The Management of Sphincter Incontinence in Children Using the Artificial Urinary Sphincter (AUS) AMS 800

FROM THE GUEST EDITOR

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I would like to thank all of the invited authors for the quality of their articles who made the production of this Dialogues issue possible. Each of the four excellent articles of this issue lucidly states the views of the authors concerning the management of sphincter incontinence in children using the artificial urinary sphincter (AUS) AMS 800.

Ricardo González has clearly demonstrated - based in his remarkable experience- his reasons for using the AUS in children with intrinsic sphincter insufficiency. In addition, Dr. González has stressed that the bladder neck, without previous operations is the most appropriate site for device implantation at this age. Our group from Buenos Aires reviewed the long-term results of female paediatric patients with sphincter incontinence treated with AUS placement and demonstrated a favourable continence outcome. Based on this review, it appears that AUS is a reliable method to provide dryness in total incontinent children, independently from patients gender.

Pedro Lopez Pereira and co-authors have presented a detailed analysis of different causes that might be responsible for functioning bladder changes after insertion of an AUS and concluded that there are no reliable pre-operative urodynamic criteria that can predict bladder function behaviour after AUS placement. Rajesh Languani and Gordon McLorie have made convincing arguments for using the AUS in children. They also emphasized that among the various procedures available in managing sphincter insufficiency, AUS placement allows the patient to empty the bladder either by normal voiding or catheterization through the urethra.

Finally, all authors agree on one very important point; that is, the importance of precise pre-operative case selection and careful long-term follow-up, including urodynamic studies.

FROM THE EDITOR

Anthony A. Caldamone, M.D.

It is fascinating to study the evolution of the artificial urinary sphincter from its beginning as a static passive resistance device to an interactive device which controls both the degree and the timing of the outlet resistance. Along with the innovative changes that have occurred with the device over the years has come a dramatic reduction in complications and device breakdown. The very first artificial urinary sphincter (AMS model) that I placed in a child with spina bifida at 7 years of age required a revision 18 years later when the child was out of college and teaching in an elementary school. The durability of the components have clearly stood the test of time. This issue looks into the uses of the artificial sphincter with excellent long-term results reported by each of the authors. The effects of additional outlet resistance afforded by the artificial sphincter on the upper tracts are also addressed.

Dr. Podesta and his co-contributors have had extensive experience with the use of the artificial sphincter in children and strongly emphasize the need for proper case selection and long-term follow-up.
In a PubMed search under the headings artificial urinary sphincter and children, there is a list of 134 publications since 1974. Of these 99 are pertinent, 11 were authored by me and 14 are from the last 5 years. I implanted the first AUS in a child in 1974 and this paper outlines my current ideas on this topic based on my experience of the last 3 decades.

1. The AUS continues to be the best means to increase outlet resistance in children with neurogenic bladder and incontinent epispadias who have not been previously operated on and who can empty spontaneously. No other surgical procedure produces variable outlet resistance. About 20% of children with myelomeningocele and the majority of incontinent epispadias patients void spontaneously after AUS implantation. Incontinent epispadias, I prefer the AUS over the Young-Dees-Leadbetter procedure that produces obstructive voiding and can alter bladder compliance.

2. To be successful, the AUS must be implanted around the bladder neck. I favor implantation via an anterior approach, placing the cuff above the endopelvic fascia and in front of the ejaculatory ducts to avoid the risk of erectile or ejaculatory dysfunction. I have not needed to use the retrovesical approach preferred by some. Some authors are exploring the role of laparoscopy to dissect the bladder neck.

3. The AUS is also the preferred method to increase outlet resistance in the male with neurogenic bladder dependent on intermittent catheterization (IC). My experience with slings in males has been unfavorable and I do not use them any longer. Bladder neck tubulization procedures invariably require bladder augmentation and a Mitrofanoff because they reduce bladder capacity and urethral catheterization is usually difficult or impossible after such procedures. I consider them only an alternative to bladder neck closure.

Periurethral slings and cadaveric fascia slings, in particular, are effective in females when constructed in conjunction with a bladder augmentation and a Mitrofanoff. Catheterization can become difficult or impossible after a successful sling. For females who wish to continue to catheterize urethrally, the AUS is the better alternative.

