Original article

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

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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-

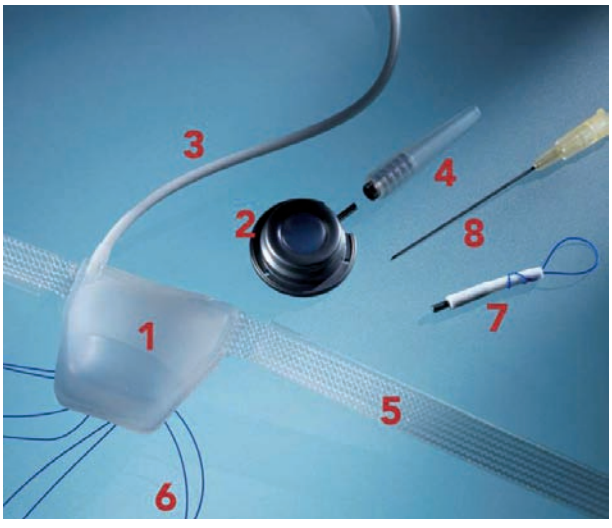

Figure 1. – ATOMS implant. 1) Cushion; 2) Port; 3) Catheter; 4) Puncture protection; 5) Mesh arm; 6) Fixation suture; 7) Catheter coupling piece. Photos courtesy of A.M.I. GmbH.

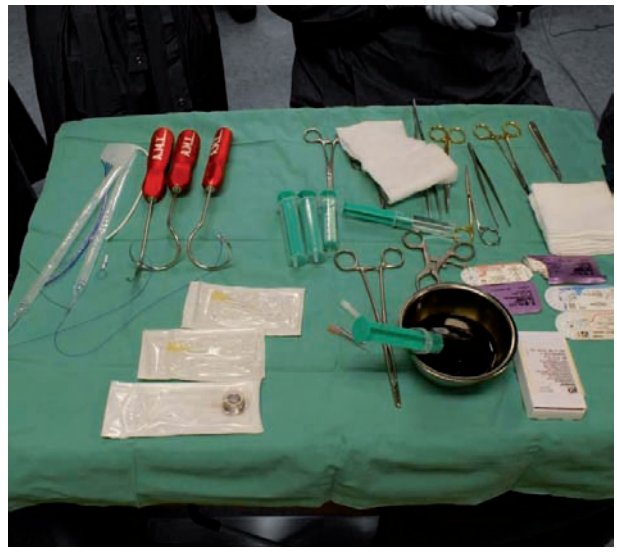

Figure 2. – Instrument table in preparation for ATOMS implantation.

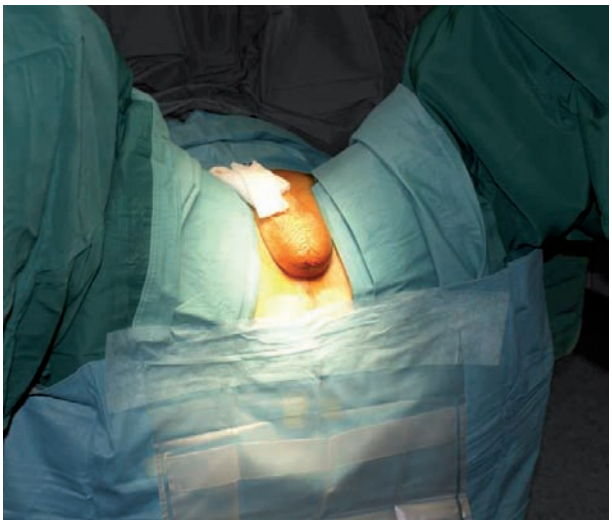

Figure 3. – Patient is placed in lithotomy position.

