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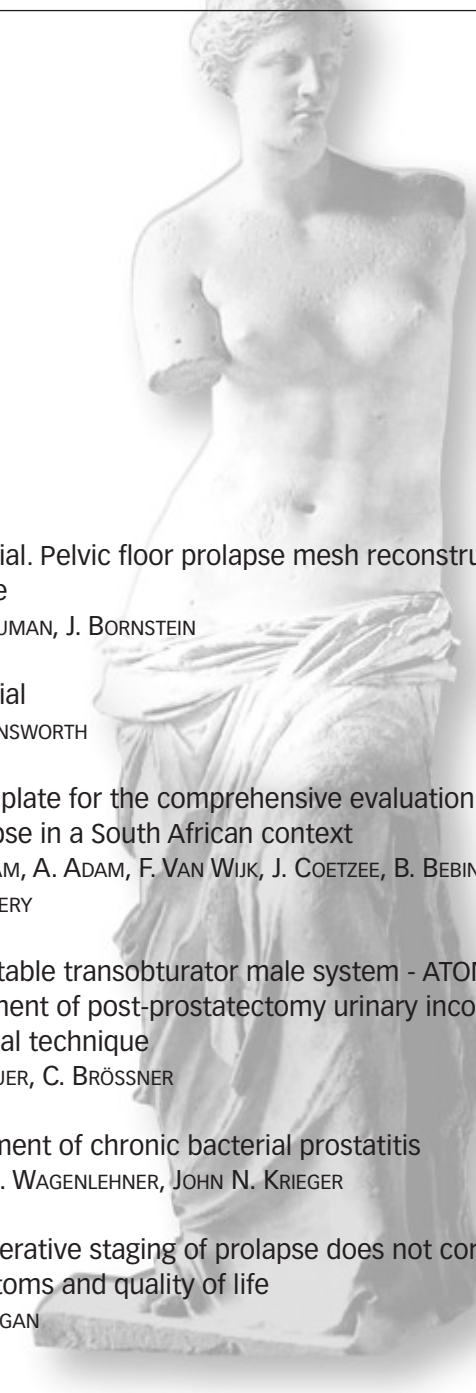
PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal



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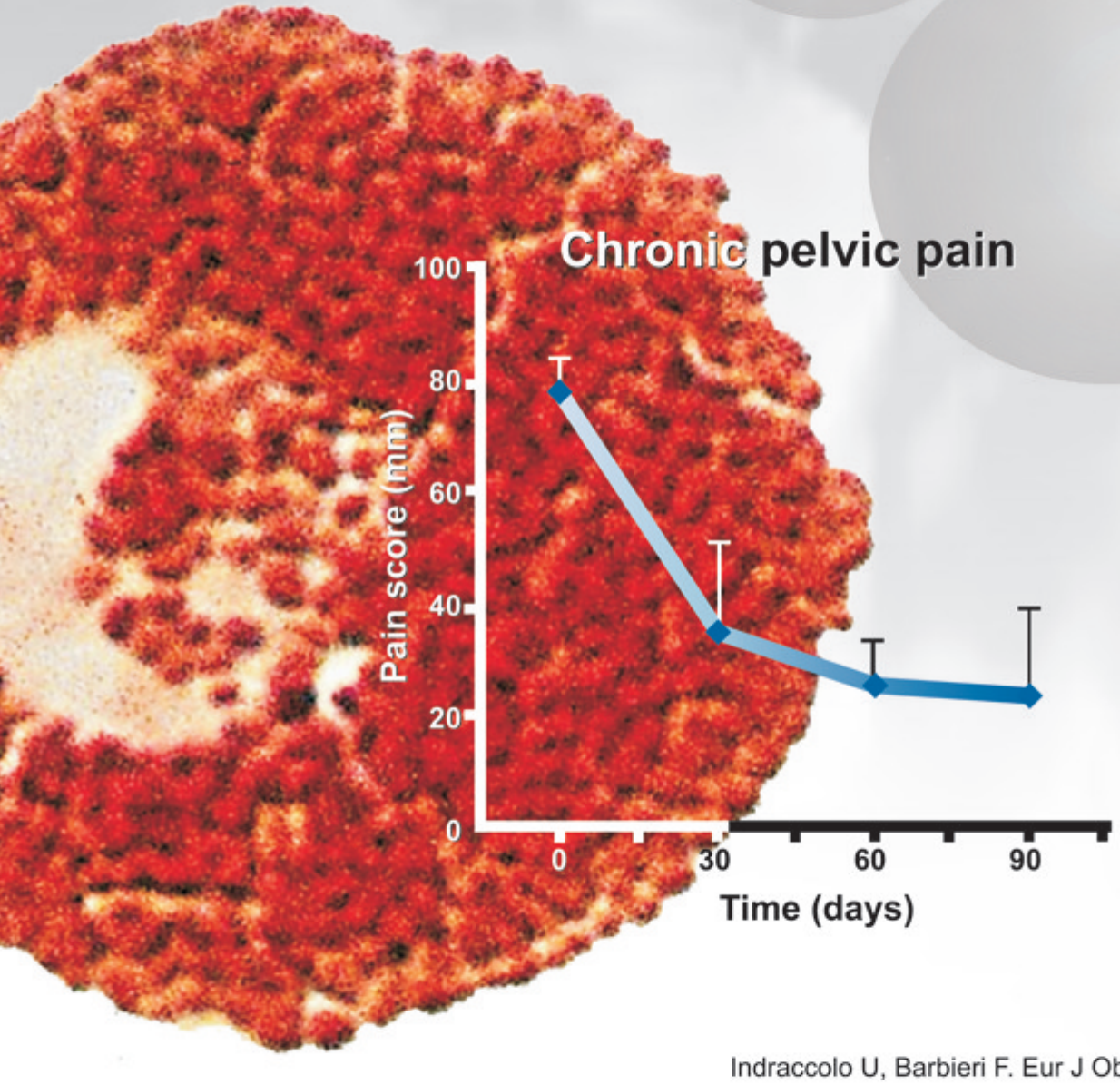

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PELVIPERINEOLOGY

A multidisciplinary pelvic floor journal

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Editorial

Pelvic floor prolapse mesh reconstruction-mesh choice

(Presented at the 12th Annual AAVIS/ISPP Scientific Meeting, 2010, Vienna)

Accurate diagnosis of all the prolapse features and site specific support requirements identification are mandatory for proper mesh choice. It is the presence of isolated apical supportive defect only at the central pelvic floor compartment or any additional anterior and/or posterior compartments prolapse that determine the requested mesh shape. It is the coexistence of urinary stress incontinence that indicates the need for additional mid-urethral support. The elected mesh or combination of meshes should be providing support for all the prolapsed pelvic floor sites. One must beer in mind that some commercially available anterior compartment meshes are designed for cystocele repair only while others provides the possibility to suspend the prolapsed uterus by cervical ring attachment, thus permitting it to be preserved. Other meshes provide support the mid urethra, concomitantly with anterior compartment reconstruction, hence avoiding the need for additional tape to support the mid-urethra separately. The later ones cure not only the anterior compartment prolapse but the uterine prolapse and/or stress urinary incontinence simultaneously with the cystocele repair. Other meshes are designed for posterior compartment reinforcement, some of provides the possibility to support the prolapsed uterus or vaginal apex at the same time. Whenever there is a need to treat several sites of pelvic supportive defects more than one mesh might be needed. There should be a dissent and convincing published body of evidence to prove the safety and efficacy of the specifically chosen mesh. The surgeon must be properly trained with any new mesh by an experienced trainer and familiar with potential hazards including their prevention and management. The mesh texture need to be as soft and light as possible, none shrinking, small in dimensions, yet sufficient for complete replacement of all defected parts of the endo-pelvic fascia and pelvic floor herniation. Thorough defected endo-pelvic fascia substitution with the artificial fascia is crucial for insuring long lasting support. Host against graft and graft against host reaction formation should be ruled out according with any particular mesh prior to usage, so should any mesh related bacteria nesting or harboring. This is generally the case with type 1 mono-filament macroporous knitted meshes, not interfering with macrophages migration. Long lasting anchoring method were reported to involve ligament through passing mesh arms, thus the particular mesh attachments to the pelvic chosen supportive points should be proved before hands for long lasting support, preferably with mesh arms through ATFP or SS ligaments anchoring. Mesh and arm delivery systems for mesh individually prepared or pre-cut kits should be proven to yield the desired correct mesh and arms placement at the pelvic floor. Some pre-cut meshes might be too small to provide the necessary complete coverage of the whole fascial defects, thus easier to place because less dissection is required. Others might provide relatively easy arm placing devices, but at the price of improper arm passage at the deep ligaments of the pelvis for appropriate high support. These meshes might be prone to operative failure and recurrent prolapse. One should not be tempted for these easy to apply kits but rather go for the highly curative ones. Bio meshes were not proven to yield any advantage over the synthetic ones and one should not endanger his patients with bio-hazards. Smilingly, the absorbable meshes were not reported to entail any superiority and one should ask himself is there any potential benefit of a vanishing mesh in herniation repair at all. The list of available commercially manufactured products expends fast and the existing ones are regularly re-shaped, thus there is no point in referring to any particular currently available mesh. With this atmosphere of many newly designed meshes popping up almost monthly, one must be extra couches when choosing his own mesh. Of huge importance is solid clinical data, proving high cure rate and low rate of complications of mild nature. One should seek for proper training before adopting any new operation and maintain his skills with frequent operation performance.

MENAHEM NEUMAN, JACOB BORNSTEIN

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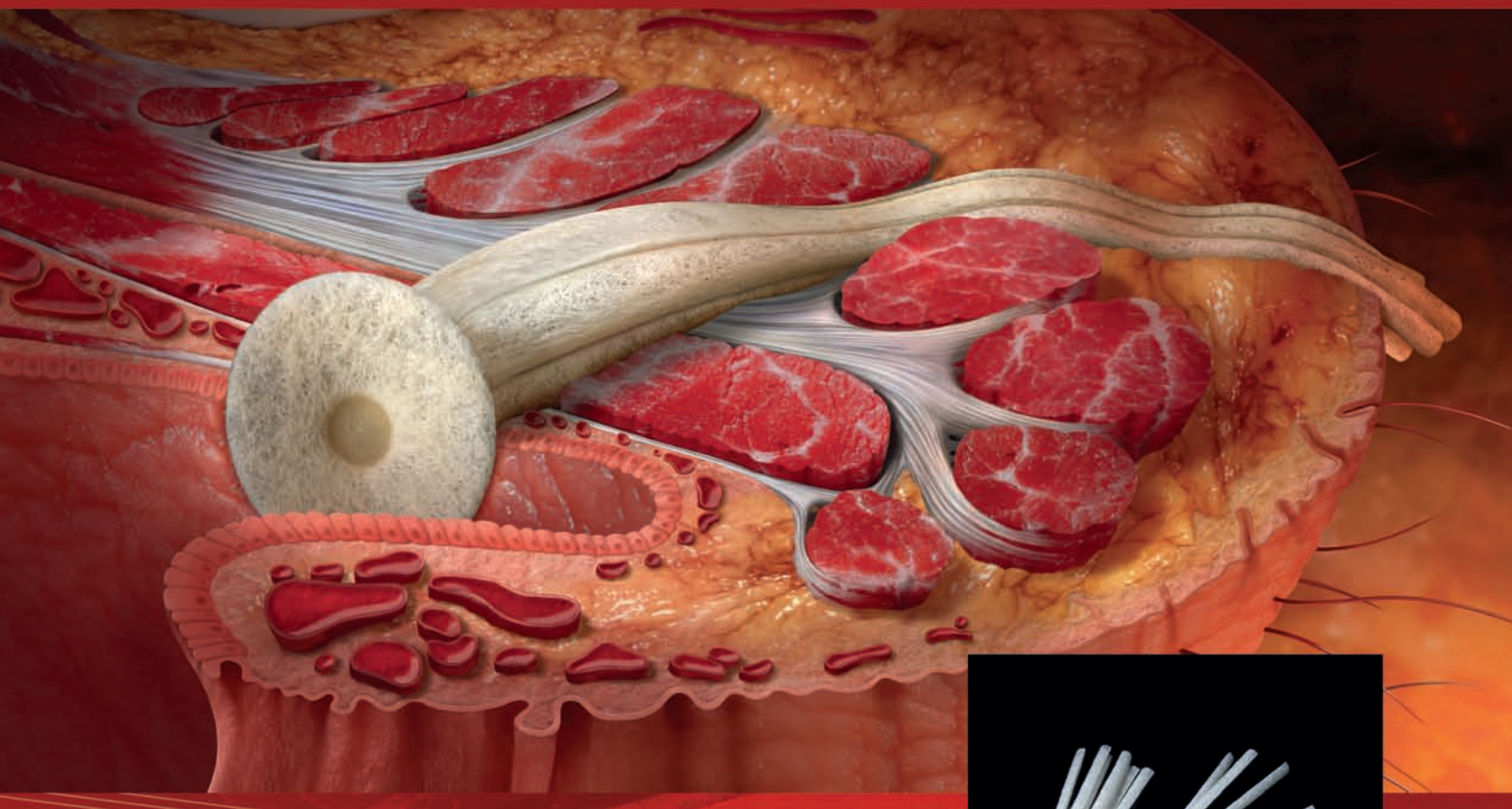

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Editorial

In 2010 GA Santoro, AP Wieczorek, and CI Bartram edited a comprehensive new textbook entitled Pelvic Floor Disorders Imaging and Multidisciplinary Approach to Management. This work is published by Springer and contains contributions from many of the most renowned International pelvic physicians and surgeons. The work presents a special emphasis on the role of diagnostic imaging.

Pelviperineology is pleased to announce that we will be publishing a series of articles highlighting the different sections of this landmark book in the months to come.