4. The need to augment the bladder is difficult to predict in myelomeningocele children who undergo AUS implantation. If the bladder capacity and compliance are adequate for age, preoperative counseling should include the possibility of needing a subsequent augmentation in about one third of the patients. Periodic cystometrogramms are required in all children with AUS whose bladder has not been augmented, even if they are clinically well. When it is decided that an augmentation is needed at the time of AUS implantation and a Mitrofanoff is not needed, I prefer the seromuscular technique with preservation of the urothelium.

5. Upper tract deterioration can occur after any procedure that increases outlet resistance effectively. Periodic urodynamic evaluations (every 6 months initially and yearly thereafter in the absence of symptoms) and renal ultrasonography are mandatory in all children after AUS implantation. With careful follow-up, the risk of hydronephrosis should be kept to a minimum.

6. The success of AUS should exceed 85%. Success is independent on the age of implantation, i.e., pre- or post-pubertal. Persistent or recurrent incontinence should be thoroughly evaluated. Causes and solutions of recurrent incontinence are listed in the table.

7. Erosion and infection are the main causes for definitive failure of an AUS. Erosions are extremely rare in the absence of previous surgery on the bladder neck. Infections are really technical failures that are preventable in the majority of cases. Meticulous technique, and operating room environment suitable to implant prosthesis, sterile urine culture, prophylactic antibiotics and in cases of simultaneous augmentation a mechanical and antibiotic intestinal preparation are essential. In my experience, performing a simultaneous augmentation has not increased the infection or erosion rate.

8. Mechanical failures have become quite infrequent. It is estimated that more than 80% of AUS implanted will function 10 years after implantation.

In summary, I continue to use the AUS to treat childhood incontinence with good success. The information provided here should be useful to counsel parents and patients and to guide clinicians in patient selection and follow-up.

## References

## Table: Cause and Solution of Recurrent Incontinence after AUS Placement

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The Artificial Urinary Sphincter in Female Pediatric Patients

Roberto Castera, M.D. and Miguel Podesta, M.D.

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The achievement of urinary continence in the management of children and adolescents with structural abnormalities or neurogenic voiding dysfunction remains a challenge for urologic surgeons involved in this field of pediatric urology. Urinary continence depends on adequate storage capacity and competent bladder outlet resistance (bladder neck/urethra). Consequently, incontinence may result from small bladder capacity for age, poor detrusor compliance, insufficient outlet resistance or a combination of these factors. Incontinence attributed to sphincter deficiency may occur due to congenital or acquired anatomical anomalies or lower urinary tract functional disorders.

Although medical treatment enables a number of patients to overcome this distressing symptom, a significant group requires surgical methods to achieve dryness. During the past several years numerous surgical procedures have been created to increase outlet resistance in patients who have either undergone anatomical reconstruction of the bladder, bladder neck and/or the urethra with persistent incontinence or who have neurogenic sphincter deficiency. Among the various procedures advocated are: 1) periurethral injection with bulking agents, 2) various open bladder neck reconstruction operations, i.e., Young-Dees-Leadbetter, urethral lengthening and reimplantation, 3) bladder wall flap techniques, 4) fascial slings, and 5) the artificial urinary sphincter (AUS). Each of these methods has advantages and disadvantages. The primary aim of this section is to discuss our approach to the management of urinary incontinence due to insufficient urethral resistance in female children, with emphasis on the implantation of the AMS 800 artificial urinary sphincter (AUS).

Briefly, our experience with transurethral injection of substances into the urethra or the bladder neck has been effective only in patients with sphincter incontinence after surgical reconstruction of long urogenital sinus anomaly and in selected patients with the extrophy/epispadias complex with continued incontinence following vesical neck operations. In our experience, this method has been consistently unsuccessful in children with neurogenic sphincter incontinence.

Also, the wide variety of surgical techniques available to treat bladder outlet incontinence reflects the unsatisfactory results obtained with bladder neck and urethral reconstruction operations. The YDL procedure and its variants need repeated surgical vesical neck revisions and additional bladder augmentation to achieve a satisfactory rate of urinary continence. Separately, the Kropp and the Pippi Salle operations attain good levels of continence, but the need for vesical enlargement and post-operative difficulties to catheterize the neourethra are both common.