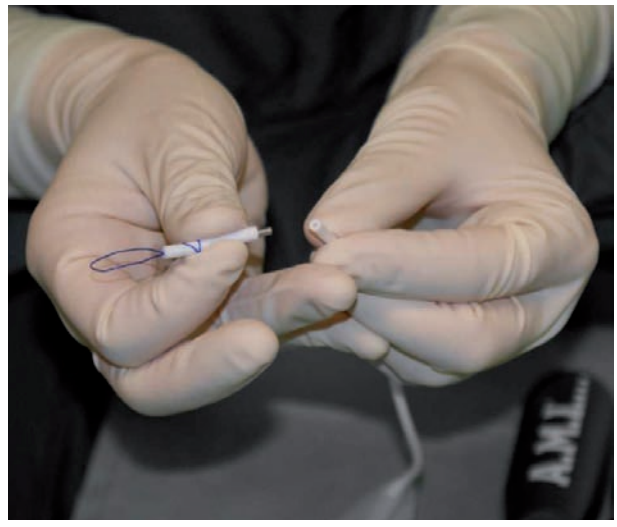

Figure 5. – Coupling piece is attached to catheter.

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).

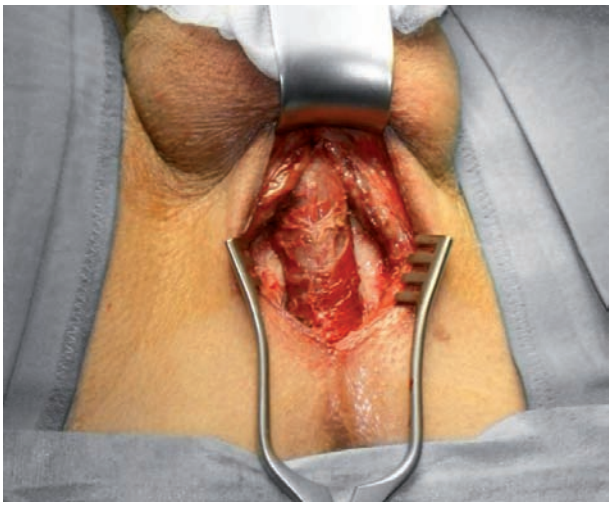

Figure 4. – Preparation of musculus bulbospongiosus.

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-

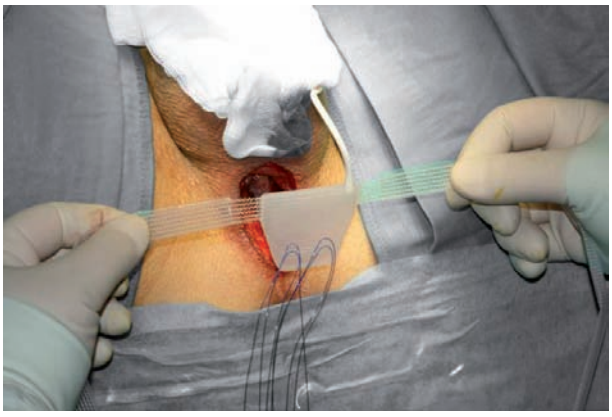

Figure 6. – ATOMS implant positioned correctly.

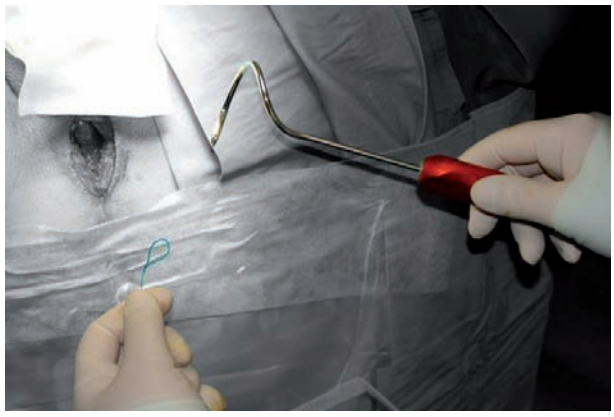

Figure 7. – Mesh arm's suture loop is hooked onto tunneller.