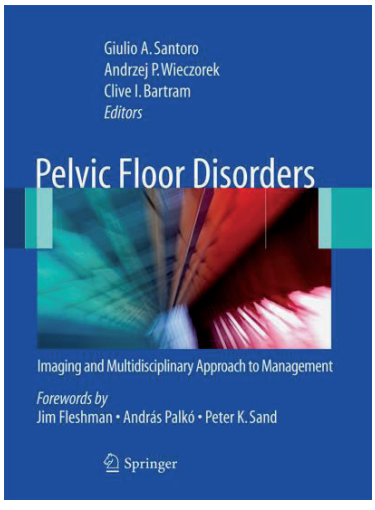
It goes without saying that this innovative work is a completely new approach covering the diagnosis and management of pelvic problems in one comprehensive volume.

This approach enables the reader to develop a sound understanding of the pathophysiology of pelvic disease seen through the window provided by the latest imaging techniques. It highlights the importance of the imaging of pelvic floor disorders especially with the advent of new innovative technologies in many areas. This work covers both diagnosis and management. The decision how to treat should arise from a comprehensive understanding of the physiopathology of the relevant disorders and identifying where any anatomical defects are located using the techniques that are so clearly described

This is a multidisciplinarity book. It is written by urologists, colorectal surgeons, gynecologists and physiotherapists and supports the concept that the approach to the pelvic floor and pelvic floor disorders should be multidisciplinary.

The International Society for Pelviperineology through our journal is proud to support this work and commend it to our readers. We hope you enjoy the forthcoming articles and will be motivated to obtain your own copy of the book.

BRUCE FARNSWORTH
drbruce505@yahoo.com.au



GA Santoro, *Regional Hospital Ca' Foncello, Treviso, Italy;* AP Wieczorek, *University of Lublin, Poland;* CI Bartram, *St. Marks Hospital, London (Editors)*

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Jim Fleshman
András Palkó
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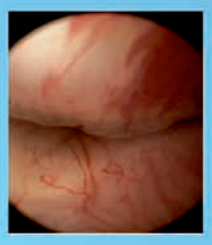

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A template for the comprehensive evaluation of Pelvic Organ Prolapse in a South African context

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Abstract: Pelvic organ prolapse is a prevalent condition affecting approximately half the population of parous women. Since the thorough assessment of this entity may be an intimidating and somewhat daunting task to both registrar and specialist alike, we identified the need for a multi-disciplinary template in its evaluation. We compiled the first, locally compiled guide to be used by general practitioners, registrars in training and by any physician who is presented with pelvic organ prolapse in the clinical context. The above proposed template had been drafted and approved by physicians representing the background disciplines of Urology, Obstetrics and Gynaecology and General Surgery, with affiliations of four leading medical schools in South Africa being embraced. A standardised practical template was constructed using a compartmental approach. Tick-boxes and scales were inserted for follow-up visits and post operative assessments.This template would serve to improve the overall management of the multitude of South African women who are affected by this debilitating condition. We also envisage this template's use as an educational tool and an invaluable aid in the field of pelvic floor disorders, which could be applied in any locality.

Key words: Template; Evaluation; Prolapse; Pelvic floor; Incontinence; South Africa.

INTRODUCTION

Pelvic organ prolapse is a prevalent condition affecting approximately half the population of parous women.[1] To date, a practical template in its evaluation has not yet been formulated for use in our setting. Since the entity of incontinence has been the most common documented symptom in the urogynaecology clinic,[2] we have incorporated it into the above template.

A systematic approach had been formulated in Italy (1996), for the evaluation of Pelvic Organ Prolapse in the clinical context. It had been constructed assessing 4 different domains in the pelvic floor (Incontinence, Pelvic floor and Prolapse, General factors and Handicap) and was thus named the "IPGH" system.[3] The original IPGH system was comprehensive but not entirely practical to implement in everyday practice. This inadequacy subsequently led to the development of the "Short-IPGH" system.[4] However, the corresponding abbreviations in the Short-IPGH system may still prove to be an intimidating milestone for the novice who is confronted with Pelvic Organ Prolapse in the clinic setting. Although these four domains are somewhat pivotal in the Pelvic Floor assessment, we attempted to incorporate the assessment into a simplified non-abbreviated system and thus began the construction of a template (appendix 1) using a more anatomically accepted, "compartmental" approach.

MATERIALS AND METHODS

The anterior, middle and posterior compartments are addressed separately in both the history and examination sections of the template. The Australian pelvic floor questionnaire[5] has been advocated for use along with this template, since it has been validated and subsequently proven to be constant whether self or clinician administered.[5] (Permission from the first author of the "Australian pelvic floor questionnaire"[5] had been obtained for its use in this context.) The above proposed template had been drafted, revised and approved by physicians representing the background disciplines of Urology, Obstetrics and Gynaecology and General Surgery, with affiliations of four different medical schools in the country being involved.

RESULTS

A standardised practical template was constructed using a "compartmental" approach. Tick-boxes and scales were inserted for follow-up visits and post operative assessments.

An assessment section was deemed to be an essential component for use in the referral process and follow-up of these patients.

DISCUSSION

We have thus constructed a clinical tool which could be implemented by both registrar and specialist alike. This template would serve to improve the overall management of the multitude of South African women who are affected by this debilitating condition.

We also envisage that a template of this sort could serve as an educational tool and an invaluable aid in the field of pelvic floor disorders, which could be applied in any setting.

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Appendix 1. – . The "compartmental" template for the evaluation of Pelvic Organ Prolapse.

Identity
Patient Name:
Date of Birth:
Age: Parity ☐ Gravidity ☐

History
Main Complaint:
History of complaint:
Previous Medical History:
Previous Surgical History:
Gynaecological History: Hormonal Status: Menopausal: Pre ☐ Post ☐ HRT: ☐ Yes ☐ No
Pap Smear.....

Obstetric History: Previous 3rd, 4th degree tear

Voiding diary:
Quality of life Questionnaire: The Australian Pelvic floor questionnaire[5] (*) Self Administered ☐ Clinician Administered ☐ SCORE:

Bladder:
Bowel:
Prolapse:
Sexual Function:
INTERPRETATION:
Sexual History: Frequency/week:
Reason for inactivity:
Dyspareunia:

Compartmental symptom Enquiry
If present, quantify using the (Visual analougue scale) VAS score, with 10 being the worst

Anterior Compartment:

Leak with cough/sneeze:	0	1	2	3	4	5	6	7	8	9	10
Urgency:	0	1	2	3	4	5	6	7	8	9	10
Urgency incontinence:	0	1	2	3	4	5	6	7	8	9	10

Frequency:	Yes ☐	No ☐	
Haematuria:	Yes ☐	No ☐	
Incomplete Emptying:	Yes ☐	No ☐	
Poor stream:	Yes ☐	No ☐	
Straining:	Yes ☐	No ☐	
Hesitancy:	Yes ☐	No ☐	
Double Voiding:	Yes ☐	No ☐	
Post micturition dribbling:	Yes ☐	No ☐	
Dysuria:	Yes ☐	No ☐	
Nocturia:	Yes ☐	No ☐	(frequency/Night) .....
Pad Use:	Yes ☐	No ☐	(frequency/24hrs) .....
Documented UTI:	Yes ☐	No ☐	
Recurrent UTI:	Yes ☐	No ☐	(frequency/year) .....

Mid Compartment:

Prolapse:	Yes ☐	No ☐
'Bulge':	Sensation ☐	Visualization ☐

Posterior Compartment:

Constipation:	Yes ☐	No ☐
Defaecatory difficulty:	Yes ☐	No ☐
Tenesmus:	Yes ☐	No ☐
Faecal urgency:	Yes ☐	No ☐
PR Bleeding:	Yes ☐	No ☐
Incontinence for solid stool:	Yes ☐	No ☐

Incontinence for liquid stool: Yes ☐ No ☐
Flatal incontinence: Yes ☐ No ☐
'Digitation': Yes ☐ No ☐
Splinting of Perineum: Yes ☐ No ☐

EXAMINATION
Weight:.....Kg Length:.....cm BMI:
General:
Neurological: S2,3,4 nerve root:
Perineal Sensation:
Patella Reflexes:

Pelvic
Inspection:
Vulva, Perineum: Atrophy ☐

Anterior Compartment:
Urethra: Masses
Stress Test: Neg ☐ Pos ☐
Q-Tip test >30' ☐ <30' ☐

Signs of stress incontinence with Unmasking : ☐ Method of Unmasking .....
Cystocele ☐ Lateral..... Central..... Combination.....
Cystocele: Grade 0 1 2 3 4
Urethrocele: Grade 0 1 2 3 4

Mid Compartment:
Vault: Atrophy: Neg ☐ Pos ☐
Length: ..... cm
Uterine/Vault: Grade 0 1 2 3 4
Cervix:
Uterus: Transvaginal ultrasound:

Posterior Compartment:
Perineal body: Length:..... cm
Anal sphincter: Tone: Normal ☐ Abnormal .....

Puborectalis: Intact: Yes ☐ No ☐
Contraction: out of 5
Enterocele: Grade 0 1 2 3 4
Rectocele: Grade 0 1 2 3 4
Perineum: Grade 0 1 2

Pelvic organ prolapse quantification score (POP-Q SCORE):

Aa	Ba	C
Gh	Pb	Tvl
Ap	Bp	D

Stage: 0 1 2 3 4

Investigations:
Urine Analysis:
Post void residual volume: ..... mL
Urodynamic study:
Cystoscopy:
Ultrasound:
Defaecogram:
EndoAnal Ultrasound:
MRI:

Assessment summary
Patient:
Age: P ☐ G ☐
Significant co-morbidity:
Previous pelvic surgery:
SINGLE Main Complaint:
Predominant compartment involved:
Grade:
Special investigations (positive findings):

Original article

Adjustable transobturator male system – ATOMS – for the treatment of post-prostatectomy urinary incontinence: The surgical technique

WILHELM BAUER, CLEMENS BRÖSSNER

Krankenhaus Göttlicher Heiland, Department of Urology, Vienna, Austria

Abstract: OBJECTIVE. To present and evaluate initial perioperative experience with a new surgical treatment for post-prostatectomy urinary incontinence. Method: Between May 2008 and December 2010, an adjustable, hydraulic substitute sphincter system (ATOMS) was implanted in a series of 120 patients. In 105 of these 120 procedures, implantation was carried out using an outside-in technique. Adjustments via the port were made intraoperatively, and again no earlier than 3 weeks postoperatively if required. Results: The median operating time, including the learning curve, was 36 minutes. There were no severe intraoperative or perioperative complications. The most common postoperative side effects were temporary perineal/scrotal dysaesthesia or pain (62% of patients), which were controlled with non-opiate painkillers and subsequently abated. Four port infections in the first 28 patients led to a change in sterile conditions, no further infections occurred. Re-operation after failure of other devices was carried out in 43% of the patients and was successful in all cases. Conclusions: The system is a safe form of therapy for post-prostatectomy incontinence, and is suitable for a wide range of patients. We believe that such implants, with the option of minimally-invasive adjustment any time from 3 weeks postoperative onwards, will play an increasingly important role in incontinence surgery in the future.

Key words: Prostatectomy; Urinary incontinence; Post prostatectomy incontinence; Artificial urinary sphincter; Sling

INTRODUCTION

The increase in the number of radical prostatectomies (RP) carried out during the last few decades has led to a higher rate of post-prostatectomy incontinence (PPI). Penson[1] reported an incidence of 14% (medium to severe incontinence) amongst a group of 1288 patients with 5-year follow-up after RP. The modern surgical therapy for PPI was established in 1972 by Scott,[2] who made significant improvements to the concept of the artificial urinary sphincter first developed by Foley.[3] Over the last ten years, the complex method of implantation, the susceptibility to failure and the difficult handling of the artificial urinary sphincter have led to the development of several alternative approaches for treating PPI, amongst others the ATOMS system (A.M.I. GmbH, Feldkirch, Austria), a hydraulic, substitute sphincter system.[4] While the implant has similar components and works on a similar principle to that of the artificial urinary sphincter, there are two major differences: the ATOMS system does not create circular compression of the urethra, and secondly, it is designed for post-operative adjustment –even long-term– without surgical intervention. As with the artificial urinary sphincter, it is implanted in the region of the bulbous urethra, however the musculus bulbospongiosus is preserved intact as an additional protective layer between the implant and the urethra. The ATOMS implant (Figures 1,2) is secured in place by two mesh arms of polypropylene, which are drawn on either side through the obturator foramen and then back to the central cushion component of the implant. The arms are then attached to the cushion, creating a firm, 4-point fixation. The implant is connected by a catheter to a titanium port, which is placed subcutaneously in the left symphyseal region, and allows the system's pressure to be adjusted postoperatively by altering the filling volume of the cushion. The effect of the implant can therefore be increased or reduced to influence the patient's continence.

This article describes the surgical technique used for implantation and presents initial intra- and perioperative experiences with the system in 120 patients over a period of 2 years and 8 months.

PREOPERATIVE STEPS / INDICATIONS

In principle, patients with all grades of stress incontinence after RP can be treated with the ATOMS implant, including those having previously undergone radiation. A preoperative examination should be made with uroflow, sonographic assessment of residual urine volumes and urethro-cystoscopy. In addition, a urodynamic examination is useful to exclude a bladder voiding dysfunction and assess the detrusor function.

TABLE 1. – Strategies for PPI revision surgery with ATOMS.

