and underwent STARR. In a specific ODS scoring system (0-40) all these patients scored  $\geq 7$  and in all cases ODS was caused by invagination and rectocele. 203 female patients were included in a trial with a mean follow-up of 36.7 months (sd 15.3, range 6-77)

**Results:** The mean height of the anterior specimen measured 6.6 cm (range 3-13), of the posterior one 5.9 cm (range 3-12). Mean postoperative pain on day of surgery was 1.2 VAS (range 0-6) decreasing during the following days. The ODS score dropped from a mean of 18.7 preoperatively to 1.2 at 6 months ( $P < 0.0001$ ). At 6 months 94.1% scored  $\leq 6$  and 61.1% scored 0. The comparative defecographic parameters showed that rectoceles were reduced from a mean of 5.5 cm to a mean of 1.2 cm, intussusception from a mean of 3.2 cm to a mean of 0.3 cm, anatomical position of hyperdescended perineum at rest from a mean of 7.3 cm to a mean of 5.8 cm, hyperdescent during straining from a mean of 5.5 cm to a mean of 3.5 cm. The descent of the Douglas pouch or enteroceles was reduced from a mean of 6.4 cm to a mean of 3.6 cm. The technique also proved to be efficacious in the improvement of preoperative associated active fecal incontinence. The mean Wexner incontinence score (0-20) dropped from 10.7 to 3.1 at 6 months. In cases of associated hemorrhoidal prolapse it was simultaneously corrected by the procedure. No major postoperative complications were noted. The most frequent complications were: temporary defecatory urgency (20.7%), bleeding (3.4%).

**Conclusion:** STARR proved to be a safe and efficacious technique. The results confirmed the initial hypothesis that the prolapsing rectum can be the cause of obstructed defecation and can induce notable anatomical and functional alterations of the pelvis. A unitary perspective is necessary regarding all rectal pathologies characterised by prolapse.

### **Current application of perineal sonography in obstructed defecation. (93)**

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Despite the substantial "learning curve" existing with pelvic floor sonography (PFS), thank to the increasingly demand by both gastroenterologists and coloproctologists, the technique is more and more frequently performed as the first imaging step in the diagnostic workup of pelvic floor dysfunctions.

While the examination procedure and image interpretation should rely on well established criteria only, PFS clinical applications are still in a developing state. More particularly, in order to include rectal voiding with PFS, a special technique has been developed by us providing details of the anorectal anatomy during evacuation of a semisolid barium sulphate suspension. Characteristically, this substance appears homogeneously anechoic at sonography, thus enhancing visualization of inner anorectal layers. For the emptying phase, patients are scanned in the squatting position, with a pad positioned on the floor of the diagnostic room while the sonographer sits in front of them.

Major drawbacks with this technique are (1) gender limitation (female only); (2) difficulty in keeping the probe fixed in place during emptying; and (3) potential risk for wrong measurements. On the other hand, clear advantages over conventional (X-ray) defecography include (1) no use of ionizing radiation; (2) evidence of soft tissue details suggestive of the lock-valve mechanism; and (3) cross-sectional measurement from the inner and outer margins of the internal anal sphincter. The latter feature has shown suffi-

cient discriminatory capacity to allow distinction between patients with and without obstructed defecation syndromes due to mucous prolapse, internal intussusception and anal sphincter dyssynergia.

### STARR Procedure: past, present, future. (94)

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It is now almost 10 years since Antonio Longo presented his paper on transanal stapling for haemorrhoidal prolapse to the World Congress of Endoscopic Surgery in Rome in 1998. In that time the understanding of the pathophysiology underlying haemorrhoidal prolapse and obstructed defecation syndrome has advanced.

The experience and patients follow-up observations with stapled prolapsectomy for treatment of haemorrhoidal prolapse led to the idea that resection of internal mucosal prolapse could improve rectal evacuation. Based on this idea, and accompanied with evidence gained from cadaveric studies, Antonio Longo proposed, in the late 2000, the full thickness resection of the lower rectum performed transanally with the stapling PPH01 device, to treat obstructed defecation syndrome (ODS) in patients with rectocele and rectal intussusception, the procedure was named STARR: Stapled TransAnal Rectal Resection.