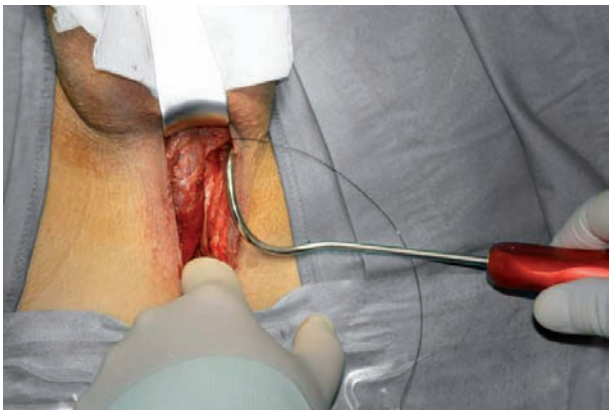

Figure 8. – Left tunneller penetrates obturator foramen.

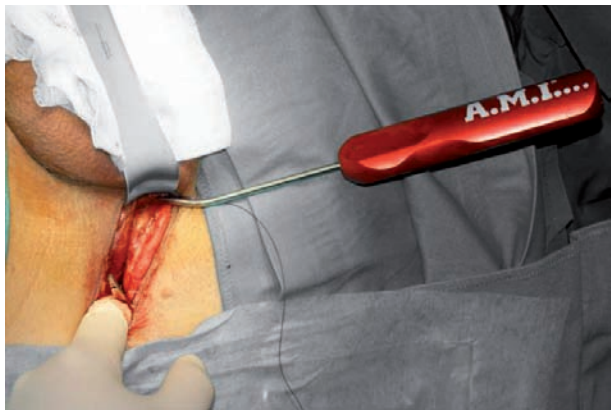

Figure 9. – Tip of left tunneller in distal perineal wound.

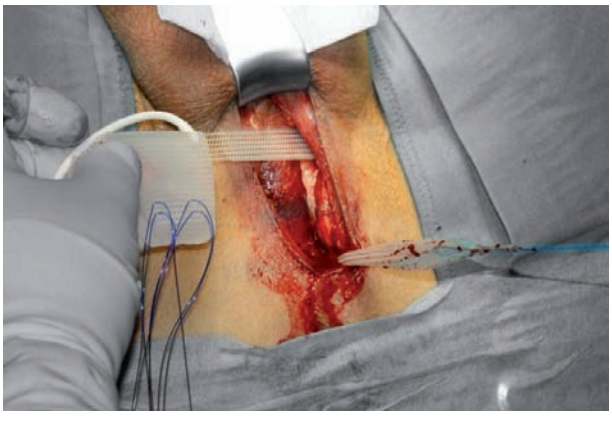

Figure 10. – Left mesh arm is pulled through.

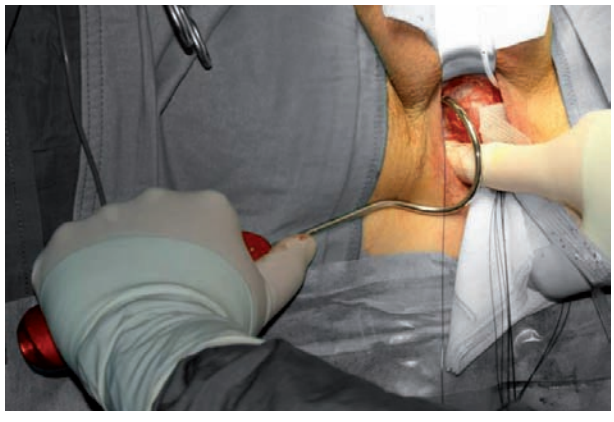

Figure 11. – Right tunneller penetrates obturator foramen.

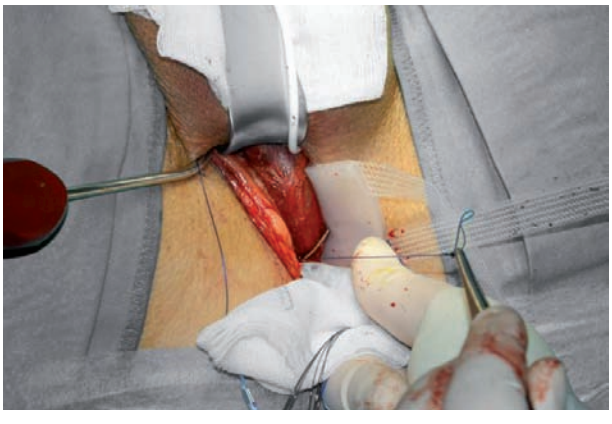

Figure 12. – Forceps release right suture loop.