Type of revision surgery	**Recommended procedure**
Re-operation after failed ProACT	Explantation of ProACT and implantation of ATOMS in one procedure
Re-operation after failed slings (e.g. AdVance)	Implantation of ATOMS in addition to slings, no explantation of slings due to risk of a major defect of the urethra
Re-operation after failed bone-anchored mesh (e.g. InVance)	Try to explant the polypropylene sutures, try to explant the loose bone screws, try to remove the silicone mesh, if carried out successfully, implantation of ATOMS in one procedure
Re-operation after failed adjustable slings (Argus, Remeex)	Explantation (Argus, Remeex) and implantation of ATOMS in one procedure
Re-operation with existing urethral erosion	Wait for erosion to heal before implanting ATOMS
Re-operation after failed artificial urinary sphincter (e.g. AMS 800)	Implantation of ATOMS approx. 8-12 weeks after removal of artificial urinary sphincter

Contraindications are the formation of residual urine, untreated infections of the urinary tract, development of fistulas and immunosuppressive therapy. The explantation of Pro-ACT, ARGUS or InVance systems can be carried out in the same session as the ATOMS implantation, however retroluminal slings, such as AdVance, should not be explanted in the case of failure, as this can lead to a defect of the urethra (Table 1). The implantation of ATOMS subsequent to such slings presents no problem, as the ATOMS is positioned more distal by the bulbous urethra. In the case of existing erosions or the explantation of an artificial urinary sphincter, it is wise to implant the ATOMS system in a second procedure after 2 to 3 months.

TECHNIQUE

The procedure may be carried out under either general or spinal anaesthesia, with the patient placed in the lithotomy position (Figure 3). Skin is washed with a betadine solution. Intraoperatively, 2.2 g of amoxicillin and 160 mg of gentamycin are administered intravenously.

After the patient has been draped with sterile covering, a permanent catheter (Ch14) is inserted. The urine bag is attached to the catheter and placed on the patient's right-hand side. The glans penis is wrapped in a sterile compress to absorb any urethral secretion and avoid any contamination of the surgical site.

A vertical incision, approx. 5 cm long, is made in the perineum, and the area on both sides of the musculus bulbospongiosus is prepared without cutting the muscle (Figure 4). A retractor is placed for better access, then the bulbous urethra and intact muscle are exposed and the area on both sides of the inferior pubic ramus and the fossa ischiorectalis prepared. Now the forefinger can easily be used to palpate the obturator foramen. At this point, the ATOMS implant may be removed from the packaging, and the special coupling piece for catheter placement that is supplied with the implant can be attached to the catheter (Figure 5).

The implant is placed in a sterile bag underneath the incision for protection from accidental contamination. The cushion's integrated, non-resorbable polypropylene fixation sutures are gathered up and held together with mosquito forceps. Subsequently the ATOMS implant is held in position to establish which arm is the correct one for implantation on the patient's left-hand side (Figure 6). The catheter must be pointing up and to the patient's left-hand side. As a result, the cushion's sutures are near the bottom of the implant and pointing towards the operator. We begin to implant the system's mesh arm on the patient's left-hand side. To get a better feel for the direction of rotation, a trial run is made with the tunneller (A.M.I. TOA Tunneller, A.M.I. GmbH, Feldkirch, Austria) by positioning it outside the body near the left inferior pubic ramus and guiding it around in the air. Note should be made of the fact that we now carry out all implantations using the outside-in approach, after having used the inside-out approach for the initial series of patients. We have found the outside-in approach easier to implement, and we no longer recommend using the inside-out technique. The pre-tied loop at the end of the system's left arm is hooked onto the tip of the tunneller (Figure 7). Now we use the left forefinger to palpate the obturator foramen, then the finger is placed under the inferior pubic ramus and the tunneller tip positioned medial-cranial on the obturator foramen. The obturator foramen is then perforated by placing pressure on the tunneller, and the tunneller slowly rotated until the fossa ischiorectalis is reached (Figure 8). The left forefinger is used to push the bulbous urethra to the patient's right-hand side, and push the rectum in a caudal direction. The tunneller can carefully be rotated further until its tip can be felt by the forefinger. Continue to rotate the tunneller towards the forefinger, and then use that finger to expose the tunneller in the distal perineal wound (Figure 9). Take hold of the left arm's loop to release it from the tunneller, and hold it in place with mosquito forceps. To remove the tunneller, rotate it backwards. By pulling on the arm's loop, the implant is brought into position on the patient's left-hand side (Figure 10). The arm with the protective sleeve is now shortened. Implantation on the patient's right-hand side is carried out in the same way as for the left (Figures 11,12). When implanting the arms, take care to avoid rotation of the tape (Figure 13).

Now pull firmly on both arms to bring the ATOMS implant into the correct position. After removing the protective sleeves (Figure 14), pull again first on one arm and then the other to bring them as close as possible to the bone, and ensure the implant is firmly in place (Figure 15). To secure the implant, the arms are held tight and the cushion's fixation sutures are threaded through the mesh arms before being tied (Figures 16,17). The cushion and the per-

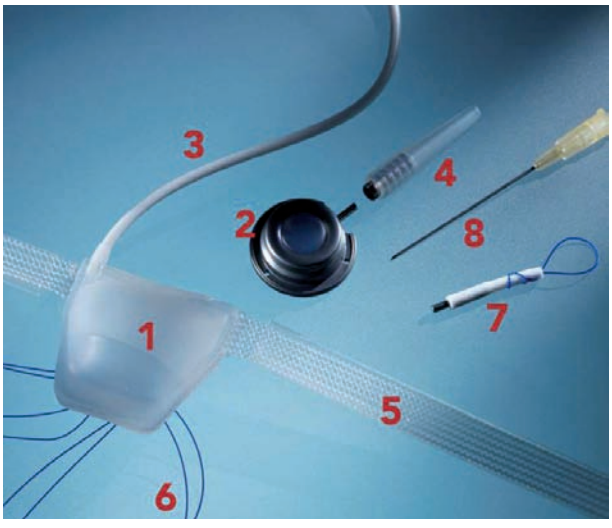

Figure 1. – ATOMS implant. 1) Cushion; 2) Port; 3) Catheter; 4) Puncture protection; 5) Mesh arm; 6) Fixation suture; 7) Catheter coupling piece. Photos courtesy of A.M.I. GmbH.

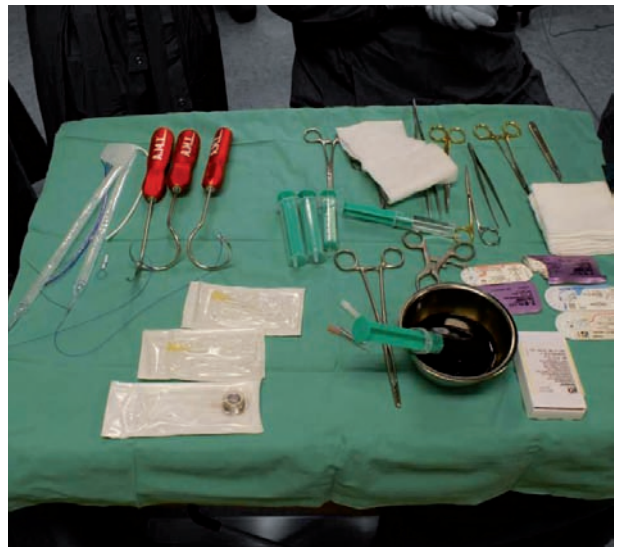

Figure 2. – Instrument table in preparation for ATOMS implantation.

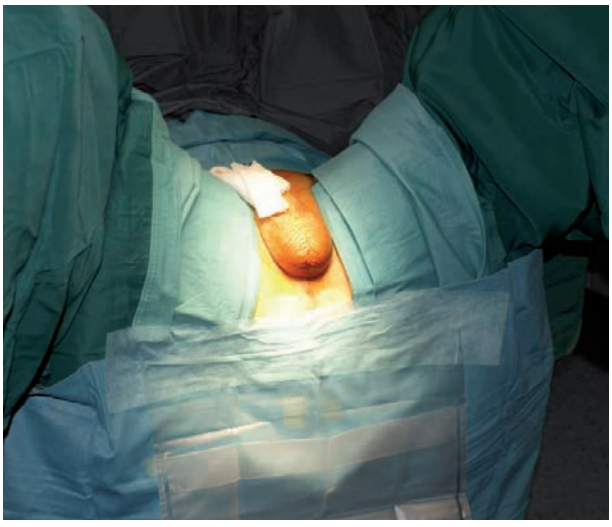

Figure 3. – Patient is placed in lithotomy position.

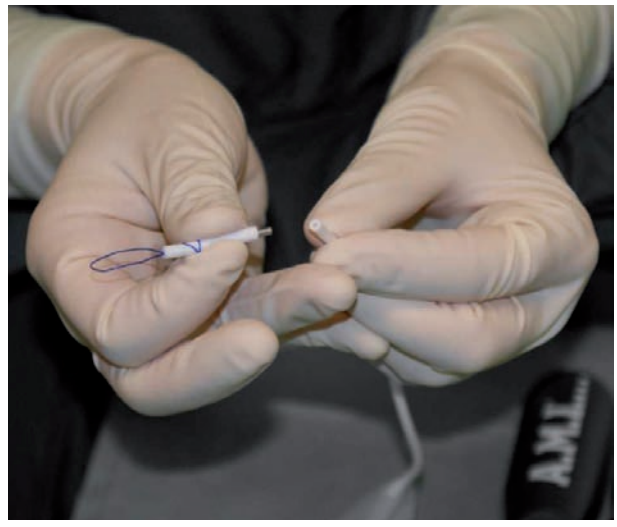

Figure 5. – Coupling piece is attached to catheter.

ineal wounds are rinsed with a betadine solution to guard against infection.

The next step is to make a port bed in the left symphyseal region. An incision approx. 3 cm long is made on the left, slightly above the base of the penis (Figure 18), and a monopolar scalpel used to prepare the bed in deep subcutaneous tissue. With help of an almost straight tunneller (A.M.I. TVA Tunneller, A.M.I. GmbH, Feldkirch, Austria) and taking care not to damage the left spermatic cord, a subcutaneous puncture is made to the left of the perineal wound and the loop of the catheter's coupling piece is hooked onto the tunneller (Figure 19). The tunneller is then pulled back to implant the catheter, and subsequently the coupling piece is removed from the catheter. Two compresses with betadine solution are placed on the skin to prevent the port from coming into contact with the skin. Now the puncture protection is unscrewed from the port and placed over the catheter (Figure 20). The catheter is then shortened and the port attached (Figure 21). The puncture protection is screwed onto the port, taking care not to turn the port. For fixation purposes, non-resorbable sutures are placed on both sides of the port (Figure 22). The port is then placed in the port bed and secured by tying the preplaced sutures (Figure 23), and the port bed rinsed with a betadine solution. A 10 ml syringe is filled with an isotonic saline solution and the special port needle delivered with the ATOMS set (A.M.I. Port Needle, A.M.I. GmbH, Feldkirch, Austria) is placed on the syringe. The port membrane is punctured, the ATOMS system filled with 10 ml and all the liquid removed again to empty the system of air. It is possible to fill the ATOMS implant intraoperatively, in order to improve the patient's continence directly after surgery (Figure 24). To this end, the system is filled again with approximately 8 ml, and the plunger of the syringe released. The system's pressure causes the plunger to be pushed back until pressure is equalized in the syringe and the ATOMS system. Our experience has shown the filling volume for this first adjustment to be between 4 and 8 ml. In cases of moderate to high grade incontinence, we fill the system with a further ½ to 1 ml after pressure has been equalized. Once completed, wounds are rinsed again with a betadine solution and closed in multiple layers with a subcuticular suture for the port region. The perineal wound is closed in three layers (Figure 25).

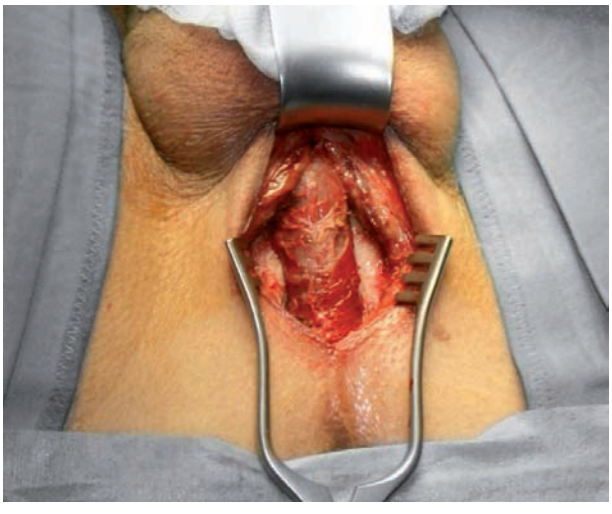

Figure 4. – Preparation of musculus bulbospongiosus.

IMPLANTATION AND PERIOPERATIVE EXPERIENCE WITH THE ATOMS SYSTEM

One surgeon (WAB) carried out 120 implantations of the ATOMS system between May 2008 and December 2010, first in the "Krankenhaus der Barmherzigen Brüder", in Vienna, Austria (Head of Dept. of Urology, Prof. P. Schramek) and subsequently in the "Krankenhaus Göttlicher Heiland" in Vienna, Austria (Head of Dept. of Urology, Prof. C. Brössner). The initial 15 implantations were carried out using the inside-out technique, all other implantations using the outside-in approach. The median operating time – including the learning curve – was 36 minutes (range 29 to 65). Re-operations (43% of patients) of other failed implants (e.g. suburethral slings) were carried out, however in the case of artificial urinary sphincters, at least eight weeks should pass after removal of the artificial sphincter before implanting the ATOMS system (see Table 1). In our series, we experienced no severe intraoperative or perioperative complications. The most common postoperative side effects were perineal / scrotal dysaesthesia or pain (62% of patients), however these could be controlled with non-opiate painkillers and abated spontaneously in all cases (between 5 days and 4 weeks). Following a total of four port infections in the first 28 patients, all of which occurred within the first two postoperative weeks, we altered our sterile conditions. These port infections led either to an ex-

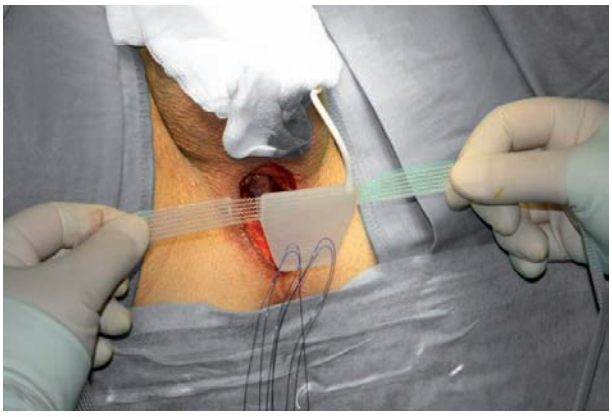

Figure 6. – ATOMS implant positioned correctly.