The aim of the STARR procedure was to produce a full thickness rectal resection, and it was distinguished from previous operations for rectal prolapse, such as Alteimer's procedure, by virtue of the fact that external dissection of the rectum was not required, but rather STARR was performed solely by a transanal approach.

Experience with the STARR technique, as proposed by Antonio Longo has proved it to be highly beneficial in the treatment of obstructed defecation symptoms in patients with intussusception and rectocele. But the original technique was performed with the PPH01 stapler, which was not designed for this purpose.

One of the criticisms of the STARR performed with 2 PPH01 staplers was that the resection could not be performed equally around the circumference of the rectal wall due to the fact that 2 separate anterior and posterior stapler firings were required.

Although the functional results achieved with the PPH01 STARR were good, there was room for improvement in the stapler to give the surgeon a degree of flexibility to improve the anatomical correction necessary for best functional outcome. For this reason a new stapler was devised specifically for use in STARR: a curved cutting stapler which looked like a Contour40 stapler but with a 30mm staple line. Ethicon Endo-Surgery (Cincinnati, OH, USA) has marketed this device under the name of Contour Transtar (STR5G). With the Contour Transtar the surgeon is afforded greater control over the operation in terms of the extent of prolapse to be resected, which can be tailored to the individual patient. The resection can be performed under direct vision and a uniform full-thickness circumferential resection achieved without the lateral "dog-ears" seen after double-stapled PPH resection. If required, a greater volume of tissue can be resected ensuring complete removal of a large prolapse.

Initial experiences with the Contour Transtar suggest that it is as safe and effective as the double-stapled PPH01 technique. Currently, therefore exist two staplers and two techniques for performing STARR. Whether the Contour Transtar will eventually replace the double-stapled PPH01 technique completely is a field of actual study. The two techniques are not necessarily interchangeable and it may be that each technique has its own indications within the context of anorectal prolapse. For the immediate future the colorectologist will continue to have both staplers (PPH01 and Contour Transtar) and both techniques at his disposal. Results of running trials and studies will clarify the appropriate indication for the device to be used to perform STARR. Anyhow the STARR journey is not ended yet and something new might be seen in the future.

### Outcomes of the STARR procedure. (95)

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STARR technique is a procedure designed to resect internal rectal prolapse / rectocele by means of staplers inserted into the anal canal with the objective of restoring a more normal anatomy and then allowing for a better anorectal function in patients presenting with obstructed defecation syndrome (ODS). In this presentation, we will discuss the risks of STARR procedure, the reported type and rate of complications occurring after STARR and the recommended guidelines to avoid/limit them.

*Personal experience:* Our experience with the STARR procedure consists of more than 70 procedures over a period of 5 years. This procedure has been initially performed with 2 PPH 01® staplers and now by using the contour trans-STARR® stapler, after specific training and proctorship, allowing us to gain experience and to start teaching the new procedure.

From July 2002 to September 2005, we operated on 65 female patients [mean age ± standard deviation (SD) 59±9] complaining of ODS in whom rectocele and rectal procidentia were identified, including our initial experience. Mean procedure duration, done under GA in 90% of cases, was 30±15 min. No intraoperative complications were observed. Postoperative complications (except urinary tract infection) occurred in three patients: bleeding (two cases - one reoperated on, no blood transfusion), and rectal stenosis (one - treated by digital dilation). Pain and discomfort were evaluated as limited and easy to control. Mean hospital stay was 3.5±1 days. Long term complications (mean FU: 19 months) occurred in six that had to be reoperated: two under LA on for pile excision (one) and staple-line granuloma (one), and three under GA for enterocele (two laparoscopic mesh suspension and one vaginal suspension through perineal approach). Another patient was diagnosed with an enterocele, but surgical treatment was deferred.

