Appendix D.—Artificial Sphincters: A Case Study

This appendix presents a case study of the development of the artificial sphincter, a surgically implantable device designed to treat urinary incontinence. Marketing efforts for this device are directed toward a small group of specialists: urologists. Primary concerns are with performance, success in accomplishing the prosthetic task, and minimizing complications.

The use of artificial sphincters is limited to the few conditions characterized by incompetence of the urinary sphincter. Since the device must be surgically implanted, it is relatively costly to use and its adoption depends on the enthusiasm of physicians, usually urologists.

In *1973,* a totally implantable, externally controllable, artificial sphincter was developed by Scott and his colleagues *(136).* The original idea came from Foley (62), who in 1947 first introduced the concept of external urethral compression using an inflatable cuff. Using a syringe-like mechanism, Foley inflated a cuff around the penis of incontinent males. This device never received widespread acceptance by the medical profession.

The device developed by Scott was made of silicon rubber and marketed by American Medical Systems (Minneapolis) as the AS 721 in the mid-1970s. Unlike Foley's device, this prosthesis could be used in both sexes and the cuff was surgically implanted to surround the urethra. The reservoir used to inflate the cuff was placed in the abdominal cavity. The two pumping mechanisms, implanted in the scrotum in males and the labia in females, were inflated and deflated by the patient. Each pumping mechanism consisted of a bulb and two valves. The valves controlled the direction of fluid flow inside the prosthesis and were designed to set the precise cuff pressure. The B4 valve was critical to controlling the pressure applied to the urethra. The valve ensured that regardless of the number of times the inflating bulb was squeezed, the cuff could reach a predetermined pressure equilibrium but avoid high, potentially harmful pressures.

The major problem with the AS 721 was valve failure. To increase mechanical reliability of the system, Model AS 761 was introduced in 1976. AS 761 eliminated the critical dependence on the valve through a pressure-regulating balloon. However, after testing the device, the Balloon Sphincter Clinical Study Group (10) found that 50 percent of the failures resulted from mechanical complications, so production was stopped.

The next model, AS 742, differed substantially from the previous devices. Rather than requiring manual inflation, the cuff of the newer model automatically inflated by fluid forced through a resistor set at a controlled rate by a pressure-regulating balloon. As a result, the patient operated only a deflating bulb. Results have shown a higher success rate (70 versus 50 percent) and fewer mechanical failures with this than with previous models. In addition, the device has been easier to implant and simpler to operate. The success of the AS *742* has depended on a balloon that maintains a low-pressure reservoir. High pressures around the urethra have been the main causes of urethral erosion, a very serious and often irreversible complication of sphincter implantation. The low-pressure balloon reservoir has reduced the number or urethral erosions but has not eliminated them completely. A major problem with the AS *742* has been the requirement that the cuff be inflated while tissue was healing in the immediate period after implantation.

Primary deactivation is a newer technique designed to reduce the rate of urethral erosion. With primary deactivation, the cuff is kept deflated after the sphincter is inserted, allowing the tissues to heal after the operation. The sphincter is activated several weeks later. Thus the newer sphincters (AS 791/792) resolve the problem of maintaining constant pressure under all circumstances with the AS *742* and are especially useful for high-risk patients (those who already have weak tissues from prior surgical procedures).

The most recent sphincter developed by American Medical Systems (AMS Sphincter 800TM) allows the initial activation of the device to be carried out without a second surgical procedure (which is sometimes necessary for AS 791 /792). Studies of this new model have not been published in the medical literature.

Studies of the older models have shown a 40 to 85 percent success rate (see above and table 3-l). According to data presented in a marketing brochure published by American Medical Systems, 4,000 children and adults have been helped by their artificial sphincters since they were first produced in 1972. Their data on the 486 implants of model AS 791/792 indicate that 74 percent were implanted in males; 32 percent in patients aged 20 or younger, 35 percent in patients aged 21 to 60; and 32 percent in patients older than 60. Thirty-five percent of these sphincters were implanted for post-prostate surgery (radical prostatectomy, 19 percent, and transurethral resection, 16 percent); 26 percent for myelomeningocele; 9 percent for spinal cord injuries; and the remainder for a miscellaneous group of conditions (generally involving necrologic abnormalities) (4).

An alternative sphincter was developed by Michael Rosen (128). This device was also made of silicon rubber and has a three-armed clamp that fits across the

urethra. One arm carries a balloon attached to a saline-filled reservoir bulb (positioned in the scrotum) and a release bulb. Compressing the reservoir bulb inflates the balloon, which partially increases the urethral resistance to maintain continence. To void, the release valve is pressed, which deflates the balloon. The advantages of this device are its relative simplicity, lack of circumferential compression, and the relatively short urethral dissection needed to implant the device.

Clinical studies in approximately 60 male patients demonstrated a 50 to 75 percent success rate (table 3-1), but some of the patients required more than one operation. Failures were most commonly caused by mechanical malfunction and infection. The longest functioning prosthesis lasted 26 months.

In summary, the artificial sphincter appears to be a treatment option for those patients with severe urinary incontinence caused by dysfunction of the bladder outlet and/or urethral closure mechanisms. This would include young patients with neurological disorders (e. g., myelomeningocele), women with stress incontinence who have not been helped by standard surgical correction procedures, and men with post-prostatectomy incontinence from sphincter damage, Thus, patients who are appropriate candidates for sphincters represent only a small proportion of the incontinent population. Improved mechanical properties of the sphincters and techniques of surgical implantation are likely to increase the success rate and diminish complications of these devices (75).