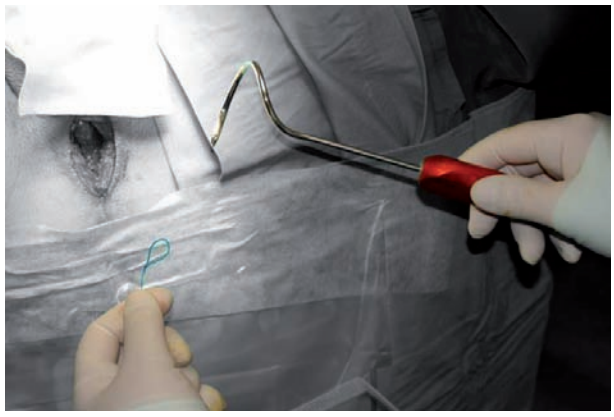

Figure 7. – Mesh arm's suture loop is hooked onto tunneller.

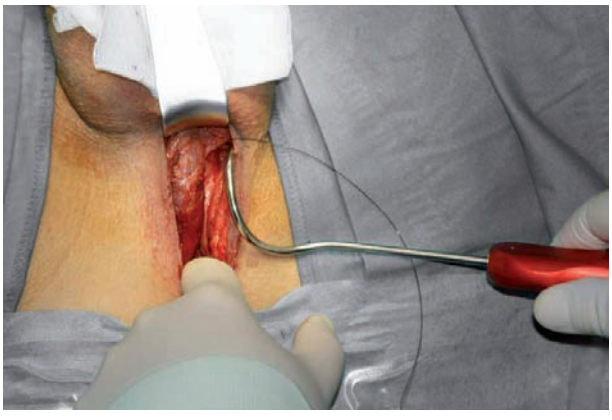

Figure 8. – Left tunneller penetrates obturator foramen.

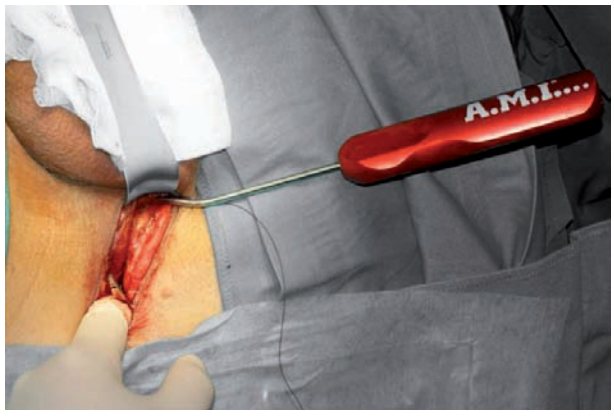

Figure 9. – Tip of left tunneller in distal perineal wound.

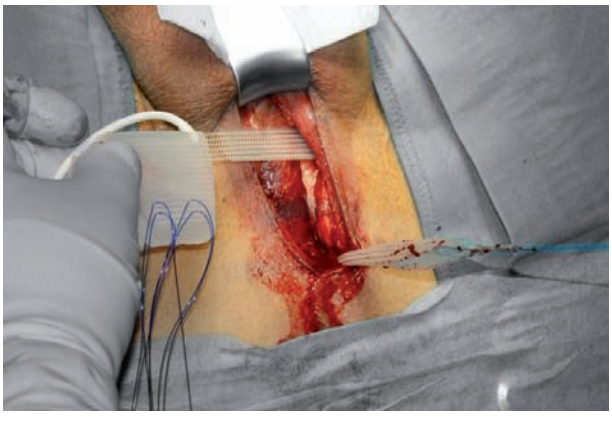

Figure 10. – Left mesh arm is pulled through.

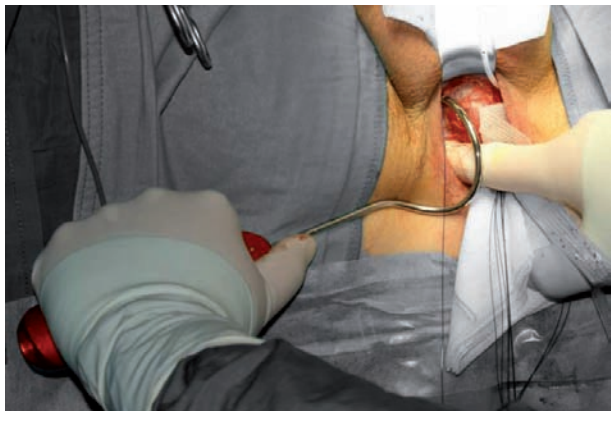

Figure 11. – Right tunneller penetrates obturator foramen.

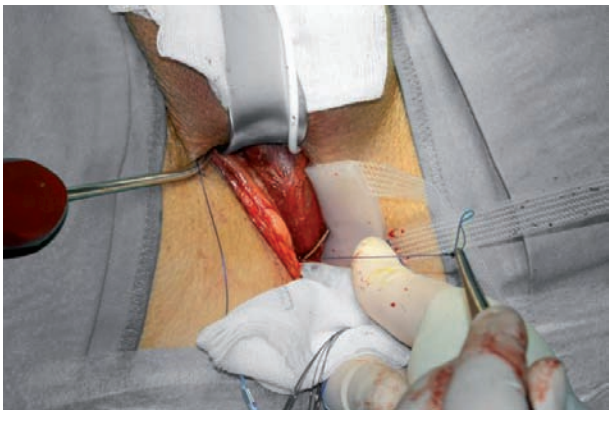

Figure 12. – Forceps release right suture loop.

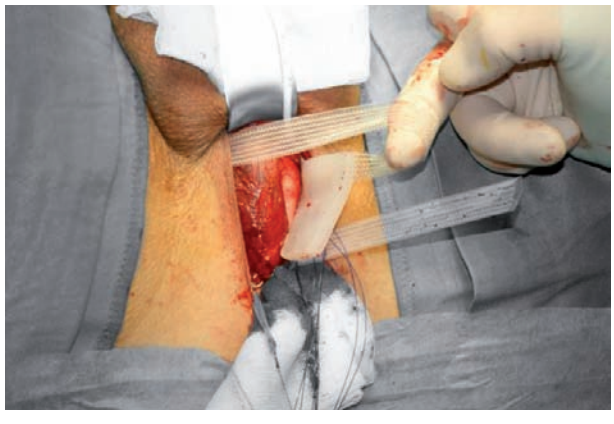

Figure 13. – Right mesh arm is pulled through.

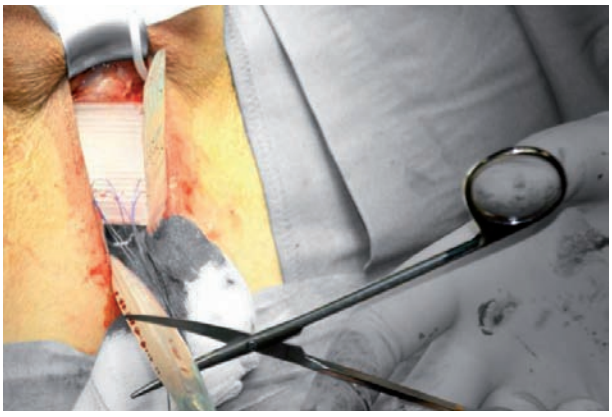

Figure 14. – Protective sleeve on mesh arm is removed.

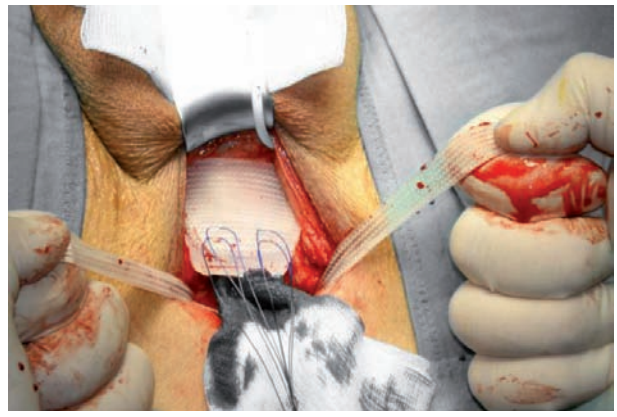

Figure 15. – Mesh arms are tightened equally.

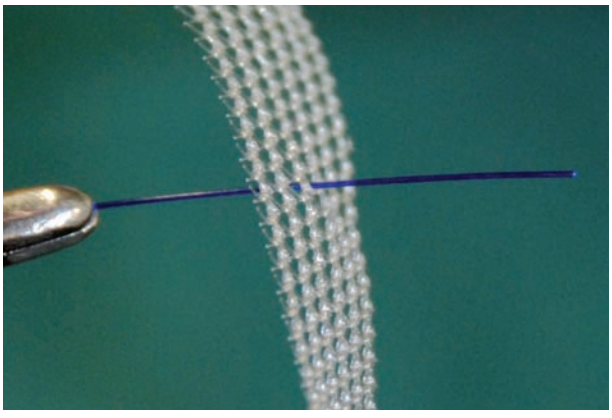

Figure 16. – Fixation sutures are threaded through mesh.

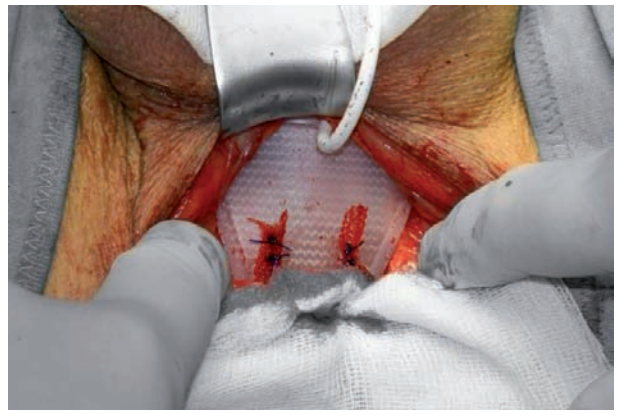

Figure 17. – All four fixation sutures are tightened.

change of the port only, or to a complete explantation (port and silicone components). Successful reimplantation of the ATOMS system in all patients followed after a healing phase of three months. Having observed no further infections since, we can draw the following considerations: a) the implant should not be removed from the packaging until we have finished preparing the site, b) the perineal implantation should be completed before we move to the port area, c) the port should be positioned subcutaneously as deep as possible, and d) the port should not end up lying directly under the skin incision (the edge of the port should be at least 1 cm away from the skin incision). On average, our patients are discharged on the third post-operative day (range 2-7), which is standard practice in the Austrian healthcare system. An earlier discharge is certainly possible from a medical point of view, however is not advisable before removal of the permanent catheter.

POSTOPERATIVELY

The permanent catheter is removed on the first postoperative day and residual urine tested. We administer 2.2 g of Amoxicillin twice daily for three days, and seven days in the case of previous infections or revisions. In the case of a penicillin allergy, we administer 400 mg of Ciprofloxacin intravenously twice daily. In addition, the patient is given analgesic therapy with 50 mg of Diclofenac three times a day for up to two weeks with gastric protection. Where necessary, the first adjustment is made no earlier than 3 weeks postoperatively. The average volume is between 2 and 5 ml for this first adjustment. Further adjustments can be made if required, usually in decreasing volumes until continence is achieved.

CONCLUSION

We have been able to show that the ATOMS system represents a safe form of therapy for the treatment of stress urinary incontinence, suitable for a broad spectrum of patients. One key advantage is the standardised surgical technique, which is easy to learn. The 4-point anchoring of the system around the obturator foramen automatically ensures the correct, stable positioning of the implant. A further aspect which separates the ATOMS system from other treatment options is the long-term, non-invasive adjustability. Continence can be achieved, and physiological voiding is possible with no form of manual activation. The system functions hydraulically, however incorporates no mechanical components, thereby reducing the potential for product failure. In this way, the ATOMS implant addresses the most significant shortcomings of the artificial urinary sphincter. We have achieved very good continence rates for mild to moderate incontinence in our series of patients treated with ATOMS, and our data for high-grade incontinence appears to be similar to results published on the use of artificial urinary sphincters. Which place the system will take amongst the various forms of treatments for male incontinence will be determined by the long-term multicentre results regarding continence rates achieved. Based on our current experience with the system, we venture to suggest that implants such as ATOMS, which can be easily adjusted to meet the patient's needs, will establish a firm foothold in modern incontinence surgery.

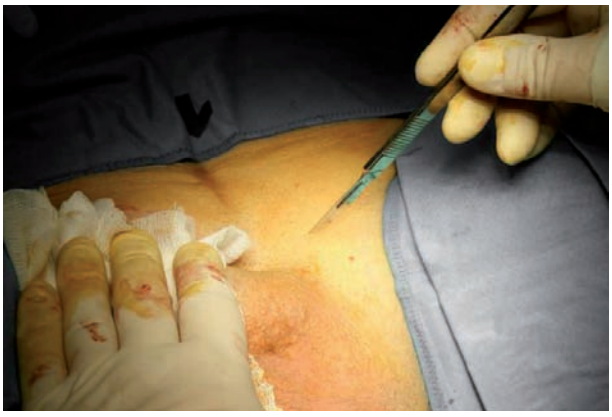

Figure 18. – Port incision is made in left symphyseal region.

