The Current Status of the Acticon[®] Neosphincter

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ABSTRACT

Severe fecal incontinence is a very debilitating condition with a tremendous impact on an individual's life. In the past if a patient was not amenable to a tissue repair or failed a tissue repair, a colostomy was his or her only surgical option. New innovations have emerged giving patients more options to regain continence. The Acticon[®] Neosphincter, which is an artificial bowel sphincter, is one of those newer options. The device is reserved for patients with severe fecal incontinence that is not amenable to lesser forms of therapy. Because it is an artificial device, the risk of infection is of particular concern. With experience, however, the infection rate has declined and the artificial bowel sphincter has become a good option for patients with severe fecal incontinence. The results are quite impressive with a significant number of patients obtaining complete continence.

KEYWORDS: Artificial bowel sphincter, fecal incontinence, Acticon[®] Neosphincter

Objectives: Upon completion of this article, the reader should be able to: (1) discuss the indications and patient selection for the artificial bowel sphincter; and (2) be familiar with the operative steps and complications of the artificial bowel sphincter.

BACKGROUND

Fecal incontinence is a life-altering condition. Its true incidence is not known, but according to a 1993 survey of US households, over 7% of the population is affected with fecal incontinence.¹ Medical therapy and tissue repairs have long been utilized in treating this condition. Unfortunately, some patients who have either failed medical and surgical treatment or who are not candidates for such treatment have been left with few options to treat their condition. In the past, these patients were relegated either to living with incontinence or to having a permanent stoma. One advance, which has given new hope to those patients with severe fecal incontinence, is the Acticon[®] Neosphincter. This artificial bowel

sphincter was adapted from the artificial urinary sphincter, which was created by American Medical Systems (Minnetonka, MN) in 1972. Christiansen and Lorentzen² were the first to publish their experience of implanting an artificial anal sphincter. They used an artificial urinary sphincter and implanted it in a patient with myasthenia gravis, who had severe fecal incontinence. The patient had excellent results at a follow-up of 3 months. In 1995, the artificial urinary sphincter was modified for fecal incontinence, creating a specific artificial bowel sphincter, which is now referred to as the Acticon[®] Neosphincter. In 1999, the device received an FDA Humanitarian Device Exemption and was formally FDA-approved in 2001.

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Table 1 Inclusion and Exclusion Guidelines for Use of the Artificial Bowel Sphincter

Inclusion Guidelines	Exclusion Guidelines
<ul style="list-style-type: none"> • Severe fecal incontinence • Fecal incontinence for at least 6 months • Failure of prior treatment or no available treatment • Sufficient dexterity to manipulate the pump • Adequate soft tissue surrounding anal canal • Intact rectum or neoanal canal • Adequate mental capacity 	<ul style="list-style-type: none"> • Pelvic sepsis • Crohn's disease • Extensive perineal radiation • Irritable bowel syndrome as only cause of fecal incontinence • Pregnancy • Anal receptive intercourse • Severe uncontrolled constipation • Nondistensible rectum

PATIENT SELECTION

Important in the success of the Acticon® Neosphincter is the selection of patients in whom to implant it. Since it is an artificial device, great attention is given to the patient's ability to heal from a surgery and not develop an infection. Thus, patients with active pelvic sepsis would not be candidates for the device. Other conditions, such as Crohn's disease or a history of extensive pelvic radiation, are contraindications to the procedure. The patient must have an adequate mental capacity to be able to operate the device and also must have the manual dexterity to manipulate the device. Above all else, to be a candidate for an artificial bowel sphincter, the patient should have severe fecal incontinence, which is not amenable to lesser forms of therapy. Thus, if a patient has a sphincter defect and is considered a good candidate for repair, that line of therapy should be pursued before considering the artificial bowel sphincter. Some patients with a very thin perineum may need a tissue bulking procedure prior to implant to decrease the risk of erosion. In the patient with irritable bowel syndrome as the only cause of the patient's fecal incontinence, medical therapy should be utilized to control the patient's irritable bowel syndrome and, if the patient remains incontinent after that, he or she could then be considered as a candidate. Other things to consider are the patient's ability to evacuate and his or her rectal capacity. Inclusion and exclusion guidelines are summarized in Table 1.

