

Urethral support with PelviSoft™ after artificial urinary sphincter erosion at revision procedures

Peter Rehder¹, Germar-Michael Pinggera², Michael Mitterberger², Alexandre E. Pelzer², Christian Gozzi², Ralf Herwig³

¹Neurology Unit, Medical University of Innsbruck, Innsbruck, Austria

²Department of Urology, Medical University of Innsbruck, Innsbruck, Austria

³Department of Urology, Medical University of Vienna, Vienna, Austria

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Die Verstärkung der Harnröhre mit Pelvisoft™ bei rezidiveingriffen nach künstlichem harnröhrensphinkter mit arrosion

Zusammenfassung. Die Implantation einer künstlicher hydraulischer Sphinktermanschette (AMS 800) wird als chirurgischer Goldstandard bei abwesender Restfunktion des Schließmuskels betrachtet. Nach einer Harnröhrenarrosion bei liegender künstlicher hydraulischer Sphinktermanschette (AMS 800) muss das gesamte System ausgebaut werden. In dem die Harnröhre über die Schwachstelle, nach Abheilung, mit einem acellulären Kollagen BioMesh (PelviSoft™) verstärkt wird kann neuerlich ein künstliches Schließmuskelsystem implantiert werden. Die Kurzzeitergebnisse sind ermutigend. Die Funktion des Sphinktersystems scheint durch die Harnröhrenwandverstärkung nicht gefährdet zu sein, bzw. die Manschette kann die Harnröhre genügend komprimieren um die Kontinenz zu gewährleisten.

Schlüsselwörter: Harninkontinenz, operative Technik, künstlichen Schließmuskel, BioMesh.

Summary. An artificial urinary sphincter cuff (AMS 800™) is regarded the gold standard for surgically treating urinary incontinence without residual sphincter function. After erosion of an AMS 800™ into the urethral lumen the whole system has to be explanted. When the urethral wall is supported and covered after healing with a porcine dermal acellular collagen matrix BioMesh (PelviSoft™), a new artificial urinary sphincter may be implanted. The follow-up of up to two years seems promising in preventing erosion of the new cuff through the strengthened urethra wall, without compromising the functionality of the artificial urinary sphincter.

Correspondence: Dr. med. univ. Peter Rehder, MD, Neurology Unit, Medical University of Innsbruck, Anichstraße 35, 6020 Innsbruck, Austria.

Fax: ++43-512-50424799

E-mail: peter.rehder@uibk.ac.at

Key words: incontinence, artificial sphincter, operative technique, BioMesh.

Introduction

The treatment of urinary incontinence in complex cases, especially after failed procedures, includes the implantation of an artificial urinary sphincter (AMS 800™, American Medical Systems, Minnetonka, Minnesota, USA). In men, the cuff is placed around the bulbar urethra, and in women and in patients with neurogenic incontinence, the cuff is placed around the bladder neck. The urethral cuff occludes the urethral lumen by pressure that is transmitted to the urethral wall by the filled circular balloon. This constant pressure on the urethral wall causes atrophy and in some cases erosion. Urethral reconstruction after erosion of an artificial urinary sphincter cuff can be rather complicated in both men and women [1]. Erosion of a cuff causes secondary infection of the whole system along the silicone sheathed tubes, necessitating explantation. After urethral closure and healing, another artificial sphincter system may be implanted. One remaining problem is the atrophied and scarred urethra, meaning that a second attempt at placing the cuff at the same position will have a high probability of re-erosion. In men, the transcorporeal approach has been used to augment the dorsal urethral surface when placing another cuff in the same position or when choosing a more distal position [2]. In women, the bladder neck may be reconstructed and covered with a peritoneal or omental flap, before placing another bladder cuff [1, 3]. In men, rather complex measures to reconstruct the urethra including cadaveric fascia have been undertaken with varying results [4]. The availability of porcine dermal acellular collagen matrix (PelviSoft™ BioMesh, CR Bard, Cranston, R. I., USA), clinically already in use in gynecology, opens new possibilities to strengthen fibrosed and atrophied tissue [5].

In this study PelviSoft™ was used to augment and buttress the urethral wall and bladder neck before inserting another artificial urinary sphincter cuff. Most patients want to maintain their natural urinary system as far as possible, and choose to have another artificial sphincter rather than a urinary bypass procedure. Experience at the Mayo Clinic, Rochester, Minnesota, USA, showed encouraging results with de novo reimplantation. De novo reimplantation is defined as implantation of an artificial sphincter following removal of a previously placed sphincter for erosion and/or infection and a waiting period of several months. Over a period of ten years, 412 AMS 800™ systems were implanted, of which 64 (15.5 %) had bladder neck or urethral erosions. Of these, only 38 (59.4 %) were reimplanted with a successful outcome in 32 (84 %) cases [6, 7]. The lack of healthy urethral tissue often prevents the placement of a new cuff, leading to persisting incontinence or urinary diversion. From own experience, peritoneal and omental flaps, tunica vaginalis flaps and local soft tissue flaps used to cover a thinned out urethra before placing another sphincter cuff did not prevent re-erosion. An innovative way of preparing the atrophied urethral wall is to cover it with a biological mesh that allows ingrowth of microvasculature and tissue. This augmented urethral wall is then stronger and better able to withstand the constant pressure of the filled artificial sphincter cuff.