In a recently published multicentre trial that we conducted, including 59 patients operated on by STARR, No intraoperative complication was reported except one patient with evacuation of blood and stool at the end of procedure with no consequences in the post-operative period. Mean (± SD) hospital stay was 2.1±1 days. Adverse events were experienced by 8 (51%) patients, usually minor including local infection (stiches fixing the anoscope), anal pain, transient incontinence, bleeding, urinary infection or depression. Two patients experienced a serious adverse event, one of which, 12 hour post-operative bleeding, was managed under GA with additional sutures at the site of hemorrhage. The second event, pain in the right upper abdominal quadrant several weeks after surgery, was considered serious because it required hospital care, but was not considered to be related to the study device or study procedure.

*Overview of the literature:* Over the last 5-7 years, many European centres have included the STARR procedure as a treatment option for ODS. As members of the international working party (June 2005), we participated in developing a consensus on the application of STARR to the treatment of certain rectal conditions, including internal rectal prolapse.

Some concerns about safety of the procedure have been expressed at the beginning of the experience with reports of severe adverse events, including pain, bleeding, rectovaginal fistula, necrotizing pelvic fasciitis, prostatitis and pelvic abscess. In a retrospective Italian cooperative study, the authors reported a group of 38 patients referred to their centres for complications of STARR done elsewhere: 14 of these underwent reoperation and one died of extensive pelvic sepsis. However it is now apparent that if performed accordingly to the described standards, STARR is a safe procedure. In a multicentre study published in 2004 on 90 patients, there was no mortality, no sepsis, 4.4% bleeding and 3.3 % rectal stenosis treated by digital dilation. Hospital stay was 2.1±1 days and a 10±4 day sick leave. In a smaller unicentre series from Spain, a similar morbidity rate was observed, with one postoperative bleeding and one stenosis over 37 operated patients. That paper mentioned better results in terms of intraoperative bleeding and staple-line granulomas following the use of a PPH 03® device normally devoted to stapled anopexy, as the size of the staples is shorter than in the PPH 01® stapler. However, we consider it risky to use for STARR as a full-thickness rectal resection is performed. Other reports accordingly showed limited risks following STARR. Reports with trans-STARR technique safety are also coming and our initial feeling is favourable.

*Conclusion:* After more than 5 years of experience with STARR, we consider it to be an innovative, technically safe and minimally invasive procedure useful in carefully selected and well-informed patients. Collection of data, best done in a registry, is critical to the process of evaluating the safety and efficacy of the STARR procedure. We will enter a new era with the contour trans-STARR® device, but if the tool changes, the concept is still similar, and the knowledge accumulated with the PPH01® procedure is not wasted and remains useful, especially when long-term outcome is concerned. Guidelines for a safe performance of STARR procedure are as follows: STARR is a safe procedure if done by a surgeon having experience with staplers and properly trained for the STARR/Trans-STARR procedure. An easily reproducible technique, the learning

curve is estimated to be 3/5 procedures for a trained colorectal surgeon. Key point for success certainly based on appropriate patient selection. Intra- or postoperative complications, although possible, are limited and, in our experience, never severe. Functional long term results are still pending in controlled series.

### Functional consequences of STARR. (96)

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**Introduction:** Since 2004, after the introduction of a new surgical technique for the treatment of obstructed defecation – the stapled transanal rectal resection (STARR) – a few reports of an extremely high rate of functional improvement (90 % of cases) lead to a quick and wide adoption of this procedure. The increasing number of patients has brought to notice a growing number of complications and procedure failures, with persistence of symptoms and poor patient satisfaction. It is now mandatory to analyze these controversial results to identify what is the real efficacy, the potential dangers of this treatment and what are the preoperative factors predicting a poor outcome.

**Functional consequences:** Beside the correction of the abnormal anatomy of the anorectum, the STARR procedure may lead to a other functional consequences: a transient decrease of the anal resting pressure due to the instrumental anal stretching usually recovered within 3 postoperative weeks. A long term increase of the anal resting pressure due to the interruption of the inhibitory rectoanal reflex that is continuously triggered by the intussusception; the reduction of the maximum tolerable volume and of the rectal compliance as result of the reduced capacity of the rectum.