TECHNIQUE

The Acticon® Neosphincter is constructed of a solid silicone elastomere and consists of three fluid-filled components, which are connected by kink-resistant tubing (Fig. 1). The components include a cuff that is implanted around the anal canal, a pressure-regulating balloon that is placed in the space of Retzius, and a control pump which is placed in the labia in women and the scrotum in men. Figure 2 shows the device in place in a female. When the cuff is filled with fluid, it occludes the anal canal. By squeezing the control pump, the fluid is transferred from the cuff to the pressure regulating

balloon, allowing the cuff to open and the patient to evacuate stool. The pressure from the balloon will transfer the fluid back to the cuff and back to its resting state, once again occluding the anal canal.

Preoperatively the patient should be counseled extensively as to the risks and complications of the procedure as well as expectations of outcome. A thorough mechanical bowel prep is necessary to reduce the risk of infection. American Medical Systems recommends a preoperative intravenous antibiotic regimen of cefotetan and vancomycin. The procedure is performed under general anesthesia with the patient in a modified lithotomy position. Prior to the skin prep, a procotomscopy is performed to remove any effluent from the rectum. The author irrigates the rectum with dilute Betadine, removes any residual, and then leaves a Betadine-soaked vaginal pack in the rectum. If the

Figure 1 An artificial bowel sphincter device, Acticon® Neosphincter (courtesy of American Medical Systems, Inc., Minnetonka, MN, www.AmericanMedicalSystems.com).

Figure 2 Artificial bowel sphincter device, Acticon® Neosphincter, implanted in a female (courtesy of American Medical Systems, Inc., Minnetonka, MN, www.AmericanMedicalSystems.com).

patient's bowel prep is inadequate, the surgeon should cancel the procedure.

To implant the device, a tunnel must first be created around the anal canal. A variety of incisional approaches can be performed to accomplish this, including a single anterior perianal incision, bilateral perianal incisions, or a transvaginal approach. The horizontal anterior incision is the most popular as it allows direct dissection of the plane between the rectum and the vagina in women. This direct visualization helps avoid injury to the rectum and also allows a higher implantation of the device. The distance from the skin to the proximal extent of dissection should be ~5 to 6 cm. This will allow at least a 2-cm distance from the lower edge of the cuff to the skin level, which is felt to help avoid infection as well as migration of the device. Once the proximal extent of dissection is completed, blunt dissection is performed out into the ischiorectal fossae bilaterally creating a tunnel completely around the anorectal junction. Meticulous hemostasis is important to avoid a postoperative hematoma that might become infected and lead to loss of the device. Once the tunnel has been created, a sizer is passed through the tunnel to help choose the appropriate length of cuff. The length of the cuff ranges from 9 to 14 cm with the 11- and 12-cm cuffs being the most commonly used sizes. The width of the cuff must also be selected. There are two cuff widths available: narrow (2 cm) and standard (2.9 cm). A wide cuff (3.4 cm) was previously available but the lack of its use and concerns over evacuation problems led to it no longer being manufactured. Of note, the standard cuff width is the more popular in the United States, while the narrow cuff is more commonly implanted in Europe.

Once the cuff has been selected and prepared, it is encircled around the anorectal junction through the tunnel and secured in place.

Using a separate sterile setup, a Pfannenstiel incision is made to implant the pressure-regulating balloon and the control pump. This surgical field is kept separate from the perianal incision to decrease the risk of infection. The tubing from the cuff is passed up subcutaneously to this Pfannenstiel incision. A pressure-regulating balloon is selected and prepared with 55 cc of solution within it. Available pressure ranges on the balloon are 81 to 90, 91 to 100, 101 to 110, and 111 to 120 cm H₂O. The 91 to 100 and 101 to 110 cm H₂O are the most commonly utilized pressure balloons. The tubing to the balloon is then connected to the tubing from the cuff, taking great care not to introduce any air into the system. This temporary connection allows the cuff to fill and the pressures to equalize. The balloon is then detached, remaining solution is aspirated from the balloon, and it is refilled with 40 cc of solution and placed into the space of Retzius. A pocket is created in the labia of women or the scrotum in men to accommodate the control pump. Tubing from the control pump, which is color-coded, is attached to the tubing of the cuff and balloon. The incisions are closed in multiple layers. The pump is repeatedly squeezed at the end of the case to cycle the device where the cuff is open and then the device is deactivated. The rectum is inspected for any injury and the rectal packing removed. The device is left deactivated for 6 weeks to allow healing. The author admits the patient to the hospital for an average of 2 days during which time intravenous antibiotics are given, a urinary catheter is kept in place for female patients, incision care is taught, and the patient is kept NPO to delay defecation.