Another method to manage sphincter incontinence in girls with myelodysplasia is the fascial sling around the bladder neck and urethra. The authors who advocate this method consider it important to obtain coaptation and compression of the proximal urethra creating a fixed and constant increase in bladder outlet resistance. However, this method often requires enterocystoplasty and the Mitrofanoff procedure to empty the bladder due to difficulties with postoperative intermittent catheterization.

For the past 20 years the AUS has been used to treat sphincter incontinence in children, but little data has been published regarding long-term results only in female children. We recently reviewed all our patients (n = 74) who had undergone placement of the AUS AMS 800 between 1987 and 2004. Of these 74 patients, we evaluated 23 females ranging in age from 7 to 20 years (mean 12.8) who underwent AUS insertion with a mean follow-up of 7.6 years (range 1-16).

The etiology of incontinence was neurogenic in 21 cases, 1 pelvic urethral trauma and 1 complete epispadias. Preoperative evaluation focused special attention to urodynamic or videourodynamic investigations. Assessment of the bladder outlet in MMC incontinent patients is the most difficult aspect of preoperative evaluation. We prescribe the device for patients who have a wide open bladder neck and low intravesical pressure (20 cm H2O) at the time of urine leakage, visualized by videourodynamic studies.1 Additional criteria for AUS placement included adequate bladder capacity for age, stable detrusor activity during filling and absence of vesicoureteral reflux. Before AUS insertion it was mandatory for the patient and his family to be familiarized with and motivated in regard to this type of treatment.

Implantation was considered successful in any patient who was dry > 4 hours between CIC or spontaneous voiding without the need for pads. At the latest follow-up 18 of the 23 patients (83%) had a functioning original device and all these patients were dry. One of the 23 patients was continent 15 years after AUS placement even though the device stopped functioning 12 years after insertion.

In the other 4 patients (17%) the AUS was removed due to infection or erosion at a mean post-implantation time of 9.5 years (range 0.75-13). One of these 4 patients remained continent despite removal of the device. Thus, at the latest follow-up, 20 of the 23 patients (87%) were dry by the above definition of continence. Consequently, the AUS success rate in female children and adolescents compares well with the success rate of 88% recently reported by Castellan using bladder neck slings in 58 children with neurogenic incontinence (43 females and 5 males) with a mean follow-up of 4 years.3 Interestingly, the authors of the latter manuscript report that all their patient population initially underwent bladder augmentation “as part of the reconstructive effort for continence”. By contrast, only 5 (24%) of our 23 patients needed enterocystoplasty - 2 patients before and 3 after undergoing AUS insertion - with 87% continence and a follow-up of 7.6 years. Furthermore, our success rate in restoring continence in female children is similar to the outcome of AUS placement reported in the literature for both boys and girls.3,4

Notwithstanding, several studies have indicated an association between AUS placement and later deterioration in bladder compliance (5). In order to reduce the need of secondary enterocystoplasty, we insist on precise preoperative selection of patients for AUS placement based on careful urodynamic investigation. However, it is important to note that this mode of preoperative evaluation does not exclude future implantation.

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The artificial urinary sphincter (AUS) is a proven excellent option for the surgical management of neuropathic incontinence as long-term data support the reliability and efficacy of this device. However, the bladder must be carefully evaluated before AUS implantation. Children with hyperreflexia or decreased compliance should first be treated with anticholinergic drugs, and, if there is no urodynamic response to these drugs, bladder augmentation ought to be performed at AUS implantation. If the response is favorable or the bladder is an areflexic reservoir with a good capacity and low pressure, the AUS is implanted and the patient is followed. However, despite the criteria mentioned above, bladder behavior changes after AUS placement have been widely reported. Most of these changes and, particularly, decreased compliance, do not respond to anticholinergic drugs so bladder augmentation becomes necessary to avoid upper tract deterioration.

Functional bladder changes after AUS implantation

A decrease in bladder compliance may occur with any procedure that increases outlet resistance, but this problem has been most frequently associated with the AUS, and, clearly, myelodysplastic children are at risk. Changes have not been documented in bladder compliance after AUS implantation in the adult population without myelodysplasia. The necessity of bladder augmentation due to decreased compliance ranges from 26% to 37% in children and adolescents with a neuropathic bladder who have received an AUS and these changes in bladder compliance can occur as late as ten years after AUS placement.