Material and methods

Six patients were identified as requiring removal of the artificial sphincter because of erosion into the lumen through the urethral wall. A de novo reimplantation was planned after waiting between three and six months for healing after the AMS 800 system had been taken out. Informed consent was obtained for augmenting the urethral wall with PelviSoft™ for a maximum of 75 % of the circumference before placing the cuff. This was only done if no other position along the urethra could be found to successfully place the cuff. The transcorporeal approach [2] was preferred if the previous cuff had eroded in the 12 o'clock position through the urethral wall, but not if erectile function was an issue. All patients preoperatively had a flexible urethroscopy and cystoscopy to exclude urethral stricture disease and bladder pathology. A urine flow study was done and residual urine measured by suprapubic ultrasound (BladderScan® BVI 3000, Diagnostic Ultrasound Corporation). Exclusion criteria were ongoing tissue and/or urinary tract infection and skin ulceration, urethral stricture disease, residual urine volume of more than 50 ml and neurogenic bladder dysfunction.

Via a midline perineal [8] or transscrotal [9] approach the bulbar urethra was carefully explored. Identification of the bulbar urethra was made easier with a 14 French transurethral catheter in-situ. Using a rounded clamp the urethra was circumferentially prepared and a vessel loop placed for retraction. After removing the transurethral catheter, retrograde saline or diluted indigo carmine was injected into the urethral lumen to exclude urethral injury intraoperatively under direct vision. After measuring the urethral circumference the sphincter cuff was positioned. The urethral wall was only augmented when it was thinned out and scarred, to decrease the chance of erosion. The rest of the AMS 800 sphincter system was implanted according to the instructions on the product insert (American Medical Systems, Minnetonka, Minnesota, USA).

The pump was positioned in the scrotum and the reservoir intraperitoneally into the pelvis. A 12 French transurethral catheter was left in situ for 10 to 14 days. All patients received intraoperative intravenous antibiotic prophylaxis (cephalosporin and an aminoglycoside) that was also given for another three postoperative dosages, followed by a five-day course of oral antibiotics (quinolone). The sphincter system was activated six weeks postoperatively.

Results

In two patients it was possible to place the new cuff around the non-scarred urethra further distal than the previous one. Cuff size in these two cases was 4 cm. In these cases it was not necessary to use the BioMesh. In four patients the scarred and atrophied urethrae were strengthened with Pelvisoft™ (Fig. 1). Maximally 3/4 of the urethral circumference was covered with the collagen matrix to maintain enough suppleness for effective compression by the filled cuff. Around the urethra and Pelvisoft™ the sphincter cuff was positioned (Fig. 2). The sizes varied from 4.5 cm (two patients), 5 cm (one patient) and 6.5 cm (one patient). The last patient had severe urethral scar-



Fig. 1. Dorsal bulbar urethral augmentation with acellular matrix via a transscrotal approach



Fig. 2. AMS 800 sphincter cuff around the bulbar urethra that is dorsally supported by PelviSoft™ to prevent erosion

ring and atrophy involving the whole circumference. Dorsally the cuff was positioned transcorporeally [2] and ventrally the urethra was augmented with the collagen matrix. In the other patients the dorsal urethral wall was covered with BioMesh. All patients had an uneventful recovery, and no longer needed pads. With a follow-up of 23 to 26 months all patients are still fully continent. One patient uses a “safety” pad. Post-operative transscrotal ultrasound (Acuson Sequoia, USA; 15 MHz probe) confirmed good healing with no fluid extravasation or scar tissue formation. After six months follow-up the collagen matrix looked like normal tissue and there were no signs of calcification at the sonographic examination. No patient experienced de novo urgency. Two patients already used anticholinergics (tolterodine) before surgery and also carried on using it afterwards.

Discussion

The thinnest part of the bulbous urethral wall is the dorsal area in the 12 o'clock position. Poor operative technique may cause urethral injury or perforation leading to cuff erosion. Patients having had urethral stricture disease with internal urethrotomy in the 12 o'clock position, previous cuff erosion or forgoing open urethral surgery are traditionally not good candidates for receiving a bulbar artificial sphincter cuff. An acellular collagen matrix BioMesh opens up new possibilities for these patients. Most patients prefer their natural urinary tract to be continent and to urinate. Even after going through a cuff erosion and explantation, it is our experience that patients rather opt for another artificial sphincter given half a chance of success. When no unscarred urethra is available the transcorporeal approach is a possibility to protect the dorsal bulbar urethral surface in a revision cuff implantation [2]. We found using tunica vaginalis or local scrotal tissue flaps to cover the injured or atrophied urethra before placing the cuff was unsatisfactory (unpublished data). After previous urethral surgery, the bulbar urethra often is very atrophied and is not resilient enough to withstand cuff pressure. An acellular collagen matrix allows ingrowth of microvessels forming vascu-

larized tissue functioning as a barrier underneath the silicone balloon cuff. We propose not totally circumventing the urethra with BioMesh, as the increase in more rigid scar tissue might interfere with the compressive occlusive effect of the sphincter cuff. These early results utilizing PelviSoft™ to strengthen the urethral wall in cases of de novo reimplantation of an artificial sphincter cuff are encouraging. The follow-up of about two years in these four patients showed that there were no complications, and the transscrotal ultrasound demonstrated that the BioMesh was integrated into the urethral wall.

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