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New Options for the Treatment of Fecal Incontinence

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ABSTRACT

Fecal incontinence, the loss of anal sphincter control leading to the unwanted release of stool or gas, is a physical and psychological handicap that has a tremendous impact on an individual's quality of life. Although medical management is the mainstay of therapy for fecal incontinence, the main focus in this review is on invasive techniques with a goal of highlighting newer technologic and therapeutic advancements. While the standard surgical treatment for fecal incontinence still remains direct sphincter repair with an overlapping sphincteroplasty, this review concentrates specifically on biofeedback, the Procon incontinence device, local injection of synthetic materials, radio frequency energy (Secca procedure), antegrade colonic enemas, sphincteroplasty, gluteoplasty, graciloplasty both stimulated and non-stimulated, the artificial bowel sphincter, and sacral nerve stimulation.

Fecal incontinence, the loss of anal sphincter control leading to the unwanted release of stool or gas, is a physical and psychological handicap that has a tremendous impact on an individual's quality of life. Aside from embarrassment, fecal incontinence can cause progressive isolation with a devastating emotional impact. Even episodic fecal incontinence can have a profound impact on an individual's self-confidence and personal image. From a societal point of view, fecal incontinence is the second most common cause of institutionalization in the United States. A number of authors have attempted to evaluate the true dollar cost of fecal incontinence. Borrie and Davidson[1] found that in a long-term care facility, a mean of 52 minutes a day was spent dealing solely with incontinence at an annual cost of nursing time and supplies of over $9,500 per patient. Furthermore, over $400 000 000 per year is spent on adult diapers and protective clothing in the US.[2]

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While the significance of the problem has been well documented, reports on the prevalence of fecal incontinence have been less conclusive. Part of the difficulty is the inherent nature of the problem. Patients are often reluctant to mention fecal incontinence to their physicians, and physicians often don't ask about the nature, characteristics, frequency, and control of bowel function. Nelson and co-authors used telephone interviews of randomly dialed digits to survey 2,570 households in Wisconsin to assess the prevalence of fecal incontinence.[3] In interviewing almost 7,000 people, they found the prevalence of significant incontinence to be 2.2% and that 63% of incontinent individuals were female. While the prevalence of incontinence increased with age, surprisingly only 30% were older than 65 years. Nonetheless, in their multivariate analysis, independent risk factors for fecal incontinence were gender (female), advancing age, poor overall health, and significant physical limitations. Corroborating these results was the 2002 study by Perry et al.[4] that utilized postal surveys of over 15 000 people. Similar to the results of Nelson et al., excluding institutionalized individuals, a prevalence of 1.4% of respondents had major fecal incontinence, and advancing age was an independent risk factor. Unlike Nelson et al., Perry et al. found no increase in incontinence in women compared to men. This suggests that, as opposed to traditional teaching, men may represent an underserved segment of the population with a significant problem.

While medical management is the mainstay of therapy for fecal incontinence for patients who fail non-invasive treatments, a variety of new techniques are available to treat this debilitating problem. The standard surgical treatment for fecal incontinence still remains direct sphincter repair with an overlapping sphincteroplasty. Other modalities include biofeedback, the Procon incontinence device, local injection of synthetic materials, radio frequency energy (Secca procedure), antegrade colonic enemas (ACE), sphincteroplasty, gluteoplasty, graciloplasty both simulated and non-stimulated, the artificial bowel sphincter, and sacral nerve stimulation.

BIOFEEDBACK

Biofeedback with or without pelvic floor strengthening exercises is often the first line of treatment for

patients with significant idiopathic fecal incontinence since it is minimally invasive, painless, and safe. In 1974, Engel, Nikoomanesh, and Schuster first described biofeedback for fecal incontinence, a modification of traditional operant conditioning.[5] The principles of biofeedback therapy are still germane today. Patients attempt to maintain continence by improving voluntary contraction of the external anal sphincter and puborectalis muscles and improve coordination of the internal and external anal sphincters in response to rectal distention.

There are two methods available for biofeedback therapy: either manometric or electoromyographic (EMG) based. While connected to an EMG machine by either an anal plug or a recording sponge, patients contract the anal sphincter muscles and are shown a tracing of the strength and duration of sphincter contraction. The goal of this therapy is to increase external sphincter strength, although an increase in anal resting pressure may be seen. Manometric techniques or sensory training involves placement of an intra-anal balloon. Patients increase the strength of contraction in response to smaller and smaller rectal volumes. Regardless of the treatment modality, therapy involves a significant patient commitment. Biofeedback sessions last from 30–60 minutes and occur at 4–8 week intervals.