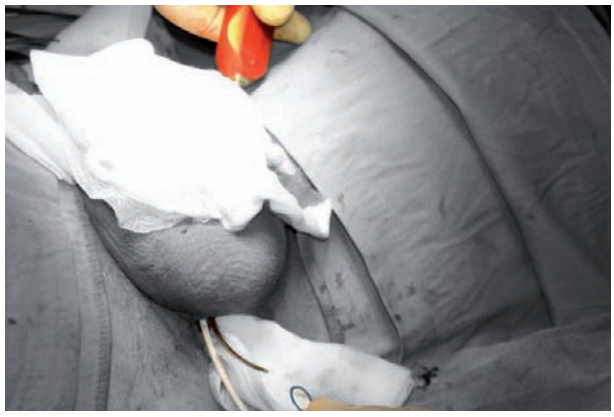

Figure 19. – Tunnelling to connect catheter to port.

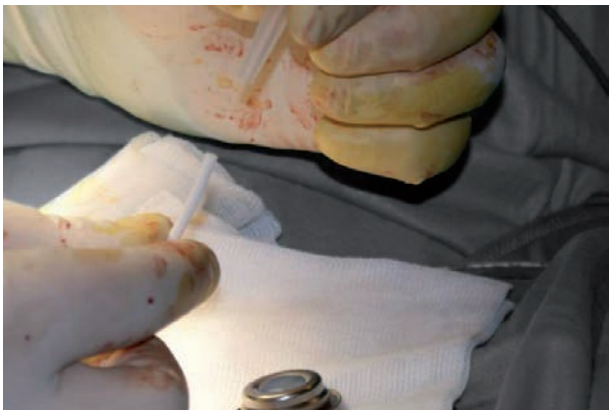

Figure 20. – Puncture protection is placed over catheter.

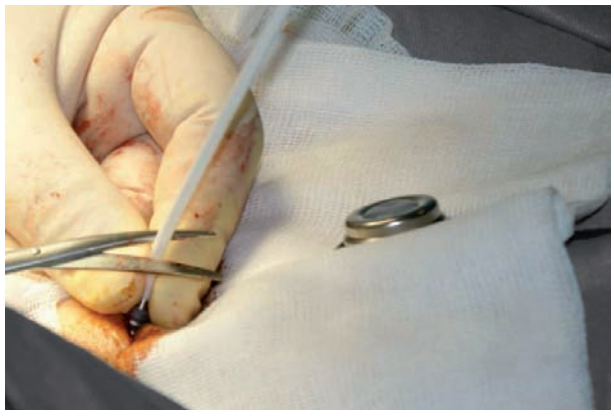

Figure 21. – Catheter cut down to correct length.

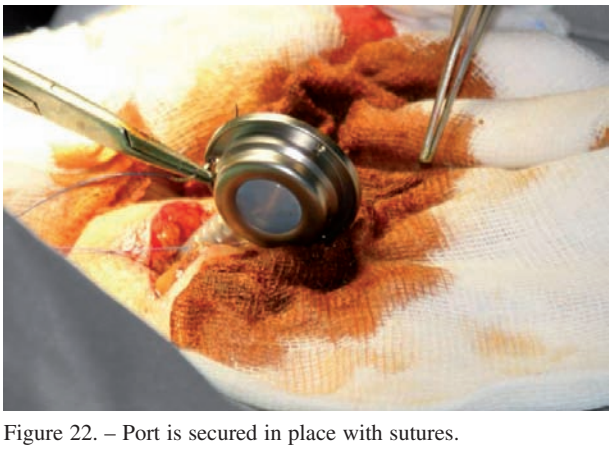

Figure 22. – Port is secured in place with sutures.

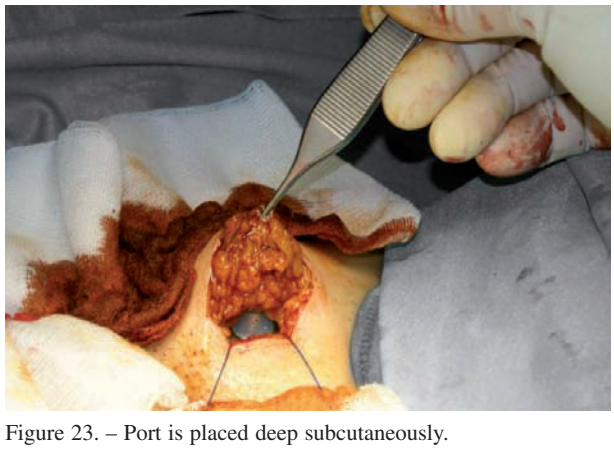

Figure 23. – Port is placed deep subcutaneously.

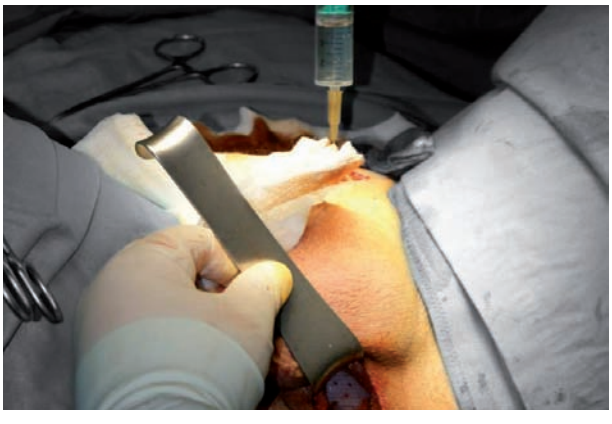

Figure 24. – Implant is emptied of air and filled intraoperatively.

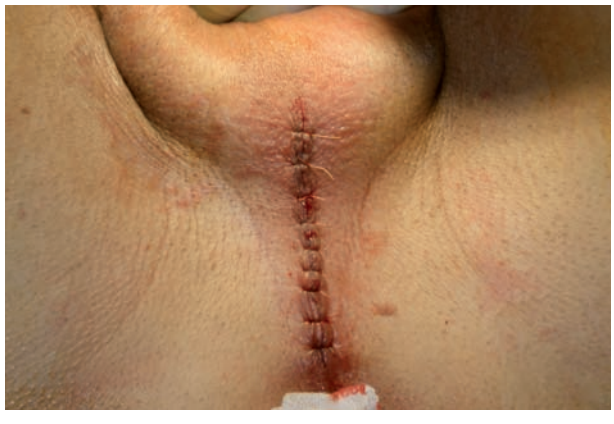

Figure 25. – Perineal wound on completion of the procedure.

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Disclosure of financial interest:
Wilhelm Bauer hereby declares a proprietary interest in the ATOMS System.

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Guidelines

Treatment of chronic bacterial prostatitis

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Abstract: Bacterial infection of the prostate can be demonstrated by the Meares & Stamey 4-glass or the pre and post prostate massage (PPM) 2-glass test in only about 10% of men with symptoms of chronic prostatitis/chronic pelvic pain syndrome. Chronic bacterial prostatitis is mainly caused by Gram-negative uropathogens. The role of Gram-positives, such as staphylococci and enterococci, and atypicals, such as chlamydia, ureaplasmas, mycoplasmas, are still debateable. For treatment, fluoroquinolones are considered the drugs of choice because of their favourable pharmacokinetic properties and their antimicrobial spectrum, with the best evidence supporting ciprofloxacin and levofloxacin. The optimal treatment duration is 28 days. Relapse and reinfection due to antimicrobial resistant pathogens are major problems in chronic bacterial prostatitis. The increasing resistance of *E. coli* against fluoroquinolones in many countries is of great concern in that respect. In patients with pathogens resistant to fluoroquinolones, but susceptible to trimethoprim-sulfamethoxazole, a three month course of treatment with trimethoprim-sulfamethoxazole can be administered. In patients with pathogens resistant to fluoroquinolones and trimethoprim-sulfamethoxazole, currently no recommendation can be given. Clinical trials with other antibiotics are urgently needed in this patient population.

Key words: Chronic bacterial prostatitis; Refractory chronic bacterial prostatitis; Antibiotic treatment; Antimicrobial resistance; Chronic pelvic pain syndrome.

Summary of recommendations: 1. The fluoroquinolone drug class is the first choice systemic treatment for chronic bacterial prostatitis, with the best evidence supporting use of ciprofloxacin and levofloxacin (GoR A). 2. Other drugs with evidence of efficacy include: gatifloxacin (discontinued in the US), lomefloxacin, moxifloxacin (no clinical data), prulifloxacin (not available in the US), and trimethoprim-sulfamethoxazole (GoR B). 3. The optimal duration of therapy is at least 28 days, with some studies supporting treatment for up to eight weeks (GoR B). 4. The optimal length of clinical follow-up is at least six months (GoR A). 5. The main unresolved issue is the increasing rate of antimicrobial resistance and lack of promising oral alternatives to the fluoroquinolones. In patients with pathogens resistant to fluoroquinolones and trimethoprim-sulfamethoxazole, currently no recommendation can be given. Clinical trials with other antibiotics are urgently needed in this patient population (GoR A). 6. In refractory chronic bacterial prostatitis repeated treatment or antimicrobial prophylaxis is recommended using antimicrobials to which the pathogen is susceptible. More studies of this important issue are however warranted (GoR C). 7. Interventions are only recommended in patients with chronic bacterial prostatitis who have proven bladder outflow obstruction (GoR C). 8. There are insufficient data on alternative and complementary medicine approaches for patients with chronic bacterial prostatitis (GoR D).

1. INTRODUCTION

Approximately 10% of men with symptoms of chronic prostatitis/chronic pelvic pain syndrome have bacteriuria with pathogens that can be proven to originate from infection of the prostate using the Meares and Stamey four-glass or the pre- and post-prostate massage two-glass test. These patients meet the criteria for chronic bacterial prostatitis (NIH category II) and represent the focus of this consultation. Most cases of chronic bacterial prostatitis are caused by Gram-negative uropathogens. The role of Gram-positive and atypical bacteria is still debateable. The purpose of this guideline is to evaluate the evidence supporting current treatment options for patients with chronic bacterial prostatitis, including treatment-refractory cases.

1.1. Prostatitis syndromes

Prostatitis syndrome is one of the most common problems encountered in urologic practice. Classification of the prostatitis syndrome is based on the clinical presentation of the patient, the presence or absence of white blood cells in the expressed prostatic secretions (EPS), and the presence or absence of bacteria in the EPS.[1] Prostatitis is described as chronic when symptoms are present for at least three months.

1.2. Classification

The internationally-accepted classification of the prostatitis syndrome follows the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)/ National Institutes of Health (NIH) recommendations (Table 2).[2] There are four categories of prostatitis.

Acute bacterial prostatitis (NIH category I) is defined as an acute bacterial infection of the prostate, associated with severe prostatitis symptoms, signs and symptoms of systemic infection and acute bacterial urinary tract infection.[3]

Chronic bacterial prostatitis (NIH category II) is defined as a chronic (3 months) bacterial infection of the prostate, proven by adequate microbiological tests, with documented bacteriuria caused by the same bacterial strain. Only about 10% of men with chronic prostatitis symptoms have chronic bacterial infection of the prostate that can be demonstrated by the four-glass test.[4]

Other categories of prostatitis are not associated with prostatic infection proven by standard microbiological methods in patients with chronic symptoms, termed chronic prostatitis/chronic pelvic pain syndrome (NIH category III), or in patients who have no symptoms but have proven prostatic inflammation, termed asymptomatic prostatitis (NIH category IV).

1.3. Epidemiology

The incidence of bacterial prostatitis may be higher than previously reported.[5] A recent study evaluated new physician-diagnosed prostatitis cases in a managed care population over a two-year interval.[6] The incidence of acute or chronic bacterial prostatitis was 1.26 cases per 1,000 men per year.

2. METHODS

We defined one major question, "What is the optimal antimicrobial therapy for patients with chronic bacterial pro-

statitis?" This question was then divided into four issues:

1. What is the first choice antimicrobial drug category and which drugs have the best evidence for clinical efficacy?
2. What is the optimal duration of therapy?
3. What is the desired length of follow-up?
4. What is the major outstanding issue for treatment?

2.1. Review of the literature

We searched the major databases covering the last 10 years (e.g., Medline, Embase, Cochrane Library, Biosis, Science Citation Index) using the search term *bacterial prostatitis* in binary combinations with the terms: *chronic, treatment, outcome, complications, antibiotic and antimicrobial*. Similar searches were also conducted using the search term *chronic bacterial prostatitis* in binary combinations with the terms: *trimethoprim, refractory, antibiotic resistance, surgery, TURP and prostatectomy*. To identify papers not yet indexed in the major databases, we reviewed the tables of contents of the major journals of urology and other relevant journals, for the last three months. Papers published in non-reviewed supplements were not included. There is also a microbiological rationale supporting restriction of the literature search to the last 10 years, because in most areas a minimal inhibitory concentration (MIC) shift has taken place in the pathogens causing chronic bacterial prostatitis.

The studies were rated according to the level of evidence and the strength of recommendations. The Oxford Centre for Evidence Based Medicine have produced a widely accepted adaptation of the work of the Agency for Health Care Policy and Research (AHCPR).[7] The ICUD consultations use a modified version of the Oxford system which can be directly "mapped" onto the Oxford system.[8]

2.1.1. Results

These searches identified a total of 1,656 articles, including 1,014 articles published from 1999-2008. Review of the titles and abstracts of the 1,014 identified articles, identified a total of 72 articles that met the criteria for detailed analysis and rating. These 72 articles were reviewed in detail for how well each study was designed and carried out using a standard checklist adopted from the CONSORT statement (available at http: //www.consort-statement.org).

2.2. Rating of the literature

Of the 72 articles reviewed in detail, in total 57 papers met the criteria for rating (Table 1). According to the hierarchy of study types these papers included: no systematic reviews or meta-analyses, three randomized clinical trials, three non-randomized cohort studies, two case-control studies, six case series, 27 articles incorporating expert opinion, two cost-effectiveness studies, and 14 *in vitro*, laboratory or animal model studies (Table 1).

2.2.1. Results

Results are shown in table 1.