RESULTS

There are multiple studies evaluating the complications and outcomes associated with the artificial bowel sphincter. The largest study was a multicenter cohort study by Wong and associates³ in which 115 patients were enrolled. The clinical study (IDE G960116) began in 1997 and was designed to assess the safety and efficacy of the Acticon® Neosphincter for fecal incontinence. A total of 19 sites participated in the study, with 13 in the United States, 3 in Canada, and 3 in Europe. Of the 115 patients enrolled, 112 patients were implanted with an artificial bowel sphincter. The mean age was 49 (range 18 to 81) years and 75% of the patients were female. Etiologies of fecal incontinence in this group of patients were as follows: obstetric trauma 29.6%, neurologic 20%, congenital abnormality 20%, anorectal trauma 18%, and miscellaneous 12%.

All principal investigators were experienced in treating patients with severe fecal incontinence, but the

majority of them had not implanted an artificial bowel sphincter prior to this study. Thus one can infer that this study includes the early experience with the device, at least here in the United States. Twenty-eight of the 112 patients implanted (25%) had infections requiring revision of the device. An additional 10 patients had mild infections, which resolved with antibiotics alone. The second most common adverse event reported in the study was erosion, with 24 patients necessitating a surgical revision due to erosion of one of the components. Other complications included malfunction of the device, migration of the device, pain, and constipation. Overall, 41 of 112 (36.6%) implanted patients had a complete explant of their device during their follow-up. Seven of those patients were able to be reimplanted successfully and an additional 9 patients were pending reimplantation. Thus 34 (29.4%) patients had removal of their device with no plans for reimplantation.

The results at the end of 1 year postactivation revealed 75 patients with a functioning device in place. Of these, 85% had a successful outcome, reflected in significant improvement in their fecal incontinence scores as well as quality of life assessment. Taking all 115 patients into account, the intention-to-treat success rate was 53%. During the course of the study, American Medical Systems proposed its standardized antibiotic regimen. The authors of the study noted that after the use of the recommended antibiotic regimen, 16 patients were implanted and only 3 (19%) had complications of the device requiring revision. The authors of the study felt that, with the use of this antibiotic regimen, as well as improvements in surgical technique, reductions in the infection rate and complications will follow.

Parker and associates⁴ published their results of 45 patients undergoing artificial bowel sphincter placement at a single institution. They compared their early results of 10 patients from 1989 to 1992 with their more recent 35 patients implanted from 1997 to 2001. The explantation rate for both groups was 40% with some of the patients being candidates for reimplantation. The infection rate for the second group of patients was reported at 34%. While the authors did not see an improvement in morbidity between the two groups, variables such as more challenging patients (for example, two patients in the second group had hemipelvectomies) undergoing implantation were not taken into account. For those patients who retained a functional device, the authors reported an 88% success rate with the patients going from being incontinent on a daily basis to being continent to solid and liquid stool.

When Michot et al⁵ analyzed their early results compared with later results, a definite improvement in morbidity was noted. Among their first 12 patients implanted, 6 devices (50%) had to be removed, compared with an explantation rate of only 20% in the more recent group of 25 patients and an infection rate of 12%. Of

those 5 patients explanted in the second group, 2 are awaiting reimplantation. Seven patients did have evacuation problems, which were minor in 5 and major in 2. Of the patients with a functioning device in place, all had significant improvement in their continence with 63% of the patients achieving complete continence even to gas.

Devesa and coworkers⁶ had similar results in their 53 patients, with 10 patients (19%) undergoing definitive explants. Of the 43 patients with a device in place, 98% were continent to solid stool and 66% had complete continence, which included gas. The infection rate in this study was 18.9%.

Lehur and associates⁷ had impressive results with their 24 patients who underwent implantation of an artificial bowel sphincter, reporting an infection rate of only 4.2%. At a median follow-up of 20 months, 83% of the patients had a functioning device in place. Using a continence scoring system of 0 (normal) to 120 (completely incontinent), the median preoperative incontinence score of 106 dropped dramatically to 25 (incontinent to gas only) postoperatively. Ortiz and coworkers⁸ were able to accomplish low infection rates as well with only 2 of their 22 (9.1%) patients developing an infection.