Simeoni et al. in a multi-institutional study noted changes in post-AUS bladder function that necessitated bladder augmentation in 22 of 87 patients after a mean follow-up of 5 yrs. Kryger et al., in their study of 33 children and adolescents with more than 10 yrs of follow-up, observed that additional bladder augmentation is necessary after implantation at a mean average of 3.7 yrs (0.7-7.3) in 37% of patients. Kroner et al., found that 15 of 38 myelodysplastic children required bladder augmentation at a mean time of 49 months (10-118) after AUS placement.

Causes that can be responsible for these functional bladder changes

The mechanism behind these changes in bladder function is not well understood but is probably multifactorial. Churchill and Bauer have suggested that deterioration of compliance after AUS implantation was more likely due to poor case selection (pre-existing hyperreflexia or low bladder compliance not detected preoperatively), spinal cord tethering, postoperative infection and/or noncompliant emptying. However, the mean interval documented in different studies between AUS placement and bladder behavior changes requiring a bladder augmentation ranges from one to ten years. This observation suggests that in most cases the worsening in bladder compliance is not due to poor case selection since impaired bladder compliance would have appeared earlier. These changes in bladder function in most of the reported studies could not be attributed to UTI, spinal cord tethering or noncompliance with CIC.

In most patients the AUS was implanted around puberty. Thus, it could be speculated that puberty might contribute to these bladder behavior changes in some patients. However, different studies have found that there was no significant correlation between patient age at the time of AUS placement and the need for bladder augmentation. In their study Kryger et al. divided the patients in two groups. Group I (21 patients) had a mean age of 6.7 yrs (4-9.5) at AUS implantation and group II (11 patients) had a mean age of 14.5 yr (11-18) at implantation. Forty-two percent of group I and 29% of group II required bladder augmentation after a mean follow up of 4.4 yrs (3.3-7.3) and 1 yr (0.8-1.7), respectively. These authors did not find statistically significant differences in the percentage requiring bladder augmentation between the two age groups. However, what is interesting on their study is that the average time to bladder augmentation was much lower in group II than in group I (1yr vs 4.4 yrs).

Experimental and clinical studies seem to suggest that the diminished functional compliance after AUS placement can be attributed to an increase in adrenergic innervation. This situation may be secondary to unmasking of already existing alpha-adrenoreceptors or the outgrowth of nerve fibers that then function as alpha-adrenoreceptors. However, it does not entirely explain the fact that some patients (very few) respond to anticholinergic medication. McGuire and Savastano found that the simultaneous administration of an alpha-adrenergic and anticholinergic agent has a synergistic effect in improving the intravesical pressure response to filling in the decentralized primate bladder. The AUS may exaggerate or stimulate this effect by allowing a greater distention of the bladder. Therefore, cholinergic and adrenergic components could be implicated in the bladder compliance worsening that occurs in some patients after AUS implantation.

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The interesting finding described by different authors that some patients are dry with no further bladder neck procedures after AUS removal due to infection or erosion, could also support this theory. Some authors have suggested that this post-AUS removal dryness could be due to bladder neck fibrosis, but this is very improbable since many of these patients perform CIC through their urethra without any problem. A more likely explanation would be that their improved dryness after AUS removal was due to some changes in cholinergic and adrenergic receptors development, as also mentioned in regard to bladder changes earlier.

Other possible etiologies behind these functional bladder changes after AUS placement could be a natural progression of the myelodysplastic bladder, a neural receptor-short neuron system dysfunction, as suggested by Elbadawi or, as Light and Pietro propose, a response mediated via the long neuron system involving the spinal cord. These hypotheses all require further analysis in future studies.

Can these functional bladder changes be predicted by urodynamic studies?