Three Level 1 studies (LoE 1b) were identified: three randomized clinical trials.[9-11] These studies included a total of 655 participants (Table 1).

The committee identified four Level 2 studies (two studies with LoE 2a, two studies with LoE 2b): two non-randomized cohort studies[12-13] and two case series.[14-16] These studies included a total o 359 participants (Table 1).

The committee identified 25 level three studies including: one non-randomized cohort study,[17] two case-control studies,[18-19] four case series,[20-23] 16 expert opinion reviews[24-39] and one cost-effectiveness study.[40] These studies included a total of 652 participants with chronic prostatitis (Table 1).

The committee identified 25 Level 4 studies including: 11 articles based on expert opinion,[41-51] one cost-effectiveness study,[52] and 14 in vitro, laboratory, or animal model studies.[53-66] These studies included no participants with chronic bacterial prostatitis (Table 1). Although the Delphi process can be used to give 'expert opinion' greater authority, we identified no article that used this approach.

3. CLINICAL PRESENTATION AND RECOMMENDED EVALUATION OF PATIENTS WITH CHRONIC BACTERIAL PROSTATITIS

Chronic bacterial prostatitis is characteristically associated with recurrent urinary tract infections caused by the same bacterial strain. Chronic bacterial prostatitis represents the most frequent cause of recurrent urinary tract infections in young and middle aged men. Chronic bacterial prostatitis can be a devastating disease, characterized by relapsing febrile episodes, if not treated adequately from the beginning. Potential complications include: urosepsis, prostatic abscess and acute urinary retention.

Accurate diagnosis of chronic bacterial prostatitis (NIH category II) depends on quantitative segmental bacteriological localization cultures and EPS microscopy. The classical four-glass procedure, first described by Meares and Stamey, remains the gold standard.[67] Nickel et al validated a simpler test to assess inflammation/infection as a screening test in primary care patient populations. The two-glass test is a reasonable alternative when EPS cannot be obtained or when microbiological assistance is not available, because EPS should be examined expeditously. Interpretation of localization test results can follow various definitions that have been evaluated, but the NIH definition is the most accepted.

3.1. Microbiology

A bacterial strain is considered a pathogen if the colony forming unit (CFU) concentration in EPS or post-prostate massage voided urine is at least 10 times higher than in midstream or first-void urine. The bacterial spectrum of chronic bacterial prostatitis has been carefully investigated in patients from tertiary care institutions.[4, 68] Similar to the experience with acute prostatitis, these series report that facultative Gram-negative bacilli (especially *E. coli*) were responsible for the great majority of cases. Recent reports from clinical series of patients have reported a preponderance of Gram-positive cocci.[10, 39] In these latter series, the median duration of patients' symptoms was 3.5 weeks. One recent report however describes that cultures suggesting localization of Gram-positive bacteria are not consistent in more than 90% of patients.[69] Nevertheless, most reports suggest that the bacterial spectrum resembles that of complicated urinary tract infections, with a preponderance of enterobacteria. *P. aeruginosa* and Enterococci are found less frequently, but are more difficult to treat.

3.2. Other issues related to clinical assessment

3.2.1. Semen culture

A comprehensive study of 40 men with *E. coli* chronic bacterial prostatitis evaluated the role of semen analysis and cultures. Bacteriospermia (>10^3 CFU/ml) was documented in 21 (53%) of the 40 men prior to treatment.[14] Therefore, semen culture is not sufficient to diagnose chronic bacterial prostatitis.[14]

TABLE 1. – Evidence Table: Studies of Chronic Bacterial Prostatitis Treatment that Include Original Data, Systematic Reviews or Meta-analysis, Expert Opinion, or Other Data (1999-2008).

Study Type	**Lead author, year, reference**	**Subjects**	**Design Aspects**	**Critical Findings**	**Rating of Evidence**
Systematic reviews and Meta-analyses					
	None				
Randomized clinical trials					
	Naber, 2002[9]	182	Multicenter, lomefloxacin 400 mg once daily vs. ciprofloxacin 500 mg twice daily for 4 weeks.	At 5-9 days, 4-6 weeks, 3 and 6 months after therapy eradication rates were 80, 72, 74, and 63% in the lomefloxacin group and 84, 81, 82, and 72% in the ciprofloxacin group.	1b, Positive (non-inferiority)
	Bundrick, 2003[10]	377	Multi-center, levofloxacin 500 mg once daily or ciprofloxacin 500 mg twice daily for 28 days	Microbiologic eradication rates 75% for levofloxacin and 76.8% for ciprofloxacin; 6-month relapse rates were similar.	1b, Positive (non-inferiority)
	Giannarini, 2007[11]	96	randomized to receive a 4-week oral course of either prulifloxacin 600 mg or levofloxacin 500 mg once daily.	6 months after therapy, microbiological cure rate was 72.73% for prulifloxacin and 71.11% for levofloxacin (p=0.86)	1b, Positive (non-inferiority)
Non-randomized cohort studies					
	Naber, 2000[12]	65	Multi-center study of ciprofloxacin 500 mg bd for 28 days	Eradication rates were 32/39 (82.1%) after 3 months, 26/34 (76. 4%) after 6 months and 13/22 (59.1%) after 9 months.	2a, Positive
	Kunishima, 2008[17]	10	Multi-center, 200 mg gatifloxacin twice daily for 4-8 weeks	58.1% symptomatic response rate 4 weeks after treatment	3, Positive
	Naber, 2008[13]	117	Multi-center open-label study of levofloxacin 500 mg once daily (p.o.) for 28 days. Patients were followed for 6 months.	Microbiological eradication rate was 82/98 (83.7%) at 1 month and the continued eradication rate was 52/57 (91.2%) at 6 months post treatment.	2a, Positive
Case-control studies	Nickel, 2008[19]	146 (average symptom duration was 8.4 weeks, median 3.5).	Multi-center study comparing levofloxacin or ciprofloxacin for 4 weeks with 6 months of follow-up	Bacteria eradication rate was 74.0% not different from men with no localization of pathogenic bacteria.	3, Positive
	Hu, 2002[18]	50	Amikacin 400 mg daily for 10 days via submucosal anal (30 cases) or intramuscular injection (20 cases).	"Cure rate" 33.3% for anal submucosal injection vs. 5% for IM injection (P<0.05)	3, Positive
Case-series	Weidner, 1999[14]	40	*E. coli* chronic bacterial prostatitis treated with 4 weeks of ciprofloxacin 500 mg bid with 12-24 months follow-up.	Microbiological eradication was 92% at 3 months and 70-80% 12-24 months after treatment.	2b, Positive
	Nickel, 2001[23]	14	Various regimens	57% "moderate to marked improvement," similar to response in patients with category III.	3, Positive
	Gutierrez, 2004[22]	105	Various regimens	Symptoms either disappeared or diminished, irrespective of whether positive cultures remained.	3, Positive
	Guercini, 2005[21]	320 with symptoms of chronic prostatitis	Antibiotic cocktails (based on cultures) with betamethasone by prostate infiltration, weekly for 3 doses.	68% of patients were "cured clinically."	3, Positive

Study Type	Lead author, year, reference	Subjects	Design Aspects	Critical Findings	Rating of Evidence
	Chen, 2006[20]	7	Combination of ciprofloxacin, doxazosin, allopurinol and biofeedback perineal massage.	Bacterial eradication rate was 71% after ciprofloxacin treatment during a follow-up of 6 months.	3, Positive
	Magri, 2007[15-16]	137	Combination therapy with ciprofloxacin, azithromycin, alfuzosin and a S. repens extract for 6 weeks.	64.2% microbiological response at the end of Rx. Of 49 patients showing persistence or reinfection at the end of treatment, 36 completed a second combination therapy cycle: 27 patients (75%) showed eradication. The cumulative eradication rate was 83.9%.	2b, Positive
Expert opinion					
	Naber, 1999		Review of guidelines	For chronic bacterial prostatitis, a category of its own is proposed rather than using the general category of complicated UTI.	4, Positive
	Lipsky, 1999[45]		Review	Trimethoprim-sulfamethoxazole or, preferably, a fluoroquinolone for 6 to 12 weeks.	4, Positive
	Stevermer, 2000[50]		Review	Antibiotics are continued for at least 3 to 4 weeks, although some men require treatment for several months.	4, Positive
	Shoskes, 2001[48]		Review	Ciprofloxacin has been shown to be effective. Newer quinolones may be more effective against gram-positive pathogens and anaerobes.	4, Positive
	Naber, 2001[26]		Review		3, Positive
	Iakovlev, 2002[44]		Review		4, Positive
	Fowler, 2002[43]		Review (minimal data)	Fluoroquinolone antibiotics given for 2 to 4 weeks will cure about 70%.	4, Positive
	Wagenlehner, 2003, 2004, 2005, 2006, 2007[32-38]		Reviews of pharmacokinetics and pharmacodynamics	Fluoroquinolones are the first choice.	3, Positive
	Croom, 2003[25]		Review	28 days of oral levofloxacin 500mg daily achieved similar clinical and bacteriological response rates to oral ciprofloxacin 500mg twice daily.	3, Positive
	Fish, 2003[42]		Review	Important role of levofloxacin.	4, Positive
	Naber, 2003[28]		Review of antimicrobial penetration into prostate tissue and seminal fluid	Fluoroquinolone concentrations at the site of infection should be sufficient for treatment of susceptible pathogens.	3, Positive
	Charalabopoulos, 2003[24]		Review of antimicrobial penetration into prostate tissue and secretions	Of agents, beta-lactam drugs penetrate poorly. Good to excellent penetration into prostatic fluid and tissue has been demonstrated with many antimicrobial agents, including tobramycin, netilmicin, tetracyclines, macrolides, quinolones, sulfonamides and nitrofurantoin. Pharmacokinetic studies of antimicrobials use heterogenous methodology. Antibiotic concentrations in prostatic fluid suitable for treatment of infections are only found with fluoroquinolones, macrolides, lincosamides and trimethoprim.	3. Positive

Study Type	Lead author, year, reference	Subjects	Design Aspects	Critical Findings	Rating of Evidence
	Skerk, 2004[49]		Croatian guidelines	Ciprofloxacin is the drug of choice.	4. Positive
	Nickel, 2005[77]		Review		3, Positive
	Zvara, 2002[51]		Review	Minimally invasive therapies (intraprostatic injections) in the treatment of chronic prostatitis are not a standard of care.	4. Negative
	Liu, 2005[46]		Review	Recommend fluoroquinolones, especially levofloxacin and gatifloxacin.	4, Positive
	David, 2005[41]		Review	Only trimethoprim and the fluoroquinolones possess both the appropriate bactericidal activity and the ability to diffuse into the prostate. Levofloxacin shows particularly good penetration.	4, Positive
	Wagenlehner, 2008[29]		Review	Follow up of at least 6 months is necessary. Most fluoroquinolones with this indication should be sufficient for susceptible pathogens.	3, Positive
	Naber, 2008[27]		Review	The fluoroquinolones (2-4 weeks) are the first choice, in particular levofloxacin is as effective as ciprofloxacin but shows a better prostatic penetration and is given once daily.	
Cost-effectiveness Studies					
	Kurzer, 2002[40]	hypothetical cohort of 100 men	Model comparing 90 days of trimethoprim-sulfamethoxazole and 14, 28 and 60 days of ciprofloxacin.	Ciprofloxacin 500 mg twice daily for 28 days appears to be the most cost effective treatment.	3, Positive
	Sanchez-Navarro, 2002[52]	50	Analysis of pharmacy and chart records		4, Positive
In vitro, laboratory, or animal model studies					
	Drusano, 2000[66]	Population pharmacokinetic analysis of prostate penetration by levofloxacin 33 subjects	Monte Carlo simulation of Levofloxacin concentrations in plasma and prostate tissue after repeated administration of 500 mg levofloxacin orally	Mean prostate tissue/ plasma concentration ratio was 4.14. 70% of the population had a penetration ratio in excess of 1.0	3, Positive
	Wagenlehner, 2006, 2008[30-31]	12 healthy volunteers and 39 TURP patients	Concentrations of moxifloxacin in plasma, urine, prostatic fluid, prostate tissue.	Moxifloxacin might be a good alternative for the prostatitis treatment.	3, Positive
	Rippere-Lampe, 2001[60]	Rat model		Cytotoxic necrotizing factor type 1-positive uropathogenic *E. coli* caused more inflammation-mediated and histological damage than isogenic CNF1-negative mutants despite similar bacterial counts.	4, Positive
	Velasco, 2001[63]	83 patients with FQ resistant E. coli isolates	Comparison of quinolone resistant E. coli isolates of invasive urinary tract infection and prostatitis cases versus cystitis cases	Quinolone resistance of invasive cases was 8% versus 20% in cystitis cases. Quinolone resistant E. coli is less likely to produce invasive disease than susceptible E. coli.	4, Positive