While the techniques available for biofeedback therapy are well known, the efficacy of treatment is less clear. Unfortunately, only a limited number of randomized controlled clinical trials have evaluated biofeedback. The Cochrane Library, utilizing an extensive search from MEDLINE, EMBASE, CINAHL, and the Cochrane Controlled Trials Registry, was able to find only 5 studies with a total of 109 patients that met the group's strict criteria.[6] They concluded that there was insufficient evidence to judge the effectiveness of sphincter exercises and biofeedback in the management of fecal incontinence. Further supporting the Cochrane library's conclusion is a meta-analysis by Heymen et al.[7] While their inclusion criteria were less stringent the outcome was similar. There is no conclusive evidence of the effectiveness of biofeedback in the management of fecal incontinence. However, the authors of both analyses did report that most of the studies showed a positive outcome for biofeedback and sphincter muscle strengthening, but the results are far from conclusive and appropriate patient selection is mandatory.

PROCON INCONTINENCE DEVICE

The Procon incontinence device is a minimally invasive device that has recently received Food and Drug Administration approval. The device is a disposable inert 70 cm long catheter with a 20 cc inflatable cuff 2 cm from the tip. At the distal tip is an infrared photo interrupter sensor and flatus vent holes. At the proximal end of the catheter is a charcoal filter for flatus. A small monitor is connected to the sensor and emits an audible sound or vibrates when the distal sensor is activated by stool. A mechanical barrier is created by the balloon and allows the patient to evacuate without soiling. In their 2002 study, Giamundo et al. enrolled 18 patients with significant fecal incontinence.[8] Seven patients were able to complete the 2-week trial. The seven who completed the trial reported a significant improvement in the fecal incontinence. They also reported a significant improvement in quality of life as evaluated by the fecal incontinence quality of life scale. Eleven patients were not able to complete the 2-week trial mostly due to manual dexterity problems. However, at this juncture the Procon incontinence device appears a viable option for individuals who are not surgical candidates.

LOCAL INJECTION OF THE INTERNAL SPHINCTER

The internal anal sphincter is responsible for the majority of resting continence. Isolated internal sphincter dysfunction from either degenerative changes or trauma is not usually amenable to direct surgical repair. Regardless of the etiology, internal sphincter dysfunction can lead to seepage, soilage, and passive incontinence. Although the internal sphincter cannot be surgically repaired, a variety of substances have been locally injected in order to improve continence. These substances include autologous fat,[9,10] glutaraldehyde cross-linked collagen,[11] polytetrafluoroethylene,[12] silicone based Bioplastique™,[13,14] and carbon coated beads.[15] The advantage of all these procedures is that they can be performed in the office with minimal patient discomfort and low morbidity. However, all of the studies involving local injection are nonrandomized and involve few patients.

Autologous fat was injected in 14 patients. The fat was harvested either with a liposuction cannula or through an infra-umbilical incision and injected into a submucosal position in the anal canal. While the short-term results were encouraging in that all patients improved for the first 2 months, 10 patients had to be re-injected. Good results were obtained in the re-injected patients but follow-up was for only 6–16 months. Like autologous fat, glutaraldehyde cross-linked collagen was injected in 17 patients with short-term symptomatic improvement in 11. There was no long-term follow-up with either procedure.

Silicone based Bioplastique™ has been injected in 16 patients in two studies. Kenefick et al. reported significant improvement in five of six patients with a

median follow-up of 18 months.[14] Not only did fecal incontinence scores improve significantly from 14 to 8, but quality of life as measured by the SF-36 improved. This was especially notable in the physical function score (26 to 79 post procedure) and the social function score (10 to 100). There was also a significant increase in mean resting pressure from 46 cm H_2O to 79 cm H_2O ($P = 0.02$), while as expected the median squeeze pressure 98 cm H_2O to 142 cm H_2O ($P = 0.1$) was unchanged. The results of Malouf et al. were not as encouraging. In 7 of 10 patients, no improvement was noted at their 6-month follow-up. There was also no change in either resting or squeeze pressures.[13]

The newest injectable therapy involves the injection of carbon-coated beads (the ACYST procedure) in the in 4–8 quadrants around the anal canal and lower rectum. Weiss et al. reported on 7 patients with a minimum follow-up of 3 months.[15] They showed an increase in the mean fecal incontinence score from 13.3 to 9.6 ($P < 0.012$) and an increase in quality of life using the fecal incontinence quality of life scale from 72 to 103 ($P = 0.018$) at 3 months. Unlike studies involving other injectable materials, they reported no increase in either resting or squeeze pressures.