To predict which patients require bladder augmentation versus those who will not after AUS implantation is challenging. Different authors have tried to find some criterion that could help us determine which patients will eventually require a bladder augmentation after AUS implantation. Levesque et al. suggested doing a bladder augmentation when the preoperative cystometrogram demonstrated a detrusor filling pressure greater than 20 cm of water at 50% or less of age-expectated-capacity (AEC). However, in their study using this criterion, bladder augmentation had to be performed after AUS implantation in 37% of their patients. In another study using a similar criterion (filling pressure less than 15cm of water at 50% or more of AEC), we were also unable to predict the need for bladder augmentation, as 6 of our 17 patients (31%) required this procedure years after AUS placement.  Badiola et al. attempted to determine if bladder capacity and compliance as determined by cystometrogram could predict the need for enterocystoplasty. They concluded that patients with a preoperative bladder capacity of less than 60% of AEC and low compliance (less than 2 ml/cm of water) should undergo simultaneous AUS implantation and bladder augmentation. However, using the Badiola criteria, González et al. in their study of 17 patients with AUS and without a simultaneous bladder augmentation, found that five (30%) required this procedure later. Surprisingly, in the studies of Castera and Hafez, the incidence of patients who require a bladder augmentation after AUS placement is very low (2.5% and 4% respectively), but, unfortunately, their studies do not describe the criteria used to determine which patients undergoing AUS placement did not require concomitant bladder augmentation.

Trying to find some urodynamic parameters that could help predict the need for bladder augmentation after AUS implantation, Kronner et al. retrospectively assessed the urodynamic studies of 38 patients and were unable to find any significant differences in preoperative urodynamic parameters between the 23 patients who did not require bladder augmentation during their follow-up after implantation and the 15 who did. Our similar study also failed to find any significant differences in the preoperative urodynamic parameters (functional bladder capacity and compliance) between the six of 17 patients who required bladder augmentation during the follow-up and the 11 who did not. We also noted that some patients with a good capacity and a compliant bladder eventually required bladder augmentation, while others with a lower bladder capacity and compliance did not.

Thus, to date, there are no firm urodynamic criteria that can accurately predict bladder function outcome following AUS placement as, even when there is a very compliant bladder without hyperreflexia we really can not be sure that the situation is not going to change in the future.

Conclusions

In the absence of any urodynamic criteria that can accurately predict bladder function evolution following AUS placement, these patients require lifelong serial upper urinary tract imaging combined with urodynamic studies to detect any unexpected bladder behavior change that may occur even years after the device was implanted. This follow-up is necessary because decreased compliance does not always manifest itself as new onset incontinence or UTI and even patients who remain continent are at increased risk for high bladder pressure and upper urinary tract deterioration from unrecognised hydronephrosis.

References

Urinary incontinence in childhood and adolescence commonly stems from CNS lesions or abnormalities resulting in either poor bladder compliance, overactive or a reflexic bladder, sphincter dysenergergy, or alternatively, primary sphincteric incompetence. Bladder exstrophy as well as ureteral ectopia are other congenital conditions which may result in total incontinence. If ignored or treatment is unreasonably delayed, there may be profound effects on the child’s upper urinary tract, as well as, on his or her psyche and self-esteem.

Surgical treatment for the incompetent urethral control mechanism has been a continuing challenge since Young first described his repairs of epispadias in children a century ago. The evolution of the Young-Dees-Leadbetter bladder neck reconstruction provided the basis of all surgical repairs until Scott introduced the artificial urinary sphincter device in the mid-1970’s. The use of the artificial urinary sphincter (AUS) in children differs greatly from its accepted and common use in adults, where it may be placed around the bulbous urethra. This site of surgical implantation is not appropriate in the pre-pubertal child, nor is it advisable in the wheelchair-bound patient. Accordingly, the AUS is routinely placed around the bladder neck in children. For almost two decades, this device was the major means of surgical care offered to children with persistent incontinence, until options such as bladder augmentation, the Mitofanoff procedure, the Monti procedure, and modifications of bladder-neck sling placement were introduced. Long-term studies have shown that changes and improvements in each one of these procedures, including the AUS, have resulted in better outcomes for patients.

The goal of treating incontinence in a child with an artificial urinary sphincter is two fold: 1) achieving urinary continence, and 2) allow a means of appropriate bladder emptying, either through spontaneous voiding or clean intermittent catheterization. The unique advantage of the AUS over other forms of surgical treatment is that spontaneous voiding, as well as, intermittent catheterization are available options once the sphincter is in place. Since the widespread utilization of bladder augmentation, coupled with alternate catheterizing stoma creation, the utility of the AUS has been questioned by some. The efficacy, safety, and long term durability of artificial urinary sphincters has been reported in many series, including those patients with various causes of sphincteric incompetence resulting in incontinence.