**Functional results:** A recent retrospective analysis conducted within the Italian Society of Colo-Rectal Surgery described a group of 85 female patients treated with STARR for obstructed defecation not responding to conservative therapies. Of these patients 73% had rectocele and intussusception, 20% had intussusception alone and 7% rectocele alone. Preoperative symptoms of obstructed defecation (straining, self digitation, sense of incomplete evacuation, use of laxatives) were all significantly improved. Overall, 89% of patients had three or more symptoms preoperatively and 52% postoperatively. Subject improvement was noted in 65% of patients. 18% of patients suffered preoperatively from incontinence and this symptom was resolved in 53% of them. New onset of incontinence developed in 6% of patients. The recurrence rate was 29% for rectocele and 28% for intussusception. An univariate analysis of preoperative factors correlated with the postoperative symptoms' improvement and rectocele or intussusception recurrence showed that the worse results were in patients with the greatest functional component of their obstructed defecation (with the exception of the rectocele recurrence in patients with preoperative larger size rectocele, that probably overcomes the technical limits of the procedure). Puborectalis dyssynergia, need of digitation and lower bowel frequency lead to a lack of improvement. Other published data suggest that puborectalis dyssynergia may be contraindication to STARR although van Dam et al. gained opposite conclusions and the lower bowel frequency and preoperative digitation have been reported as negative prognostic factors by many authors. It has been suggested that in these patients the restored rectoanal anatomy after STARR could be recommended to give a better chance of good response to biofeedback rather than in presence of rectocele or intussusception, but it has also been shown how performing only rehabilitation procedures the 12% of patients with rectocele and the 33% of patients with intussusception obtained complete resolution of symptoms.

**Conclusions:** As shown by the described clinical data and as a consequence of the complex and poorly understood physiopathological paths underneath many cases of obstructed defecation the patients affected by severe pelvic floor and colon motility dysfunction may not take advantages of the STARR procedure because it does not affect the real causes of their symptoms but only their organic consequences. To date the results are worse than at the beginning of the STARR experience and more similar to the results of many other surgical procedures for obstructed defecation and exactly like them needs a careful selection of patients and a surgeon experienced in the evaluation of pelvic floor disorders.

### UK experience with STARR. (97)

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Obstructive Defecation is a common cause of constipation occurring in up to 20% of women. It is commonly underdiagnosed and is

more common in multiparous patients. Symptoms include excessive straining, laxative and enema dependency, incomplete evacuation, fragmented defecation as well as rectal pain and bleeding. Patients also often need to use perineal support or digitation in order to defecate. Examination of patients often reveals a degree of distal redundancy, which manifests itself as a combination of rectocele, internal rectal intussusception and muco-haemorrhoidal prolapse. In order to address these physical findings in symptomatic patients Longo developed the STARR procedure. It was introduced into the UK in 2003. At that time there had been no formal evaluation of the technique, limited data was available and was accompanied by reports of serious adverse events. NICE issued a statement in 2006 concerning its possible safety profile – resulting in a statement that the procedure should not be used without arrangements for consent, audit and research. Two strategies were adopted – a structured education and training programme and a UK STARR registry. The registry was set up under the auspices of the ACPGB&I to assess short-term safety and efficacy. Although 49 registered interest only 12 surgeons inputted data. Twelve month follow up data is available and 196 patients were enrolled, 97.6% female with a mean age of 53 years. The mean length of stay was 2 days with a mean operative time of 38 minutes. Symptom severity score improved from pre-op scores at 6 months and was maintained at 12 months ( $p < 0.01$ ) as did the ODS score. The most frequent complications were faecal urgency (27.8%), bleeding (12.1%) and incontinence (11.6%). There were no deaths. The same approach for training and proctorship of the Contour30 Transtar has been adopted in the UK. Surgeons must have a well defined pelvic floor interest before enrolling for training.

### STARR procedure for external rectal prolapse. (98)

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**Purpose:** A perineal approach to treating rectal prolapse is ideal for frail patients. Recently, internal rectal redundancy has been successfully treated with transanal resection using the Contour® Transtar™ stapler. This technique has been modified to the perineal stapled prolapse resection. The surgical technique and the preliminary results of the new procedure for external rectal prolapse are presented.

