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Annotations

Artificial urinary sphincters

Artificial sphincters have been in the news recently, in both the lay press (and specifically on the radio) and the medical press. As a result there has been a surge of interest from various 'pressure groups', such as the Association for Spina Bifida and Hydrocephalus and the Multiple Sclerosis Society, and patients are now asking their medical advisers for information on the subject, particularly those who have heard, through their societies, or know of others who have been treated with these devices.

The only type of artificial sphincter that has received a general recommendation among urologists is the Brantley Scott artificial urinary sphincter (AUS), which is produced in the USA by American Medical Systems, Inc. None of the other currently available devices can be recommended and will not, therefore, be discussed further.

Brantley Scott artificial urinary sphincter

The Brantley Scott artificial urinary sphincter consists of a fluid filled cuff that is wrapped around the bladder neck in either boys or girls, or the bulbar urethra in boys, to provide a circumferential occlusive force. The pressure within the cuff is determined by a pressure regulating balloon connected to the cuff by means of a control pump. The control pump may be a single component (AS 800) or two separate components (the control assembly being one, the pump the other: AS 791/792) depending on which particular model of the device is being implanted. The function of the control assembly is to regulate the flow of fluid between the cuff and the balloon, which is always from balloon to cuff, thereby providing the occlusive force. When the pump is squeezed two or three times, however, thereby reversing the direction of fluid flow so that the cuff is emptied into the pressure balloon, the occlusive force is removed thus allowing the patient to void. The cuff then refills spontaneously from the pressure balloon over a three to five minute period, by virtue of the valve arrangement within the control assembly, thereby restoring the occlusive force.

The cuffs come in various lengths so that each device can be accurately fitted in its desired location, and the pressure regulating balloons are precalibrated during manufacture to produce pressures within specified ranges, so that in each patient an occlusive force appropriate to the local tissue characteristics can be chosen by the implanting surgeon. The entire device is internal and therefore

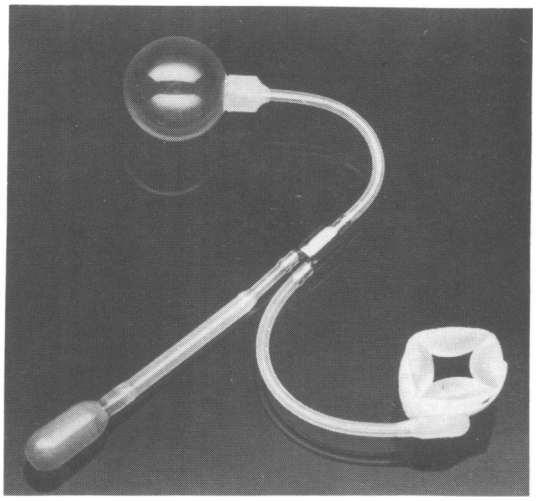

Fig. 1 *Brantley Scott Sphincter (AS791/792)*

The pump on the left is placed in the scrotum or the labium majus.

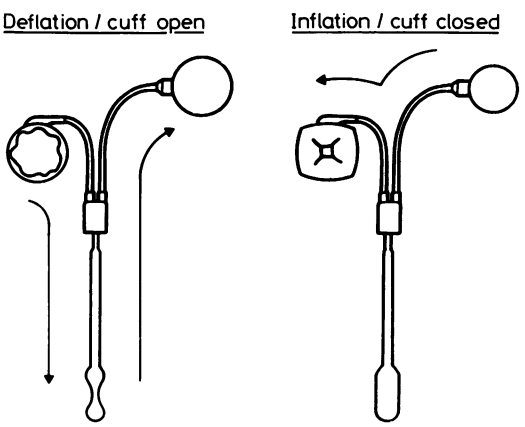

Fig. 2 *Diagram of mode of action.*

invisible; the pump is sited in the scrotum or labium majus to make it accessible to the patient. The smaller size of the pump in the model which has the control assembly and the pump as two separate components (AS 791/792 make that particular model more suitable for children.

Effectiveness of the sphincter

The models currently available are derived from an original model that was first implanted in 1971, and there have been several intermediate stages in their development. Overall, there are therefore 15 years of experience with the artificial urinary sphincter, although most implants, particularly in Britain and with currently available models, have occurred in the past five years. With this in mind, it is probably best not to assess the durability of the device in relation to the overall 15 year experience, but to assess its effectiveness in relation to the results over the past five years, during which time more than 2000 devices have been implanted worldwide.