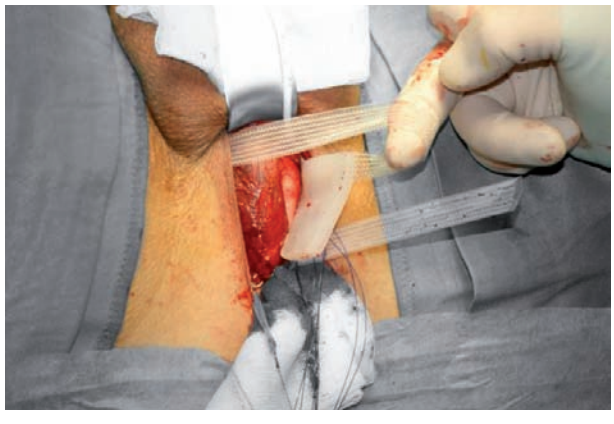

Figure 13. – Right mesh arm is pulled through.

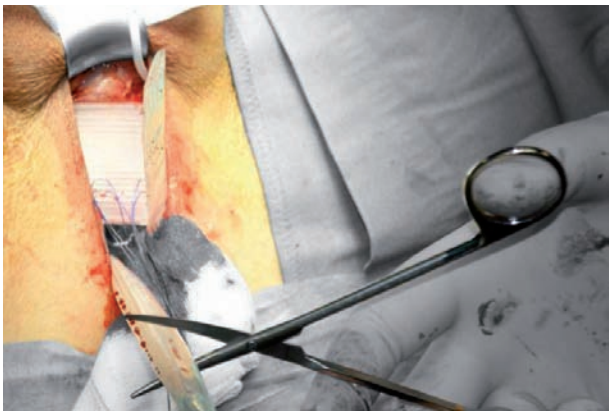

Figure 14. – Protective sleeve on mesh arm is removed.

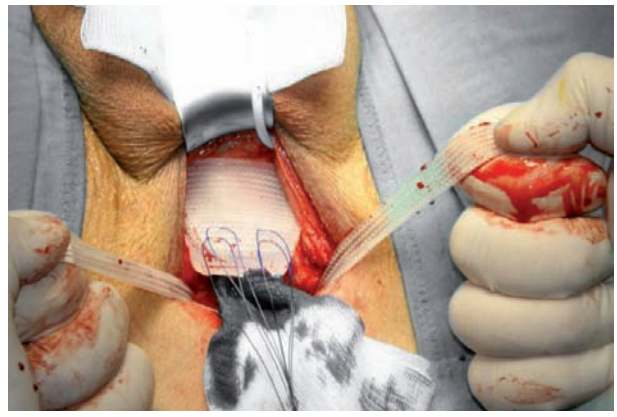

Figure 15. – Mesh arms are tightened equally.

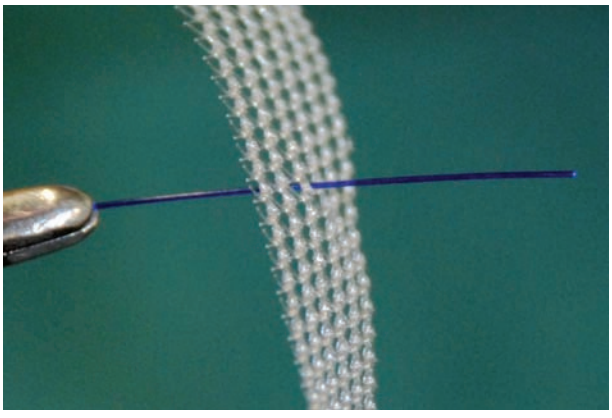

Figure 16. – Fixation sutures are threaded through mesh.