Study Type	Lead author, year, reference	Subjects	Design Aspects	Critical Findings	Rating of Evidence
	Naber, 2001[59]	10 normal volunteers	Gatifloxacin concentrations in plasma, urine, ejaculate, prostatic and seminal fluid, and sperm cells.	Good penetration into prostatic and seminal fluid suggest that gatifloxacin may be a good alternative.	4, Positive
	Giannopoulos, 2001[54]	50	Pefloxacin concentrations in serum and prostate tissue after 800 mg intravenuous pefloxacin were determined in BPH tissue using a microbiological plate assay	Tissue levels of pefloxacin were well above MICs of common bacteria causing bacterial prostatitis. Pefloxacin could be a satisfactory alternative for surgical prophylaxis and treatment of bacterial prostatitis	4, Positive
	Scelzi, 2001[61]	12 TURP patients	Lomefloxacin concentrations in serum and prostate tissue after 400 mg oral application	Tissue/ serum ratio was > 2 in prostatic capsule and > 1.6 in adenomatous tissue. Lomefloxacin could be an efficacious therapeutic option for treatment of chronic prostatitis	4, Positive
	Horcajada, 2002[56]	23 *E. coli* isolates	Emergence of quinolone-resistance in faeces of patients with prostatitis treated with ciprofloxacin for 1 month.	11 of 23 patients, developed quinolone-resistant strains, during and just after therapy. 2 months after treatment, these were completely displaced by quinolone-susceptible *E. coli.*	4, Positive
	Lee, 2005[58]	Rat model	Catechin, an extract of green tea.	Combination treatment of catechin and ciprofloxacin had synergistic effect.	4, Positive
	Johnson, 2005[57]	17 *E. coli* prostatitis isolates	Molecular analysis	Prostatitis isolates exhibited more virulence factors than cystitis isolates (n=23).	4, Positive
	Cattoir, 2006[53]	1	Quinolone resistance me-	chanisms in an *E. coli* clinical isolate (Ar2).	4, Positive
	Wang, 2006, 2008[64-65]	Rat model	Vancomycin and amikacin evaluated	Higher antibiotic concentration in the prostate tissues than in sera.	4, Positive
	Soto, 2007[62]	32 *E. coli* prostatitis isolates		Strains causing prostatitis produced biofilm in vitro more frequently than those causing other urinary tract infections and had a higher frequency of hemolysin (p = 0.03 and 0.0002, respectively).	4, Positive
	Han, 200855	Rat model		Lycopene may have a synergistic effect with ciprofloxacin in prostatitis treatment.	4, Positive

3.2.2. Imaging studies and urodynamics

The role of transrectal prostate ultrasound and urodynamic investigations was evaluated in a prospective study of 164 men. This study found that these investigations had no role in discriminating chronic bacterial prostatitis from chronic prostatitis/ chronic pelvic pain syndrome.[70]

In one study magnetic resonance imaging of four acute bacterial prostatitis and five chronic bacterial prostatitis cases were compared to prostate cancer, benign prostatic hyperplasia and chronic prostatitis/chronic pelvic pain cases.[71] Bacterial prostatitis showed some features similar to carcinoma suggesting that magnetic resonance imaging may provide little diagnostic specificity.

In another study 19 patients with chronic bacterial prostatitis were compared to controls and patients with chronic pelvic pain syndrome.[72] Hot uptake was found in 68% of chronic bacterial prostatitis patients and 70% of patients with chronic pelvic pain syndrome. Therefore, the data suggest that imaging procedures are of limited or no benefit in diagnosing chronic bacterial prostatitis or in predicting response to treatment.

3.2.3. National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI)

The NIH-CPSI provides a standardized assessment of prostatitis symptoms.[73] The NIH-CPSI was designed as a tool for monitoring response in clinical trials of chronic prostatitis/chronic pelvic pain syndrome rather than as a diagnostic tool. Only limited data are available to validate use of this instrument in assessing the clinical response to therapy in patients with chronic bacterial prostatitis.

4. PRINCIPLES OF THERAPY

4.1. Antimicrobial treatment

Appropriate antimicrobial therapy represents the cornerstone of successful treatment for patients with bacterial pro-

statitis. For effective antimicrobial therapy the pathogens at the site of infection must be exposed to a drug concentration sufficient to inhibit bacterial growth or even eradicate the pathogens from that site. Although it remains unproven in humans, evidence suggests that bacteria in prostatic tissue may survive in a milieu protected by biofilms.[62, 74] Although the efficacy of antimicrobial therapy is markedly less against biofilm-associated bacteria, fluoroquinolones and macrolides are more active in biofilm than other antimicrobials, e.g. beta-lactams or aminoglycosides.[75]

A rather extensive review on pharmacokinetic studies of antimicrobial agents and their penetration into the prostate has been performed by Charalabopoulos et al.[24] If only studies with a suitable methodology are used, e.g. assessment of antibiotic concentrations in prostatic fluid, than antibiotic concentrations in prostatic fluid sufficiently high to treat chronic infections in the prostate are only found with fluoroquinolones, macrolides, lincosamides and trimethoprim. Encompassing pharmacokinetic and pharmacodynamic aspects, the fluoroquinolones are considered the drugs of choice for antimicrobial treatment of chronic bacterial prostatitis. All clinical studies within the last 10 years have been performed with fluoroquinolones.

Because clinical experience suggests that relapse and reinfection are common observed in patients with chronic bacterial prostatitis, only the results of clinical studies with a follow-up of at least six months is recommended.[76] Overall, it appears that 60-80% of patients with *E. coli* and other Enterobacteriaceae can be cured with a four-week course of fluoroquinolone therapy (Table 1). However, clinical experience suggests that prostatitis due to *P. aeruginosa* or enterococci seem to cause more failures. Therefore fluoroquinolones with a broad anti-bacterial spectrum, like levofloxacin, gatifloxacin, or moxifloxacin with improved activity against Gram-positive pathogens might be a better option in case of enterococci, although comparative RCT data suggest that these agents are equivalent to results of ciprofloxacin treatment. Levofloxacin was investigated in two recent clinical studies. The study by Bundrick et al.[10] was a randomized double-blind multicenter study comparing levofloxacin 500mg once daily to ciprofloxacin 500mg twice daily and found levofloxacin was equivalent to ciprofloxacin. Microbiological eradication was however only followed up to four weeks and patients were not required to have documented bacteriuria with the localizing bacterial "pathogens." In this study, the microbiological eradication rate by patient at four weeks was 75% in the levofloxacin group and 77% in the ciprofloxacin group. The specific eradication rate of *E. faecalis* was 72% with levofloxacin and 76% with ciprofloxacin. The eradication rate of *P. aeruginosa* was not indicated in this study. The other recent study by Naber et al.[13] was a non-randomized patient cohort study investigating levofloxacin 500mg once daily, patients were not required to have documented bacteriuria with the localizing bacterial "pathogens." The study also used different classification schemes for the diagnosis of chronic bacterial prostatitis.

The corresponding[10] total eradication rate at four weeks was 79%, and at six months 92%. The specific eradication rate of *E. faecalis* in the comparable classification scheme to the Bundrick study[10] was 56% (10/18) and of *P. aeruginosa* 100% (3/3).

4.2. Duration of antibiotic treatment and clinical follow-up

We identified no clinical studies comparing different durations of antibiotic treatment. Almost all studies used a four week treatment regimen.[9-13,19] In one study treatment with gatifloxacin was four to eight weeks,[17] but this was not a comparative study. A cost effectiveness study comparing different antibiotics and duration concluded that ciprofloxacin 500 mg twice daily for 28 days was the most cost-effective treatment.[40] Based upon these results in chronic bacterial prostatitis, an oral fluoroquinolone should be given for at least four weeks after the initial diagnosis (LoE 2, GoR B).

Follow up in most clinical studies was at least 6 months,[9-14, 19-20] which therefore should also be performed in clinical routine (LoE 2 GoR B).

4.3. Procedures

One study investigated amikacin 400 mg daily administered for 10 days via submucosal anal or intramuscular injection.[18] This study reported inferior results. Non-systemic application of antibiotics is therefore not recommended (LoE 3, GoR C).

No published study from the last 10 years evaluated interventions in chronic bacterial prostatitis. Expert opinions only recommend interventions in patients with chronic bacterial prostatitis who have proven bladder outflow obstruction although this has not been validated in studies (LoE 4, GoR C).

4.4. Alternative and complementary medicine approaches

One animal study investigated catechin, a green tea extract, in combination with ciprofloxacin in the treatment of chronic bacterial prostatitis.[58] The authors reported a statistically significant decrease in bacterial growth and improvements in prostatic inflammation compared with the ciprofloxacin only group.[58] Further studies are necessary to validate these observations.

One retrospective clinical study evaluated results of a 6-week course of combination therapy with ciprofloxacin, azithromycin, alfuzosin and a *Serenoa repens* extract in patients with chronic bacterial prostatitis.[15] Microbiological eradication rates were between 75.5% and 82.3%, and clinical success rates between 78.8% and 85.7%, depending on the pathogens isolated and were thus not higher than in those studies with antibiotics alone.[10,13] Thus, there are insufficient data on alternative and complementary medicine approaches for patients with chronic bacterial prostatitis (LoE 4, GoR D, no recommendation possible.)

4.5. Refractory patients

There are limited data available on treatment outcomes for patients who fail initial therapy for chronic bacterial prostatitis. One study investigated 36 patients with relapsing chronic bacterial prostatitis. 16 Of these 36 patients, 27 (75%) were cured by a second cycle of combination pharmacological therapy with antibacterial agents (ciprofloxacin/azithromycin), alpha-blockers (alfuzosin) and the phytotherapeutic, *Serenoa repens*. No other study evaluated patients with recurrent disease. More studies of this important issue are therefore warranted, therefore currently no recommendation can be given for refractory patients.

5. DISCUSSION AND CONCLUSIONS

Antimicrobial resistance to fluoroquinolones is increasing world-wide. The impact of fluoroquinolone resistance on the treatment of chronic bacterial prostatitis has not been evaluated systematically. However, from a pharmacological viewpoint, treatment failure with increasing pathogen MICs has been observed anecdotally in our patients with chronic bacterial prostatitis, as we have seen with urinary tract infections and other urogenital infections, such as gonorrhea (for which fluoroquinolones are no longer recommended in the USA). In patients with pathogens susceptible to trimetho-

prim-sulfamethoxazole and resistant to fluoroquinolones, expert opinion recommends a three-month course of treatment with trimethoprim-sulfamethoxazole LoE 4, GoR C). In patients with pathogens resistant to fluoroquinolones and trimethoprim-sulfamethoxazole, currently no recommendation can be given.

Clinical trials with other antibiotics are therefore urgently needed in this patient population (LoE 4, GoR A).

6. FUTURE RESEARCH

The microbiological success of treatment of chronic bacterial prostatitis mainly depends upon the antimicrobial´s pharmacological properties in the prostate and the susceptibility of the pathogens. Future research should therefore especially be directed to the activity of other antibiotics, not tested up to now, and substances active in biofilm, to evaluate possible synergism, in the treatment of chronic bacterial prostatitis.

Table 2. – National Institutes of Health Prostatitis Syndrome Classification.[2]

I	Acute Bacterial Prostatitis
II	Chronic Bacterial Prostatitis
III	Chronic Prostatitis/Chronic Pelvic Pain Syndrome a) Inflammatory b) Non-inflammatory
IV	Asymptomatic Inflammatory Prostatitis

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Preoperative staging of prolapse does not correlate with symptoms and quality of life

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Abstract: *Introduction*. Several studies have shown minimal or no correlation with POP-Q stage and symptoms of pelvic organ prolapse (POP). This study evaluated the correlation between POP-Q stage, ordinal measurements, symptoms and quality of life (QOL) in women presenting for surgical management of POP. *Methods*: Forty-five women completed a preoperative questionnaire (PQOL) evaluating symptoms and QOL. These data were correlated with POP-Q stage and the ordinal measurements undertaken at the same visit. Prolapse was also categorised as mild or severe as determined by the most distal point in relation to the hymenal remnant. The best fit of data correlating QOL and anatomical severity of prolapse was established by reiterating analysis in successive 1cm increments from the hymenal remnant. *Results*: All women had at least stage 2 anterior prolapse and most women had coexisting apical and posterior prolapse. POP-Q stage did not correlate with symptoms and QOL. Correlations (r 0.28-0.36, $p<0.05$) were detected in five QOL domains when prolapse was defined as severe and Aa or Ba was ≥2 but not ≥1. *Discussion*: Anatomical findings, symptoms and QOL are distinct parameters that are all relevant in the evaluation of women with POP. Ordinal measurement of POP is useful in the evaluation of women presenting for surgery, however POP-Q staging may not be useful and POP-Q stage 2 is not an appropriate threshold for determining surgical outcome.

Key words: Pelvic organ prolapse, Correlation POP-Q, Symptoms, Quality of life.

INTRODUCTION

The POP-Q system published in 1996[1] has become the standard system of quantification of pelvic organ prolapse (POP). Experts devised POP-Q for anatomical staging based on extensive clinical experience and opinion. However, there was no attempt to relate the staging in this system to other clinical parameters, notably function. Previous studies have found only a weak correlation between anatomical findings and symptoms associated with POP with the strongest correlation between maximal descensus of the anterior compartment and the symptom of presence of a bulge noticed by the patient.[2-7] For the anterior compartment, the best anatomical threshold discriminating women with symptoms was maximal descent to within 0.5cm of the hymenal ring[3,7] – equivalent to point Aa or Ba of -0.5 in the POP-Q system. In an NIH-sponsored document it has been recommended in surgical trials that cure of POP be defined as POP-Q stage 0 or 1.[8] POP-Q stage 2 (maximal descent -1 to +1cm) is the critical range that defines surgical failure and this range includes what has been defined as the most discriminating point for correlation of symptoms. In postmenopausal women presenting for annual pelvic examination as part of the Women's Health Initiative trial asymptomatic stage 2 POP was present in 62.9%.[9] The stage of POP that is currently recommended to define surgical failure may include many asymptomatic women.

POP is primarily a condition that affects quality of life (QOL) and there are now several disease-specific questionnaires that address this. Gutman et al used the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire to assess symptoms of POP in a mixed group of women presenting to a gynaecology clinic.[10] That study, primarily aimed at determining the impact of POP on sexual function, determined that descensus distal to the hymenal ring by 0.5cm (equivalent to Aa or Ba at +0.5) was the best predictor of symptoms of bulging and protrusion but could not detect a threshold to predict other symptoms. The primary aim of this study was to determine using the English version of PQOL (a validated POP questionnaire)[11] the correlation between the POP-Q stage and QOL in women presenting for surgical management of anterior compartment vaginal prolapse. These women are symptomatic and represent the typical POP surgical workload of the practising gynaecologist.