**Methods:** Patients not suited for perineal prolapse resection were included prospectively for perineal stapled prolapse resection. Feasibility, complications, and reinterventions were assessed.

**Results:** In 17 of 18 patients, perineal stapled prolapse resection was performed without complications in a median operating time of 33 (range, 22-52) minutes. One procedure was changed to an Altemeier because of a staple line disruption. Two patients required reintervention as a result of postoperative haemorrhage. No other severe complications occurred. At follow-up, all patients were well and showed no early recurrence of prolapse.

**Conclusions:** Perineal stapled prolapse resection is a new surgical procedure for external rectal prolapse, which is easy and quick to perform. Functional results and longterm recurrence rate must be investigated further.

### A gynaecologist's view of obstructive defaecation. (99)

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Rectoceles are common findings in patients with intractable evacuatory disorders. Typical symptoms are difficulties to evacuate, incomplete evacuation, assisted digitation to aid defaecation, faecal incontinence, constipation, impression of a pelvic mass, pelvic pain and dyspareunia. Occult rectal prolapse has been found in 33% of patients with rectoceles and defaecatory dysfunction. Endorectal, transvaginal, transperineal, abdominal or combined approaches are treatment options discussed for symptomatic rectoceles. In the normal pelvis the sacrouterine ligament functions as the most important supporting structure for the uterus, vaginal apex and via the rectovaginal fascia, also for the posterior vaginal wall and rectum. The rectovaginal fascia (RVF) attaches to the perineal body (PB) below and levator plate (LP) above. The levator plate is attached to the posterior wall of the rectum. Contraction of the levator plate (LP) stretches both walls of the rectum during anorectal closure and defecation. In cases with disrupted rectovaginal fascia, a rectocele may form. Due to distended sacrouterine ligaments, the rectum can no longer be kept in its normal position, and consequently proximal rectal parts may bulge into the distal rectum causing intussusception (syn: internal rectal prolapse). According to the Integral Theory, dysfunctions of anorectal opening (evacua-

tion disorders) and closure (faecal incontinence) are mainly caused by connective tissue damage in the vagina or its suspensory ligaments. The explanations offered above expand these concepts to the pathogenesis of rectal intussusception. Based on this pathogenetic concept we hypothesised that the restoration of the sacrouterine – rectovaginal anatomy could cure rectal intussusception and obstructive defecation. The infracoccygeal sacropexy (“posterior IVS”) procedure belongs to the family of “tension free tape” operations. An implanted polypropylene tape (Tyco Healthcare), reinforces the uterosacral ligaments by irritating the tissues to create a linear deposition of collagen. It aims to restore the normal vaginal axis and the rectovaginal fascia anatomically correctly, thereby reestablishing normal function. In a recently published study we could prove the validity of this concept. The study will be presented and practical implications of the study results will be discussed.

**Conclusion:** Connective tissue damage to the anterior rectal wall supports may cause it to sag inwards, “intussusception”. The posterior sling creates a foreign body reaction which restores the damaged ligament and “reglues” its fascial attachments to levator plate and cervical ring to suspend and stretch the rectal wall. This concept offers a minimal invasive treatment option for patients with obstructive defecation.

*References available from the author on request.*

### **A new technique of surgical treatment for descending perineum, rectal and vaginal proci-dentia. (100)**

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The nature of descending perineum is complex, associated with different pelvic floor pathologies such as rectal or vaginal proci-dentia. Therefore the surgical repair must compromise all of these abnormal conditions.

**Background.** Presentation of the results of surgical treatment for complex pelvic pathologies using a prosthetic material.

**Material and methods.** A mesh was used to repair the recto-vegi-nal septum, suspend descending pelvic floor as well as to fixate the rectum and vagina to the sacral periosteum. A firm pelvic floor sus-pension was achieved by suturing the lower pole of a case-tailored mesh to the perineal body and to the levator muscles. This type of prosthetic material implantation was performed by abdomino-transvaginal approach. Five patients were operated on from april 2006 to october 2007. Age ranged from 47 to 70 years (mean: 57 years). In four of them a polypropylene mesh was used, in one a collagen tissue (Pelvicol, Tissue Science Laboratories plc).

