



Editorial – referring to the article published on pp. 574–580 of this issue

## Reflections on a New Artificial Urinary Sphincter

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Before the early 1970s the treatment of urinary incontinence owing to intrinsic sphincteric deficiency, particularly in men with this problem after prostatectomy, posed a nearly insurmountable challenge. Operations using the patient's own tissues as well as bulbous urethral sling-type procedures with various types of prosthetic materials produced inconsistent and nondurable results [1–4]. The artificial urinary sphincter was introduced in 1973 [5]. In the first 10 yr after its introduction the basic device design changed four times. The fifth generation model, the AMS Sphincter 800 (American Medical Systems, Minnetonka, MN), was introduced in 1983 [6]. To decrease mechanical failure numerous changes have been made to the various components of this device; however, its basic design and mode of operation have remained unchanged for >20 yr.

The AMS Sphincter 800 consists of three components: a urethral cuff, a scrotal pump-control assembly, and a single pressure-regulating balloon (PRB), which is usually implanted in the retropubic space. These three components are implanted individually and then connected by two tubing connectors. The control assembly, which is above the pump, has valves controlling the direction of flow, a delayed filled resistor, and a deactivation button. After the device is implanted, the pump is

used to open the cuff, and the device is then deactivated. At the time of the first postoperative office visit when tissue swelling due to the urethral dissection has resolved and the tenderness around the scrotal pump has subsided, the device is activated by forcefully squeezing the pump. The patient is then instructed on how to use the artificial sphincter.

After device activation when the patient wishes to void, he squeezes the pump until it stays collapsed, signaling complete cuff emptying. During this process cuff fluid is transferred into the PRB. During micturition, fluid is transferred back from the PRB through the delayed filled resistor into the cuff until cuff and PRB pressures are equal. The PRB thus serves as a reservoir for cuff fluid during voiding, as the engine for cuff refilling, and as the regulating device for cuff pressure. When the patient is at rest, the PRB and urethral cuff pressures are between 61 and 70 cm H<sub>2</sub>O, which is believed to be safe for the urethra. When bladder pressures increase because of physical activity, PRB pressures increase by a similar amount, thus potentially protecting against stress-induced loss of urine.

The delayed activation button is not only useful for device activation after implantation, but it can also be used to deactivate the device at anytime after implantation. This becomes useful if urethral

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catheterisation is needed. If the device is deactivated and a small urethral catheter is used, a catheter can remain for several days without cuff erosion.

A short-coming of the AMS Sphincter 800 is that not all patients are protected against incontinence secondary to sudden increases in intra-abdominal pressure, suggesting that the PRB is not always efficient in this regard. Atrophy of the urethra is also another potential cause for stress incontinence. Currently, both of these problems are often managed by tandem cuff revision [7]. Another problem is urethral cuff erosion, which, when it occurs soon after implantation, is probably secondary to injury during urethral mobilisation. Late urethral erosion often follows the use of an indwelling urethral catheter without device deactivation or possibly after improper device deactivation. The incidence of late cuff erosions and urethral atrophy might be reduced if lower urethral cuff pressures were used. Implantation of a second artificial sphincter after cuff erosion is now often facilitated by the transcorporeal cuff approach [8]. A final problem with the AMS Sphincter 800 is cuff leaks, which most often occur along creases in the cuff.

Knight et al. [9] describe and report results using the first commercially available artificial sphincter alternative to the AMS Sphincter 800. Their device is implanted as a single unit, thus eliminating the need for tubing connections. The prosthesis consists of a urethral cuff, a scrotal pump-control assembly, and two PRBs. When healing is complete, a self-sealing port at the bottom of the pump allows the device to be activated by fluid injection. Furthermore, pressures can be adjusted at a later date by injecting additional fluid. The circular occlusion cuff reportedly minimises creasing and thus potentially cuff leakage. Unlike the AMS Sphincter 800, this new device does not have a deactivation feature although presumably deactivation could be accomplished by withdrawing fluid from the port with subsequent reactivation being done by the repeat injection of fluid. Whether this method of device activation and deactivation will be equal or superior to the deactivation feature built into the AMS Sphincter 800 will become apparent with longer follow-up.

A proposed advantage of this new device is the lack of tubing connections. If tubing connections significantly lengthened implant time or were a source of mechanical failure, this might be true. The average time for us to make both tubing connections is <5 min and filling the components with isotonic contrast also takes <5 min. The empty PRB is

implanted into the retropubic space through a fascial puncture, which just admits the surgeon's index finger. It is filled with fluid after implantation. This significantly reduces the time for PRB implantation probably compensating for the time to fill the components and make the two connections. Since the introduction of the sutureless Quick Connect (American Medical Systems, Minnetonka, MN) system in 1985, we have not experienced any connector failures, and it is probable that connector-related failures are now close to zero. Given these observations, I find it preferable to have components packaged and implanted separately; however, this is admittedly a personal preference.

Three important potential advantages of this new artificial urinary sphincter are evident. The second PRB may allow for more effective protection against stress-induced incontinence. If creasing is reduced, the circular cuff may prove to be more durable because cuff leaks with the AMS Sphincter 800 tend to occur in cuff creases. Finally, mean urethral pressures as measured by urethral pressure profilometry beneath the cuff in this study were < 40 cm H<sub>2</sub>O. These lower pressures may reduce urethral atrophy and erosion.

Knight and associates emphasise that this new device needs to be implanted in greater numbers of patients from multiple centres and with longer follow-up periods. If this experience reveals that any or all of the potential advantages exist, this new artificial urinary sphincter will become an important tool in the management of men, and perhaps women and children as well, with incontinence owing to intrinsic sphincteric deficiency.

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