While injection of various substances may hold promise especially because of the ease of administration, no long-term data or randomized trials have proven its efficacy.

RADIO FREQUENCY ENERGY

Interest in using radio frequency energy has been growing recently. It has been applied to a variety of clinical conditions in cardiology, dermatology, orthopedics, and gastroenterology. The basic science of this intervention is similar to that of laser energy application and involves the heating of tissue. Collagen responds characteristically to heat: It becomes denatured, and its configuration becomes disorganized. Thus, the application of heat can be used to shorten collagenous soft tissue, functionally improving the barrier function of the anal sphincter mechanism similar to radio frequency energy treatment of the lower esophageal sphincter. Two studies are underway involving a total of 60 patients that evaluate the effectiveness of radio frequency energy (SECCA procedure) in the treatment of fecal incontinence.[16,17] Neither study has significant long-term follow-up, but both show short-term promise. In both studies, there was a significant improvement in the fecal incontinence score as well as the fecal incontinence quality of life scale. Subjectively patients noted significant improvement in continence, but there was no change in either the measured resting or squeeze pressures. Both of these studies show significant promise, and the use of radio frequency energy is waiting the results of ongoing long-term outcome studies.

ANTEGRADE COLONIC ENEMAS (ACE)

Antegrade colonic enemas involve the construction of a catherisable conduit in the proximal colon through which enemas or irrigation fluid can be given to evacuate the colon and rectum. Although this procedure is most commonly used for chronic constipation, it can be utilized in incontinent individuals. The original procedure was first described at the turn of the last century by Dalby[18] and modified in 1905 by Keetley,[19] who used the appendix as the conduit. It was not until the 1990s, when Malone adapted the procedure for chronically constipated children, that its use became more widespread. The procedure is performed by isolating the appendix and its blood supply, amputating the distal end of the appendix and reimplanting it in the cecum. The proximal end of the appendix is exteriorized. A skin flap is used to bury the appendix, minimizing mucous drainage. In 1991, Wheeler and Malone reported on 13 children with either constipation or incontinence, with encouraging results.[20] It took between 20–30 minutes to empty the colon, and only two children had minor leakage; 11 remained clean between enemas for 48–72 hrs. Since adults don't always have an appendix, Williams et al in 1994 further modified the procedure, utilizing the transverse colon for the conduit in 9 patients.[21] Although the results were very good, in that all 9 had no leakage, follow-up was short (median 4 months). However, long-term results appear just as encouraging; 20 of 26 patients had significant improvement in both their continence scores and quality of life measurements (Williams et al, unpublished data, 2005). These results suggest that in a specific subset of patients, those with constipation and incontinence, ACE is a viable option.

GLUTEOPLASTY

Surgical transposition of gluteal muscles, one of the oldest surgical treatments for fecal incontinence, is experiencing a modest renewal of interest. Initially reported in 1902, the use of the gluteus muscle has been touted for a variety of reasons. It is well vascularized, supplied by the inferior gluteal artery. It is larger and stronger than the gracilas muscle and provides more bulk to help buttress the anal canal. It is activated during walking, which allows it to function as a significant adjunct to the external sphincter. Finally, mobilization of the gluteus muscle does not impair gait or pelvic stability. A variety of techniques have been used, but the most studied method involves division of both gluteus muscles from the

sacrum, splitting one muscle, subcutaneously tunneling, and wrapping one strip anterior and one strip posterior to the rectum. These muscle strips are then sutured together and to the ipsilateral mobilized muscle.[22] In an elegant cadaver study, Pak-art et al. proposed a modification of this procedure.[23] They found that increased muscle length and thus decreased tension could be achieved by using a proximally based gluteal flap as opposed to a distal based gluteal flap.

Devesa et al. have the largest recent series.[24] Of 20 patients who underwent bilateral gluteoplasty, over 50% had a significant improvement in incontinence, and only 8 people had poor functional results. The patients who had good results showed a significant increase in mean resting pressure and squeeze pressures. Overall, most people in this study and in the literature were pleased with the outcome, although quality of life data are absent in all studies, and it appears that patients are continent of solid stool but have difficulty with liquid stool or gas.