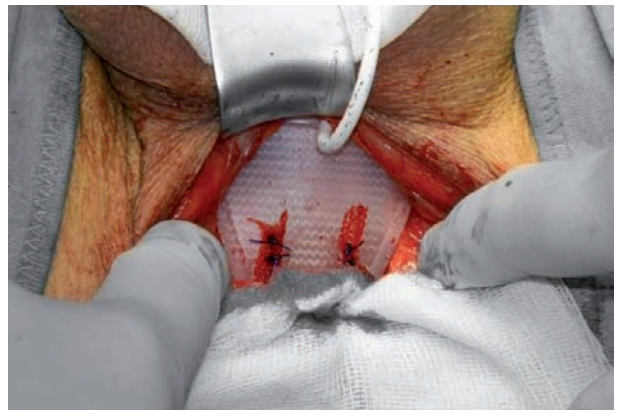

Figure 17. – All four fixation sutures are tightened.

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.

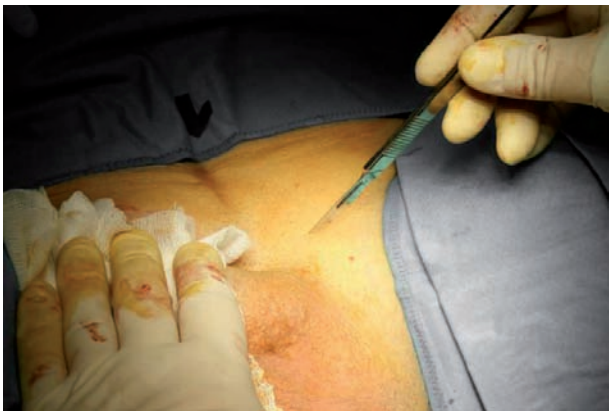

Figure 18. – Port incision is made in left symphyseal region.

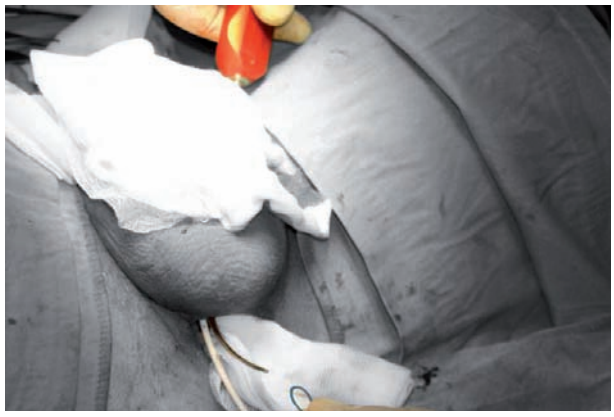

Figure 19. – Tunnelling to connect catheter to port.

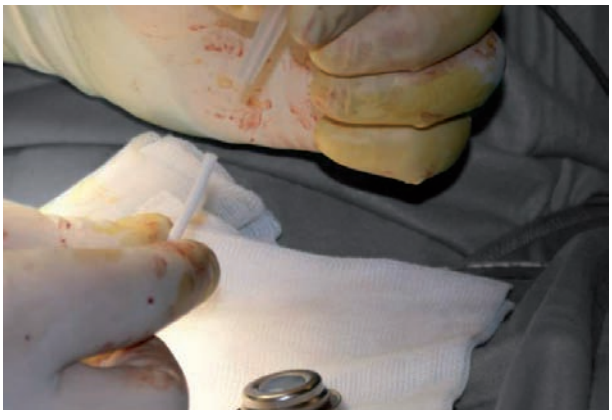

Figure 20. – Puncture protection is placed over catheter.

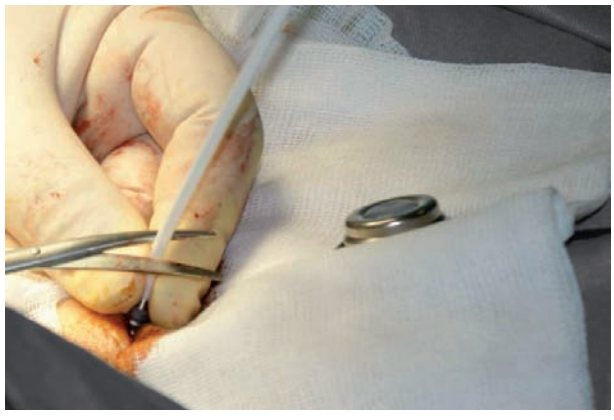

Figure 21. – Catheter cut down to correct length.