Within the first decade following its initial introduction, the AUS was revised several times. The present model of AMS 800 offers advantages over its predecessors, such as single unit control of cuff inflation as well as potential for delayed activation and delayed de-activation. In addition, modifications to the tubing have decreased the incidence of tube disruption and fractures. However, problems still continue, albeit at a much lower incidence, secondary erosion, infection and mechanical failure, all of which usually result in a repeat surgical procedure for removal or replacement of the device. Patient selection is also of critical importance as appropriate bladder capacity and bladder function as well as patient compliance with teaching and proper use of the sphincter can effect long term outcomes.

Early outcome analyses, in the 1980, disclosed a high rate of erosion in specific subgroups of patients. This led most centers to avoid placement of the AUS around the previously reconstructed bladder neck. These early results also led us to recognize that interposing omentum between the tissues and the device was of benefit in selected cases. At the present time long term studies are limited by differences in patient population, including age and pathophysiology responsible for incontinence, as well as some smaller differences in artificial sphincter models used within each study. We will summarize each of these recent studies.

González reported outcomes after a 15 year follow up in children after artificial urinary sphincter placement. Of 32 patients followed for a mean of 15.4 years, 13 patients had their AUS removed secondary to infection or erosion while 19 patients continued to have their sphincters intact at follow-up. Eighteen of these 19 patients were dry and 7 continued to void volitionally. It was noted that risk factors that resulted in removal included prior AUS erosion, prior bladder neck surgery and balloon pressure of > 70 cm H20. They concluded that placement of the AUS is a durable and effective surgical option and the only technique that may preserve volitional voiding.

Hafez et al had similar long-term follow up with a mean of 12.5 years in 79 children. Their series incontinence was a result of neuropathic bladder as well as bladder exstrophy. Sixty-three of 79 patients had an intact AUS at mean follow up of 12.5 years. Sixteen patients had their AUS removed secondary to erosion at a mean of 5.6 years. Four of the 16 patients had bladder exstrophy. Of the 63 remaining patients 57 were completely dry. The overall 10 year survival of the AUS was 79%. It was noted that survival of the sphincter was not influenced by age, sex, model, previous bladder neck surgery, augmentation cystoplasty or intermittent catheterization. Continen rates reported were 90%. It was concluded that although 10 year survival and continence rates are high in patients with neuropathic bladder, AUS does not seem advisable in patients with bladder exstrophy, all of whom have had extensive bladder reconstructive surgery.

A 22 year single institution experience was reported by Herndon et al, which evaluated AUS implantation in 142 patients. AUS models initially placed included AMS 742/792 as well as AMS 800. Of the 134 patients evaluated, continence was achieved in 86%. Mechanical complications, sphincter erosion and revision were noted to be significantly higher in patients who had the AMS 742/792 in place as compared to patients with the more recent AMS 800 in place. A total of 30 sphincters were permanently removed.
A recent publication from Ruiz et al., from South America has reported similar success rates in a large number of patients operated upon for non-neurogenic sphincteric incompetence. They reinforced the unique benefits of spontaneous voiding.

In all of these studies, it was noted that even after removal of the AUS device, some patients continued to maintain continence, thus achieving the primary goal of treatment, particularly those who were utilizing intermittent catheterization. Artificial urinary sphincter placement continues to be one of many surgical options available to the pediatric urologist for treatment of sphincteric incontinence in children. Other techniques, such as the Young-Dees-Leadbetter, or the Pippi-Salle bladder neck reconstruction procedure for exstrophy-epispadias, may lead to a more poorly compliant, small capacity bladder. This, in turn, may require augmentation cystoplasty to achieve continence. Similarly, placement of a fascial sling often requires combined enterocystoplasty and may be less effective in male patients.

The current AMS 800 offers advantages over previous models in that it may be controlled with external manipulation. Placement requires that the patient have an adequate bladder capacity as well as good bladder compliance. Further pre-requisites include manual dexterity, and intellectual reliability. The AUS allows the patient to volitionally void as well as intermittently catheterize, but also requires that the patient or caregiver be able to activate/de-activate the pump mechanism.

Long-term follow-up studies have shown artificial urinary sphincters to be durable, safe and efficacious. The current model has decreased rates of erosion and mechanical malfunction resulting in lower revision and removal rates. Long-term results have also supported that placement and successful outcome are independent of patient age and sex. It appears that artificial urinary sphincters have stood the test of time and continue to be a good surgical option in the treatment of incontinence in children.

**References**


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