STIMULATED GRACILOPLASTY

Similar to the gluteus muscle, gracilis muscle transposition has been used in treating fecal incontinence. The use of the gracilis muscle transposition was first described by Pickrell et al. in 1952 for neurogenic incontinence in children.[25] The gracilas muscle seemed to be an excellent choice due to its proximity to the anal canal, easy mobilization, proximal blood supply, and innervation. However, improvement in continence was only marginal in these children because of the rapid fatigability of the gracilis muscle. The gracilis was unable to maintain sustained contraction since it is a fatigue prone Type II (fast twitch) muscle. Salmons and Henriksson in 1981 found that with electrical stimulation skeletal muscle undergoes profound changes in morphological, physiological, and biochemical character.[26] In essence, electrical stimulation converts the gracilis muscle to slow twitch (Type I) muscle allowing it to function as a sphincter.

After the patient is placed in lithotomy position, either one long incision or two short incisions are made on the inner aspect of the thigh. The muscle is identified and detached from it insertion on the tibial tuberosity. Care is taken to preserve the proximal based neurovascular bundle. The muscle is then transposed around the anal canal through two lateral incisions and sutured to the contralateral tibial tuberosity. Six to eight weeks later electrodes are implanted through a subcutaneous tunnel into the muscle and a neuro-stimulator is implanted in a pocket in the abdominal wall. Stimulation of the gracilis muscle involves progressive increase in activation of the generator. After 8 weeks the nerve stimulator is left on continuously. The patient is given a magnet to turn off the nerve stimulator to defecate.

Several authors have detailed the procedure and short-term results. The largest and most complete collection of data involved the Dynamic Graciloplasty Therapy Group. In a series of articles published between 2000 and 2002, the authors describe the safety, efficacy, and long-term results of 129 patients who had undergone the procedure at 20 institutions.[27–29] Inclusion criteria for these patients were incontinence to solid stool >1 day a week or liquid stool all the time. Exclusion criteria included inflammatory bowel disease, chronic diarrhea, anorectal agenesis, excision of the anorectum, and significant neuromuscular abnormalities. The short-term result for patients who did not have a protective stoma showed success for 63% and minor improvement in 11%. At 18 months success decreased to 57% and minor improvement increased to 13%. For patients who had a protective stoma, early success was only 33% but improved to 60% at 18 months. Anal resting pressures and squeeze pressures showed no increase after muscle transposition and prior to stimulation. After stimulation resting pressure increased significantly from 38 mmHg to 58 mmHg and squeeze pressures from 50 mmHg to 93 mmHg. The long-term results at 24 months in non-stoma patients showed 15% were continent 100% of the time, 42% had a >50% improvement in continence from baseline, 10% had <50% improvement in continence, 6% had a stoma created and 21% exited from the study. In patients who had a preexisting stoma prior to graciloplasty, 33% had 100% continence, 17% a >50% improvement in continence, 22% a <50% improvement in continence, 6% a stoma re-created, and 22% exited from the study. Long-term results in patients without a stoma did show a decrease in both liquid and solid stool incontinent bowel movement as well as decreased pad use at 24 months; however, these results were not statistically significant.

This procedure was not without complications. Of 121 patients, there were 211 adverse events. Eighty-nine of these were classified as severe requiring hospitalization or surgery. Fifteen percent experienced major infectious complications that required re-operation to treat. Nine patients had significant pain or numbness that required repeat surgery. A number of other complications included minor infections, thromboembolic complications, lead dislodgement, constipation, and complications associated with stoma closure. While this procedure is associated with a high morbidity rate, most complications can be treated successfully, and although post procedure continence is not perfect, patients do

receive a significant improvement in their quality of life.

ARTIFICIAL BOWEL SPHINCTER

Recently, implantation of an artificial bowel sphincter has become a viable option for patients with end-stage fecal incontinence who did not have success with conventional treatment. The artificial bowel sphincter is a modification of the highly successful artificial urinary sphincter for urinary incontinence. The currently used device is the Action™ Neosphincter (American Medical Systems, Inc., Minnetonka, Minn.). This totally implantable device, made of solid silicone, consists of three interconnected parts: an occlusive anal cuff, a pressure regulating balloon, and a control pump. The cuff is implanted around the anal canal and occludes the anus via pressure along its entire length. The pressure-regulating balloon is implanted in the space of Retzius and the control pump is implanted in either the labia or scrotum. The patient deflates the cuff via the control pump and evacuates the rectum; the cuff fills passively over the next 5 minutes restoring continence.