**Results.** In all patients the vaginal wounds healed very well. Tolerance of prosthetic non resorbable material and collagen mesh was good. No outlet obstruction was observed. The symptoms of descending pelvic floor as well as vaginal or rectal proci-dentia receded.

**Conclusions.** Abdomino-transvaginal implantation of prosthetic material to the perineal body, repair of the recto-vaginal septum with colpo and rectopexy may be effective in the treatment of proci-dentia of pelvic organs and structures.

### **IPFDS KEYNOTE SPEAKER PROFESSOR ECKHARD PETRI**

#### **Experience with more than 400 surgical repairs after alloplastic slings and meshes. (101)**

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Surgery for stress incontinence in the 1980's witnessed prosthe-ses such as the silastic slings and artificial urinary sphincter. In the late 1990's, there was the clinical introduction of the suburethral synthetic slings for urodynamic stress incontinence (USI) using mesh, the tension-free vaginal tape (prolene mesh). The trocars, which have the potential for causing prosthesis or graft insertion complications, were combined with a variety of different prosthetic materials. In prolapse surgery anatomical perfection may be quite different from functional acceptability for the patient. “Kits” have been introduced for all types of prolapse repairs, again involving the use of different materials with different fixation devices or tro-cars. The use of prostheses or grafts has progressed questionably in some areas from an indication for recurrent prolapse to that of using them in primary procedures. Prostheses or grafts potentially add to

the complication profile the aspects of trauma of insertion; reaction of the body to the prosthesis in terms of inflammation, infection and/or rejection; the stability of the prosthesis over time. During the last years an increasing number of patients with complications after insertion of alloplastic materials have been referred to our unit, some being treated conservatively, > 400 so far needing surgi-cal intervention. Having no information on absolute sales figures of different products and the operative spectrum in different hospitals we cannot give correlations and incidences, but, describe character of complication and the possible reason for the problem. 46% of the slings were inserted in a technically wrong way, either not “ten-sion-free” or at a wrong anatomical place or both. Apparently the traditional bladder neck sling with tension for better results (and the calculated risk of obstruction) still is in mind when placing an alloplastic sling. It is our impression that many surgeons lack an adequate knowledge of urogynecological pathomechanisms, not knowing, how short an “incontinent” urethra might be. Another 44% of problems were caused by a wrong indication. OAB as pre-dominant symptom, mainly a complete paravaginal defect in our view a no indication for an isolated distal sling. Kinking at the site of the sling, secondary OAB, residual, dysuria, incontinence during intercourse are typical symptoms. We believe that this anatomical entity rather needs a colposuspension than a distal sling. The loss of knowledge of pelvic floor anatomy and a loss of surgical skills in reconstructing pelvic floor defects should not be an indication for insertion of large meshes. Of course, there might be limitations of the anatomical structures left after several deliveries, multiple unsuccessful previous reconstructions, but, there is no indication for the use of alloplastic meshes in primary cases, especially in very young women – this is an ethical and medico-legal aspect with concerns as to an adequate informed consent without any reliable data. Should a mid- and long-term review in terms of complica-tions be sufficiently adverse, the procedure and/or the prosthesis or grafts for prolapse surgery should be abandoned. A decisive factor apparently is training. It has been shown, that a minimum of 40 procedures performed annually reduces complications rates to an acceptable range. “Occasional” surgeons should refrain from the use of alloplastic slings and meshes.

#### **Is the dietary intake of gum arabic a useful step in diagnostic and therapeutic program for obstructive defecation syndrome? (102)**

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**Aim:** Obstructed defecation syndrome (ODS) is a subset of con-stipation due to different abnormalities in defecation mechanisms: rectocele, intussusception, mucosal prolapse, anismus, descending perineum. Often these anatomical and functional conditions coexist and psychological disturbance may also be present. The complexity of ODS physiopathology makes difficult the choice of the treat-ment due to the unpredictable results. This study aims to evaluate the efficacy of gum arabic (FD Liquid system ®) in the treatment of ODS. The preliminary results are presented.