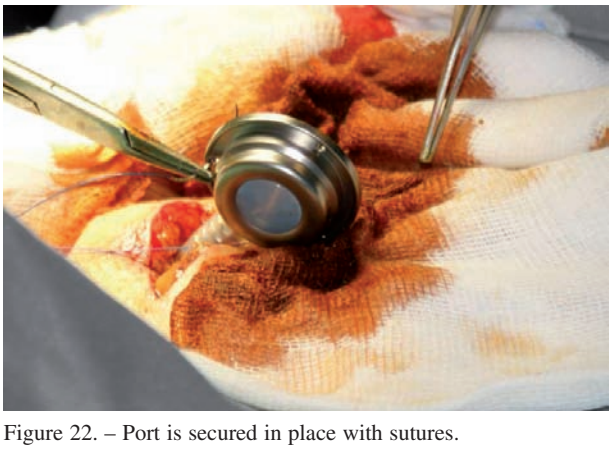

Figure 22. – Port is secured in place with sutures.

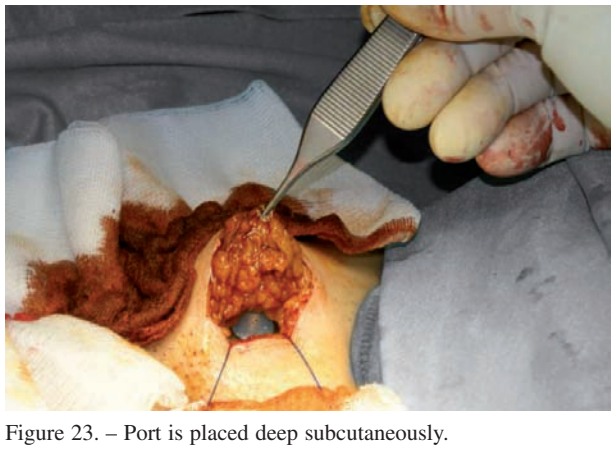

Figure 23. – Port is placed deep subcutaneously.

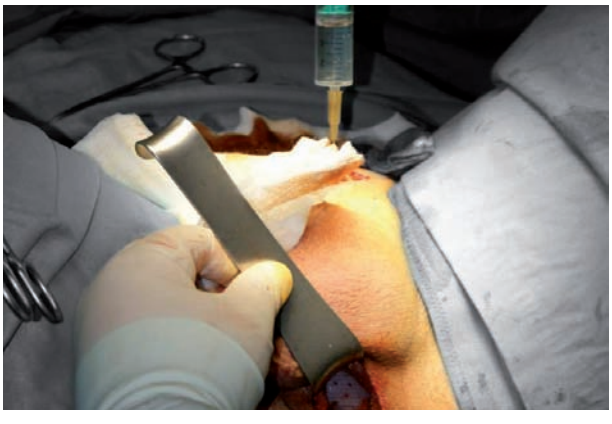

Figure 24. – Implant is emptied of air and filled intraoperatively.

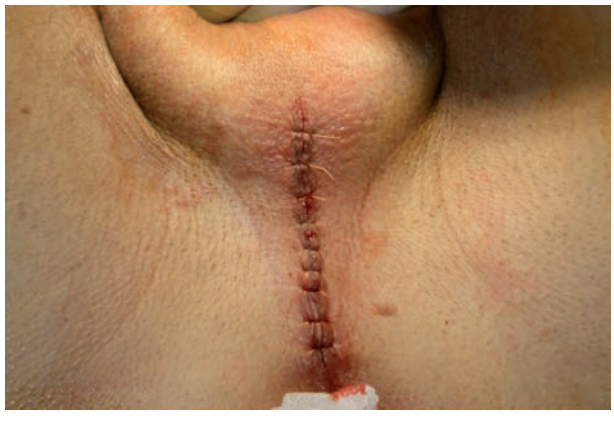

Figure 25. – Perineal wound on completion of the procedure.

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

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