With the infection rate such a concern and the rates varying so widely from 4% to 34%, a Best Practice Group consisting of 5 colorectal surgeons was convened in 2003 to review their patients and search for common practices that potentially contributed to lower morbidity.⁹ Of 56 patients who underwent implantation of a neosphincter by this group, only 5 (8.9%) patients developed an infection. Seven additional patients required explantation of their device: 4 for leaks in the system, 1 for erosion, 1 for patient dissatisfaction, and 1 for mental instability. Four of the patients explanted were able to be reimplanted and at the end of the study, 82% of the patients had a functioning device in place with a high satisfaction rate. The surgeons participating in this Best Practice Group agreed upon common factors that they felt might contribute to a reduction in the morbidity associated with the artificial bowel sphincter. Those common factors are listed in Table 2.

It is difficult to compare the artificial bowel sphincter to other treatment modalities for fecal incontinence, especially since the device is reserved for patients with severe incontinence who have failed prior therapies or are not amenable to lesser forms of therapy. For example, the patient with severe incontinence who has bilateral pudendal neuropathy, a patulous anus, and no discernible resting tone or squeeze could be a good candidate for the artificial bowel sphincter but would not be a good candidate for a sphincteroplasty or sacral nerve stimulation. This type of patient in the past received either a colostomy or possibly a muscle transposition procedure. The therapy most appropriate to compare with the artificial bowel sphincter is the

Table 2 Consensus of Best Practice Group for Implantation of Artificial Bowel Sphincter

<ul style="list-style-type: none"> • Use preop and postop antibiotics; irrigate with antibiotic solution frequently • Perform no procedure concomitant to implanting neosphincter (rectocele, etc.) • Place Betadine-dampened plug/pack in rectum; allow Betadine scrub to dry • Use two completely separate instrument set-ups • Make incision distant from anus; single anterior transverse incision preferred over bilateral perianal incisions 	<ul style="list-style-type: none"> • Change gloves after inserting finger in rectum or vagina; commonly change gloves five or more times per case • Implant cuff to guarantee a minimum of 2 cm between skin and edge of cuff • Assure hemostasis to minimize hematoma formation • Close incisions in multiple layers • Abort case if stool, due to poor prep, cannot be cleared, or if anus or rectum is perforated
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muscle transposition. Ortiz and colleagues¹⁰ did a prospective study comparing the artificial bowel sphincter to the dynamic graciloplasty, which is held by most to be the best muscle transposition procedure. The results of the study revealed that the frequency and severity of complications were similar for the two techniques. However, a better functional outcome was achieved with the artificial bowel sphincter.

THE FUTURE

The life expectancy of an artificial bowel sphincter is unknown. Christiansen et al¹¹ in 1999 reported on their long-term results, with 8 of their 17 patients at that time retaining their original artificial bowel sphincter for more than 5 years. Parker and coworkers⁴ had patients with functioning devices in place more than 10 years after implantation. With time and experience, the life expectancy of the device will become more evident.

The artificial bowel sphincter is now being used in more complex patients. It has been implanted successfully in a patient after a total proctocolectomy with ileal J-pouch.¹² Its use in patients requiring an abdominoperineal resection has been reported as well.¹³ Eight patients underwent total anorectal reconstruction, five were synchronous with the abdominoperineal resection, and three cases were delayed procedures in patients who had been living with a colostomy. All but one patient reportedly achieved a good grade of continence. Patient satisfaction and quality of life scores were higher in the group of patients that had delayed procedures. Obviously, more experience and data are necessary in this complex group of patients before this procedure can be recommended.

SUMMARY

The Acticon[®] Neosphincter has given new hope to patients with severe fecal incontinence. Because it is an artificial device, infection is a special concern. However, acceptable infection rates of less than 10% are achievable. The device is not without complications but its success rate is impressive, especially when taking into account

that these are patients who have either failed or are not amenable to other therapies for fecal incontinence. The artificial bowel sphincter has not only been shown to improve continence but has actually taken patients who were incontinent to solid stool on a daily basis and made them completely continent even to gas. Obtaining successful outcomes with low morbidity requires good patient selection, experience with the procedure, and dedication to optimizing the outcomes.

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