**Methods:** In 15 patients with ODS observed in the Outpatient Clinic, constipation was quantified with CCS and ODS scores (*Altomare DF et al. Set-up and statistical validation of a new scor-ing system for ODS. Colorectal Dis 2007*) including time spent in toilet, unfruitful attempts, digitations/enema, use of laxatives, incomplete defecation, straining. Scores were calculated at time of enrolment after 3 weeks of wash-out when the patients avoided assistance and at 9 weeks after the end of treatment. During daily intake of gum arabic (11.7 grams) no other assistance for constipa-tion was allowed. A diary was filled to calculate the scores: before enrolment, at the end of wash-out, at the end of the treatment and after 9 weeks.

**Results:** From November 2006 to February 2008, 15 women (average 60.2±10.5 years old) were enrolled. All the patients com-pleted the study, 8 had a rectocele, 2 intussusception, 5 mucosal prolapse, none had anismus. An improvement in the scores was observed with a significant reduction ( $p<0.05$ ) of the ODS items. Dietary fibres intake didn't significantly modified the number of defecations per week. Improvement in CCS and ODS scores persisted 9 weeks after stopping the treatment. The gum arabic improved the QoL of the patients.

**Conclusions:** Gum arabic is a valid first step medical treatment for ODS and it should be recommended before planning any inva-sive approach to this condition. Its efficacy seems to be due to a prebiotic action.

## FUTURE INNOVATIONS IN PELVIC SURGERY

### Adjustable sling for incontinence. (103)

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*Hypothesis/aims of study:* There is a delicate balance, after tension-free tape implant, between incontinence, continence and obstruction as it is difficult to calculate the correct degree of tension to be applied during surgery. When the tape is too tight, urinary obstruction is produced. On the other hand, when the tape is too loose incontinence persists.

To test a new mesh for treatment of female stress incontinence which permits to readjust postoperatively the tension applied to the tape is our objective.

*Study design, materials and methods:* Within-subject study initiated in January 2005. TOA (AMI) is a macroporous polypropylene monofilament non-elastic tape with two groups of polypropylene threads permitting postoperative readjustment of tension that are removed when continence without obstruction is achieved. Seventy-seven incontinent women (29.9% stress incontinence, 70.1% mixed incontinence) received TOA tape in our Department. The local ethics committee approved the study.

Patients were monitored 1, 6 and 12 months post-surgery and annually thereafter by medical history, cough test, flowmetry, PVR, I-QoL, ICIQ-SF and PGI-I questionnaires. Objective cure for stress incontinence was defined as no leakage on cough test. Subjective cure was defined as answering "never" to the ICIQ question: How often do you leak urine?. It has also been analyzed whether subjective failure was due to stress, urge, or mixed incontinence (item 6, ICIQ-SF).

*Results:* Fifty-one (66%) were continent in the immediate post-surgical evaluation. Twenty-six (34%) were incontinent. Eight of the 51 continent patients were obstructed (Qmax. inferior to 10 ml/s and/or more than 50 ml residue). After adjustment, all patients rendered continent, none had PVR and mean Qmax was 16.7±5.7 ml/s. On no occasion was vesical catheterization necessary. Mean follow-up was 14.8±8.5 months. Objective cure rate was 89.6%, with 7.8% greatly improved. Subjective cure rate: 54.7 % of patients never leak urine. The subjective failure depended on the existence of urgency incontinence 25 patients (32%), mixed incontinence 4 patients (5%) and pure stress incontinence 5 patients (6%). Qmax was 21.3±7.2 ml/s. The QoL questionnaire improved from 31.4±20.3 to 85±17.2 points and the PGI-I showed 90.7% of patients to be better or very much better than before. There were no cases of bowel, nerve or major vessel injury. No infection, vaginal or urethral erosions were identified.

*Interpretation of results:* This is the first time that an adjustable regular mesh has been described that allows post-operative adjustment of the tension applied during surgery enabling us to correct any persisting stress incontinence and to avoid obstruction. Our data suggest that with TOA tape better results can be obtained than those with the traditional non-adjustable mesh, furthermore without increasing surgical complications.