There is no argument that the sphincter is an extremely effective way of dealing with incontinence caused by weakness of the natural sphincter mechanisms, when that is the only cause of incontinence. Most centres show at least a 75% long term cure rate in these cases. Factors that lead to concern are the problems and complications of the device, the cost effectiveness of the artificial sphincter compared with other forms of treatment for sphincter weakness incontinence, its role in the overall treatment of incontinent patients, and the logistic problems raised by all these factors when one comes to consider the provision of an incontinence service for a community.

Problems and complications

The problem with the artificial urinary sphincter is that of providing sufficient occlusive force to give continence without impairing the blood flow to the tissues being compressed to a degree that would lead to erosion of the cuff through those tissues. Erosion is mainly a problem in the elderly, and therefore is usually seen in patients who have had an artificial urinary sphincter for incontinence after prostatectomy. In younger patients, usually children with spina bifida, this is rare, particularly if a few weeks are allowed to elapse between implantation and activation of the device, to allow the local tissue response to surgery to resolve before the cuff is pressurised. Thus, although the overall continence rate after implantation is 75%, the success rate is about 90% in the younger age group.

By contrast, insufficient pressure leads to residual stress incontinence, and this is seen in about 10% of patients. It is treated by replacing the pressure balloon with one with a higher pressure range, and this almost invariably cures the problem.

Additional complications are rare, and are mainly infection, which is largely prevented by meticulous preoperative preparation and perioperative care to avoid contamination at the time of implantation, and mechanical failure, usually due to leakage of fluid from the system. The latter obviously requires replacement of the defective component and fortunately occurs in only 2 or 3% of patients.

Cost effectiveness

An artificial urinary sphincter costs about £2000 at current rates of exchange. This is expensive but doubtless will cost less when there are equally effective alternative devices on the market. Nonetheless, the cost of providing protective pants and absorptive pads or long term stoma care as alternatives makes an artificial urinary sphincter cost effective after about five years, over and above any other considerations relating to the desirability of continent urethral voiding.

Who should have it

The artificial urinary sphincter is a treatment for sphincter weakness only—and then only when other methods fail or are inappropriate. In general, non-neuropathic sphincter weakness incontinence can usually be treated without recourse to this device, and neuropathic sphincter weakness incontinence is commonly associated with abnormalities of detrusor function. It is therefore mandatory for all patients, and particularly those with neuropathic dysfunctions, to have a full videourodynamic evaluation as part of their preoperative assessment to identify detrusor abnormalities and, if at all possible, for any of these abnormalities to be treated before implantation of an artificial urinary sphincter.

Urodynamic factors are not the only ones that have to be considered. The largest single group for whom an artificial urinary sphincter may be considered is the group of children and young adults with congenital cord lesions. Traditionally, incontinence in this group has been treated either by pads, appliances, or indwelling catheters on the one hand or by urinary diversion on the other. The artificial urinary sphincter provides an alternative method of management which gets rid of the need for the former but avoids the 'stigma' of the latter; hence its attractiveness to the 'pressure groups' referred to earlier. On the other hand, irrespective of the high

incidence of multiple urodynamic abnormalities in these patients and the consequent need for additional surgical procedures to deal with these, which the patient's general condition may mitigate against, there is the need to consider the factor, common in this group, of the general desirability for continence in a patient confined to a wheelchair. Given that it is usually fairly easy to provide 'social dryness' in these patients (particularly boys) with appliances and catheters, thereby avoiding the need for the regular and maybe frequent transfer from wheelchair to an appropriate toilet and back again, the artificial urinary sphincter and other types of reconstructive surgery are probably best reserved for patients who are mobile, unless, particularly in girls, conservative methods of management have failed.

Logistic problems

It follows from the above considerations that to provide a complete service for the treatment of incontinence and related voiding dysfunctions, a unit must be able to provide full videourodynamic investigations and have the ability to perform not just artificial urinary sphincter implantation but also all the other surgical procedures that may be necessary for the functional reconstruction of the urinary tract. These require special expertise and experience that are really only to be found in specialised centres with the necessary surgical and urodynamic expertise and the equally necessary nephrological, neurological, radiological, and anaesthesiological back up. Unfortunately, there are very few of these centres at present and many patients therefore have to travel some distance if they are to get adequate management of their problem.

Conclusion

The artificial urinary sphincter is a very effective way of eliminating sphincter weakness incontinence when other methods fail or are inappropriate, but is only one of a number of techniques that are currently available for the functional reconstruction of the urinary tract. These techniques require investigational and technical expertise that are to be found only in specialised centres, which are few and far between and are obviously expensive in both staff and equipment. This expenditure, however, is more than offset by the long term cost effectiveness of the artificial sphincter when compared with the alternative of providing pads, appliances, and stoma care for the lifelong management of children with neuropathic incontinence, who form the largest group for whom this treatment is applicable.

A R Mundy
Department of Urology,
Guy's Hospital,
London SE1 9RT