Since 1987 several authors have reported their results with the artificial bowel sphincter, and as of September 2002 over 200 have been implanted on protocol in America, Europe, and Australia.[30–32] Wong et al. reported the largest and most comprehensive study in 2002.[33] In this multicenter cohort study 112 sphincters were implanted. Exclusion criteria included only minor fecal incontinence, inflammatory bowel disease, and previous pelvic radiation. In the eligible patients the etiology of fecal incontinence was obstetric trauma in 29.6%, neurologic 20%, congenital abnormality 20%, trauma 18%, and miscellaneous 12%. After implantation and activation, continence improved significantly with mean improvement in continence score of 51 points. This meant that individuals who were completely incontinent to liquid and solid stool now only had occasional minor seepage. Patients with working implants also had an increase in all quality of life measures. Patients whose implant worked properly were 100% continent at 2-year follow-up.

Although the device demonstrated a significant improvement in patient continence and quality of life, it was not without complications. Of 38 patients who experienced device-related infections, 28 required surgical revisions. Patients also experienced erosion of the cuff and/or the pump, pain with activation, constipation, and fecal impaction. Overall 36% of patients had complete device explantations. While seven patients could be re-implanted, the overall failure rate was 30%. The results of Wong et al. mirror those reported by other authors. Overall the artificial bowel sphincter, even with its high complication rate, is an excellent option for patients with severe fecal incontinence who do not respond to more traditional therapy.

SACRAL NERVE STIMULATION

Similar to the artificial bowel, sphincter sacral nerve stimulation is an adaptation of a urologic technique used for urinary incontinence. While the direct mechanism of action is unknown, it is thought that during sacral nerve stimulation two reflex arcs are activated by excitation of the S2–S4 afferent nerves. This increases sympathetic hypogastric activity and parasympathetic lower motor neuron activity to the anal sphincter. The result may be direct voluntary contraction of the sphincter, activation of the internal sphincter mediated by sympathetic and parasympathetic fibers causing tonic stabilization of the internal sphincter or an inhibition through a sacral interneurons arc of rectal muscle contraction.

The implantation of sacral nerve stimulation involves two stages. First the leads are implanted and the individual undergoes test stimulation. With the patient in prone position the S2, S3 and S4 foramina are located through bony landmarks. Under local anesthesia and fluoroscopic guidance a 20-gauge insulated needle in passed transcutaneosly into the S3 foramina. The needle is stimulated causing a contraction of the pelvic floor. To confirm which nerve roots are being stimulated another needle is passed into the S2 foramen. With stimulation there is lateral rotation of the leg and movement of the toes. Once S3 placement is confirmed a permanent lead is placed and connected to an external stimulator. The stimulator provides a unipolar monophase impulse with a rectangular pulse wave at 210 microsec, frequency of 25 Hz and amplitude of 2–8 V depending on patient tolerance. After initial adjustments, changes in voltage are made to optimize patient function and tolerance. In approximately 1 to 2 weeks the lead is tunneled subcutaneously and attached to an implanted pulse generator.

As with most new technologies, long-term results are absent but the initial results are encouraging. Malouf and colleagues in 2000 reported on 5 women with severe incontinence to liquid or solid stool at least once per week.[34] With 16-month follow-up all patients had dramatically improved with 5 of the 6 achieving normal continence. This group of patients also showed a significant improvement in their quality of life measures. Further supporting these findings was the 2001 report by Ganio et al. of 20 patients evaluated for placement of sacral nerve stimulation.[35] Of 19 patients who completed the 1-week test stimulation, 17 had a greater than 50% reduction in

incontinence episodes and 14 were completely continent. Permanent pulse generators were implanted in 5 patients who had good response with the device active and returned to baseline incontinence levels when it deactivated. At a median follow-up of 19 months all patients showed continued improvement in continence and in resting and squeeze pressures. As with other new technologies, long-term outcome data are still missing but sacral nerve stimulation may be the answer for a select group of patients. A current US study has completed accrual and is now in long-term follow-up.

CONCLUSION

While the standard surgical treatment for fecal incontinence still remains direct sphincter repair with an overlapping sphincteroplasty, a variety of new treatment options are available for patients with fecal incontinence. The availability of these treatments allows the practicing surgeon the ability to tailor the specific treatment to individual patients. Unfortunately, with all of these new technologies we are still waiting for long-term outcome measures.

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