METHODS

This was a secondary analysis of a prospective randomised trial of 45 women presenting to gynaecology units in the Central Northern Adelaide Health Service for surgical management of anterior compartment POP. The women were symptomatic and had been referred for management of anterior compartment prolapse by their local doctor, with randomisation to occur between anterior mesh and traditional colporrhaphy. Preoperative data for all women enrolled in the trial are presented. The booking gynaecologist performed POP-Q staging at the same consultation as the patient completed the PQOL questionnaire. The PQOL questionnaire is a validated POP QOL questionnaire originally in English[11] and now validated in numerous other languages.[12,13] It consists of eight domains and the raw scores for each domain are converted to a percentage with larger numbers indicating a greater adverse effect on QOL. The correlations between (1) the POP-Q staging and PQOL scores and (2) the most distal point of the prolapse measured to the nearest cm in each of the anterior, apical and posterior compartments and PQOL scores was calculated (Spearman correlation, Graph Pad Prism for Mac OS X). As there was no correlation between cardinal and ordinal POP-Q values and PQOL scores the prolapse was then categorised as either mild or severe as determined by the most distal point of the prolapse in relation to the hymenal remnant commencing at the hymenal remnant (Aa or Ba 0 - this point was chosen as there were few women with maximal descensus of the prolapse proximal to the hymenal remnant) and Spearman correlations rerun with the dichotomised data. The process was reiterated in increments of 1cm distal to the hymenal remnant until the best fit of data correlating the anatomical findings and QOL were obtained.

In addition to collecting data on QOL, the PQOL questionnaire collects data on symptoms with possible ratings of "Not applicable" "None" "A little" "Moderately" or "A lot". These data were combined in to symptom complexes of overactive bladder, stress incontinence, urinary voiding difficulties, vaginal discomfort, bowel dysfunction and sexual dysfunction. Each of these categories was dichotomised

as either (1) present or absent and (2) absent-mild or moderate-severe. Spearman correlations were calculated between symptoms, POP-Q and PQOL data. Approval for this study was obtained from the Ethics Committee of the Central Northern Adelaide Health Service and all participants gave written informed consent.

RESULTS

All women had stage 2 or higher anterior compartment prolapse and most women had coexisting apical and posterior compartment prolapse (Table 1). The mean (SD) age of the cohort was 61.5 (11.7) years and median parity 3 (range 1-8). Fifteen women had previous hysterectomy. Twenty-five of the thirty-six women who were sexually active reported some difficulties sexually, thirty women reported stress incontinence, forty-two overactive bladder, forty-three voiding difficulties (straining to void, slow stream or sensation of incomplete voiding). Three women whose predominant symptoms were overactive bladder reported no sensation of a vaginal bulge (each with prolapse at or beyond the hymenal remnant). There was no significant correlation between the POP-Q stage of the prolapse of any compartment and any of the eight domains of the PQOL questionnaire (Table 2). Analysis of the correlation between QOL and the most distal part of the prolapse measured in 1cm increments commencing at the hymenal remnant showed that the most critical point was + 2cm, in which significant correlations were detected in five of eight domains (Table 3). However, all the significant correlations were weak or mild, with r ranging from 0.28 to 0.36. Symptoms dichotomised into absent-mild versus moderate-severe most closely correlated with QOL parameters (Table 4) and the symptoms of overactive bladder most closely correlated with QOL, though again the correlations were at best mild (r □0.49). Although forty-two women complained of symptoms of a bulge or related vaginal discomfort there was no correlation between those symptoms and the severity of the prolapse.

DISCUSSION

This study shows that PQOL domains as expected are measuring an adverse effect of POP in symptomatic women. However, in contrast to Digesù et al,[11] we found no correlation between POP-Q stage and PQOL scores. Digesù et al devised the PQOL questionnaire and reported statistically significant, moderate correlations between POP-Q stage and QOL domains in 145 symptomatic women. Although our smaller study size is a limitation, the very low correlation coefficients (table 2) do not suggest a type II error and it is more likely that the contrasting findings are explained by differences in populations. In our study all women had been referred for surgical management of anterior compartment POP. 42% of our population had prolapse beyond stage 2 in contrast to 24% in the publication by Digesù et al. It is possible that women with POP who are electing surgery have a significant adverse effect on QOL that is independent of the stage of the prolapse. In this study the best correlation between QOL and the severity of the anatomical defect was observed when the most distal part of the prolapse was more than 1cm beyond the hymenal remnant. This suggests that the POP-Q staging system is insensitive and that surgeons would be better advised to use ordinal data to describe the anatomy.

This study found that symptoms did not correlate with POP-Q staging but did correlate somewhat with QOL. Presence of a bulge (and/or its related discomfort), voiding dysfunction and overactive bladder were the commonest symptoms in this group and of these overactive bladder had the best correlation with QOL. Three women (6.6%) with stage 2 prolapse did not complain of a bulge and were predominantly troubled by overactive bladder. We found no correlation with symptoms of a bulge and either anatomical findings or QOL, in contrast to other reports.[3,7] The difference is best explained by different populations. This study has reported on a surgical population with predominantly anterior compartment prolapse and others on mixed clinical populations including symptomatic and asymptomatic women. POP-Q staging of prolapse does not relate well to function and POP-Q stage 2 does not appear to be a good choice to determine surgical failure. We found the correlation between the anatomical severity of the prolapse and QOL to be statistically significant but weak and only when the prolapse had extended more than 1cm beyond the hymenal remnant. Poor correlation between symptoms and anatomical findings is a consistent finding in the literature.[2-7] QOL questionnaires go further by semi-quantitatively measuring the effect of symptoms as opposed to just noting their presence. In symptomatic women presenting for surgery there may be no useful correlation between anatomical findings and QOL. The reason for this poor correlation is poorly understood and it creates a dilemma for surgeons and researchers. The literature on test-retest reliability suggests that both anatomical diagnoses and QOL data are reproducible.[1, 11-13] The poor correlation between "objective" anatomical criteria and subjective symptoms and QOL data

TABLE 1. – POP-Q stages for each compartment in 45 women presenting for surgical management of anterior compartment prolapse.

Compartment	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
Anterior	0	0	26	19	0
Apical	21	8	14	2	0
Posterior	11	13	21	0	0

TABLE 2. – Quality of Life and Spearman correlation coefficients for PQOL domains and highest POP-Q stage of the prolapse.

Domain	Median (interquartile range)	Correlation with stage of prolapse (p value)	Domain	Median (interquartile range)	Correlation with stage of prolapse (p value)
General Health	25 (6-25)	0.17 (0.28)	Personal Relations	50 (4-83)	-0.36 (0.11)
Life Affect	67 (33-100)	0.08 (0.59)	Emotions	33 (14-66)	0.08 (0.59)
Role Limitations	32 (0-66)	0.23 (0.13)	Sleep and Energy	33 (20-66)	0.28 (0.07)
Physical and Social Limitations	23 (7-52)	0.12 (0.42)	Severity Measures	25 (16-48)	0.21 (0.17)

TABLE 3. – The Spearman correlation between QOL parameters and anatomical severity of prolapse in 45 women presenting for prolapse repair. Data dichotomised for analysis as "mild" or "severe" commencing at and then in 1cm increments distal to the hymenal ring.

Domain	≥0cm	p value	≥1cm	p value	≥2cm	p value	≥3cm	p value
General Health	0.05	0.73	0.09	0.53	0.36	0.01*	0.20	0.17
Life Affect	0.06	0.66	0.01	0.91	0.28	0.05*	0.07	0.63
Role Limitations	0.11	0.46	0.24	0.11	0.28	0.05*	0.12	0.40
Physical and Social Limitations	0.13	0.39	0.06	0.65	0.28	0.05*	0.01	0.95
Personal Relations	-0.17	0.46	-0.45	0.04*	-0.01	0.95	-0.01	0.95
Emotions	0.04	0.78	0.01	0.90	0.29	0.05*	0.04	0.75
Sleep and Energy	0.38	0.01*	0.10	0.50	0.22	0.13	0.13	0.38
Severity Measures	0.24	0.10	0.09	0.52	0.24	0.11	0.02	0.85

TABLE 4. – Spearman correlation coefficients between symptoms, POP-Q stage, POP-Q ordinal measurements and QOL parameters in women presenting for surgical management of prolapse (** p <0.05, # p <0.10).

r	Overactive bladder	Stress incontinence	Voiding dysfunction	Vaginal discomfort	Bowel dysfunction	Sexual dysfunction
POPQ stage anterior	-0.09	-0.11	-0.28	-0.07	0.00	-0.28 #
POPQ stage apical	-0.18	-0.10	-0.11	0.05	0.09	-0.02
POPQ stage posterior	0.05	0.23	-0.20	0.01	0.15	0.14
Aa	0.02	-0.14	-0.13	-0.20	0.07	-0.22
Ba	0.00	-0.28 #	-0.10	-0.03	-0.01	-0.09
C	-0.05	-0.22	-0.12	0.13	0.08	0.08
D	-0.09	-0.30	0.05	0.03	0.09	0.18
Ap	-0.07	0.32 **	-0.19	-0.02	0.20	-0.06
Bp	-0.04	0.25	-0.24	0.17	0.22	0.10
General Health	0.32 **	-0.03	0.16	0.00	0.02	0.04
Life Affect	0.43 **	0.26 #	0.35 **	0.08	0.14	0.21
Role Limitations	0.28 #	0.28 #	0.20	0.01	0.27 #	0.04
Physical and Social Limitations	0.36 **	0.36 **	0.37 **	0.15	0.15	0.22
Personal Relations	0.42 #	0.20	0.15		0.00	0.41 #
Emotions	0.43 **	0.34 **	0.25	0.14	0.21	0.30 #
Sleep and Energy	0.49 **	0.20	0.17	-0.05	0.36 **	0.05
Severity Measures	0.44 **	0.29 #	0.31 **	0.15	0.12	0.03

could be explained by factors that we tend not to measure such as behavioural traits of the woman, her personal resilience and ability to cope, and the effect that family, friends and also perhaps her medical practitioner may have on her perception of her health. Using an analogy, perception of pain from similar stimuli (e.g. an operation such as a routine hysterectomy) varies widely amongst individuals and can be modified by expectation. In a similar manner it is likely that the perception of discomfort from a prolapse of a defined magnitude will vary widely and that personal resilience and the influence of others may serve to either alleviate or exacerbate this.

In conclusion, in women presenting for surgical management of POP there appears to be no useful relationship between anatomical findings, symptoms and QOL. All are important parameters that measure different things - how a prolapse looks, how it feels and how those feelings effect the woman's life. In contrast to the opinion expressed in the original POP-Q paper [1] it appears to be more useful for surgeons to express the anatomy of a prolapse using ordinal descriptors rather than POP-Q staging. In particular, POP-Q stage 2 is not a useful discriminator between surgical success and failure. However, most clinical trials or retrospective research will not be sufficiently powered to use continuous (ordinal) data in analysis without making some arbitrary decision to dichotomise between "success" and "failure" based on a threshold value of maximal descensus. This value would appear to lie between –0.5 and +0.5 for discriminating between symptomatic and asymptomatic women in unselected populations[7,11] but this does not appear to be an appropriate threshold for surgical populations. More research is required to determine what if any threshold value should be used to define surgical "success" and "failure".

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MECHANICAL CLEANSING OF PERINEAL WOUNDS

Mechanical cleansing of secretions is considered as an essential procedure for healing in the management of open perineal wounds (post fistulectomy, etc.) varying both in size and depth.
The disposable, biocompatible sponge "**SPONGY"** is indicated for use after removal of the haemostatic gauze/plug, which is applied in the operating room. A few hours after application, the sponge is already soaked with secretions that entirely penetrate into it. Frequent replacement of the sponge in the wound (every 6-8 hours) allows removal of either serous, fibrinous or purulent secretions, thus considerably facilitating the granulation process of tissue repair.
The sponge is supplied in sterile blocks in various sizes, and it may be introduced into the wound either dry or after dampening with saline. For the first application, the doctor shapes the sponge with scissors to suit wound size and shape, and applies it inside the wound, ensuring good adherence to wound edges. The patient can later shape the other sponges likewise. These will gradually grow smaller. As days pass, insertion of the sponge will become slightly more difficult, but not painful. Either weekly or fortnightly follow-up examinations will enable the doctor to evaluate the healing status of the wound.

Disposable, biocompatible sponge made of hydrophilic polyurethane - supplied in three sizes - for the management of wounds that heal by second intention.

FAECAL INCONTINENCE, OBSTRUCTED DEFECATION, DYSSYNERGIA, VAGINISMUS

PRAP 2000 / Pelvic Rehabilitation Active and Passive is a simple and precise tool for objective and repeatable assessment of sphincter contraction and release capacity by means of the **Solid-Sphere Test**. The **PP Sphere** /Push-Pull Sphere is a disposable anal or vaginal probe comprising an ovule, a rod fitted with safety disk and a ring. Evaluation of anal resistance to friction yields data on voluntary contraction pressure (assessment of the external sphincter) and on resting pressure (assessment also of the internal sphincter). Anal hypertone and incapacity to contract and/or to release the external sphincter can be evaluated, and also the incapacity to release pelvic muscles in vaginismus. Once the ovule/sphere is inserted into the rectum (in case of constipation or of faecal incontinence) or into the vagina (in case of pelvic floor muscle deficiency with urinary incontinence and prolapse), the **PRAP 2000** hook is inserted into the probe ring; **PRAP 2000** is switched on and P.E.T. (Peak Effort Traction) values are reset on the screen. At this point a detailed three-phase study (Solid-Sphere Test) can be performed: the first step implies the slow extraction of the probe at rest, the second with contracted muscles and the third during strain.
The electric signal produced by **PRAP 2000** presents an approximate variation of 0 - 2.4 Volts for traction in the range of 0 - 2000 P.E.T.
Processing of values displayed on the screen leads to the choice of the most suitable treatment for the patient, also for use at home.

Prap 2000 and PPSphere, evaluation tool of sphincter contractile capacity.

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