### The future of prostheses in prolapse surgery. (104)

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The future of mesh has to deal with two questions ; firstly the quality of the mesh and secondly the way we use it implantation and size and suspension. There is no question that for the implantation of the mesh we can argue about the size and design of the mesh, and we can find ways to improve the technique of implantation, vaginally, laparoscopically or perhaps injectables. The quality of the mesh is a more difficult topic. We describe the reasons to think that we should improve the mesh regarding contraction of meshes with the actual materials, degradation of the PP mesh with time and the mechanical properties of the mesh that are far away from the normal tissues that they have to replace. For each of these questions we can propose solutions for the future of synthetic meshes.

### Rectal mucosal descent – the tip of the iceberg. (105)

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Rectal mucosal descent is a condition frequently associated with rectocele. The treatment of the condition closely resembles the

treatment for haemorrhoids. This lecture explores the association between mucosal prolapse and other pelvic floor abnormalities. How should the condition be investigated and managed? The similarity between mucosal prolapse and haemorrhoids is also considered along with the various treatment modalities available to the surgeon.

### Cadaveric fascia. Is it the answer? (106)

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In recent years prolapse surgery using prostheses has become very popular even though few data are available. While monofilament macroporous polypropylene meshes were initially thought to be the best option, problems with potential complications led to increased use of biological tissues. Initial data showed fewer complications with biological mesh but the long term efficacy of biological mesh is unknown. While allotransplant of non irradiated cryoconserved human pericardium is under valuation our attention and research is moving to tissue engineering. In 1998 FDA approved reimplantation of skin-like tissue after proliferation on scaffold in vitro. Naturally the more complex an organ is to build in vitro the more difficult is the proliferation of tissue. In reconstructive vaginal surgery an autologous connective tissue will soon will be available. We want to explore this opportunity.

### Posterior pelvic floor sling: a minimally-invasive procedure for treatment of fecal incontinence. (107)

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*Background:* Fecal incontinence (FI) is a significant medical problem as well as a socially debilitating issue. The posterior pelvic floor sling is a minimally invasive procedure that places a synthetic sling behind the anorectum to provide posterior support, in a manner similar to the natural support provided by the puborectalis muscle. This is a retrospective analysis designed to assess the efficacy of the posterior pelvic floor sling for the treatment of Fecal Incontinence.

*Methods:* 15 patients with refractory FI underwent the procedure between January 2006 and September 2007. Patients were asked to fill out intake questionnaires, bowel diaries and Fecal Incontinence Quality of Life Questionnaires (FIQOL) pre-operatively and post-operatively. The posterior pelvic floor sling procedure was performed using a transobturator approach. First, 2 buttock incisions are made 2 cm lateral and 3 cm posterior to the anus and a tunnel is created between the incisions. The sling is then placed so that the wider belly lies in the tunnel under the anorectum. A curved introducer needle is then placed through a medial thigh stab incision, through the obturator foramen, and was directed posteriorly into the ischiorectal fossa. The arms of the sling are brought up through the medial thigh incisions and sling adjustment is performed before removing the plastic sheaths.

*Results:* At 6 weeks post-operatively, the average number of incontinence episodes and incontinent days decreased after surgery overall. 2 patients reported complete continence. One postoperative complication, a wound infection with separation of the post-anal incision and mesh exposure, resulted in sling removal. FIQOL data indicated an improvement in symptoms for all four categories addressed

*Conclusion:* This preliminary retrospective study suggests that the post-anal sling provides an effective, minimally-invasive option for patients with refractory FI.

### Ethical issues relating informed consent for surgery on the pelvic floor. (108)

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At the best of times informed consent can be challenging. With the "explosion" of new procedures in the management of pelvic floor dysfunction problems in this area are multiplied. This presentation deals with the ethical issues surrounding informed consent. It will be argued that informed consent is necessary out of respect for a patient's autonomy. However legal, financial, surgical skill, and the industry are a few of the compounding influences often making ethical decisions more difficult in a volatile environment.

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