## CHAPTER 25

## Committee 19

# **Surgery for Faecal Incontinence**

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### REFERENCES

#### ESSENTIAL ABBREVIATIONS

ACE: Antegrade Continence Enema FIQL: Fecal Incontinence Quality of Life PNTML: Pudendal Nerve Terminal Motor Latency SF-36: Short Form 36 Health Survey Questionnaire SNS: Sacral Nerve Stimulation

## **Surgery for Faecal Incontinence**

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#### INTRODUCTION

Therapy for fecal incontinence has traditionally been divided into three approaches: conservative care, biofeedback, and surgical repair. Selection of treatment modality is based upon a number of considerations, including the severity of incontinence, structural integrity of the anal sphincter, and results of electromyography and anorectal physiology tests.

Conservative therapy is most applicable to relatively mild cases of incontinence. Biofeedback retraining can be attempted for incontinence of any cause or severity, as the therapy is painless and risk-free. Biofeedback has been considered a particularly useful option for incontinent patients whose sphincter muscle is intact. However, the added benefit of biofeedback to standard supportive conservative care has recently been called into question in a randomized controlled trial. [1]

The most widely accepted operation for fecal incontinence is overlapping sphincteroplasty. This procedure, useful only in cases in which there is an anatomic sphincter defect, has been reported to provide good results in many case series. However, several recent studies have shown that results of sphincteroplasty deteriorate with time. [2, 3]

A number of operations were developed in the early to mid 20<sup>th</sup> century to provide a treatment option for patients whose native sphincter was either intact but weak or not reparable. Muscle transposition procedures using either gluteus maximus or gracilis were devised to create a functional biological neosphincter, but the approach did not gain widespread popularity. The Parks postanal repair was devised in 1975 to treat patients with incontinence due to pelvic neuropathy. [4]

Dissatisfaction with available operations for fecal incontinence led to development of a variety of novel

procedures during the last 20 years. The stimulated (dynamic) graciloplasty and the artificial anal sphincter were devised as salvage procedures for patients who had failed or were not candidates for standard therapy. Recently, a novel approach, adopted from its better-defined role in urinary voiding dysfunction, is the use of sacral nerve stimulation. Moreover, there has also been a trend towards development of minimally invasive approaches to fecal incontinence, such as the use of injectable biomaterials and radiofrequency ablation.

Importantly, a number of caveats apply to interpretation of the results of surgery for fecal incontinence reported in the literature. First, the vast majority of reports are uncontrolled case series. Randomized controlled studies are rare, and those reported include only small numbers of patients. Second, numerous quantitative measures have been used to report outcomes, but only recently have any of these been validated. Similarly, criteria for "successful" outcomes have been variable and often arbitrary. Third, the quality of data reported is variable, though it has generally improved with the passage of time. For example, early reports of sphincteroplasty may not include details of data collection and reported results are based upon chart review. Later reports are usually based on results of a patient questionnaire, but patients are often queried by the operating surgeon. Still later reports recognized the need for an independent data auditor. The most recent studies utilize daily continence diaries, widely considered to be the most stringent continence measure. Despite the fact that studies using lax data collection are certain to report better results than those using methodology that is more stringent, of necessity, composite reviews of surgical results include studies using various methods of data collection. Finally, results are not always reported on an intention to treat basis, particularly in the implantable device literature.

### I. STANDARD SURGICAL THERAPY

#### **1. Sphincter Repair /Sphincteroplasty**

Anal sphincter repair continues to be the standard accepted surgical approach to patients with an anatomic anal sphincter abnormality as the basis for their fecal incontinence. Nearly all patients with sphincter injuries are parous women. [5]

Meta-analysis of 717 vaginal deliveries revealed the incidence of new anal sphincter defects was 27% among primiparous women and 9% in multiparous women. [6] Interestingly, 70% of such defects were asymptomatic. Risk factors for fecal incontinence include maternal age, prolonged second stage of labor, instrumental vaginal delivery, and sphincter rupture. [7] This rather high rate of injury, the concomitant obstetrically-related injuries to the innervation of the sphincter and pelvic floor which appear to worsen and become increasingly symptomatic over time, and the relatively modest results of surgical management of such injuries, [2] has prompted increasing discussion that vaginal delivery may be much more hazardous to the long-term quality of life than previously believed. Indeed, fully 32% of female obstetricians in the United Kingdom would choose C-section for their own first uncomplicated pregnancy. [8]

Surgery performed acutely upon discovery of a third degree or fourth degree obstetrical tear, is correctly termed sphincter repair. This is performed immediately in the delivery room, usually by opposing or overlapping the ends of the acutely severed and greatly retracted ends of the external anal sphincter. [9] [10]. One randomized trial showed no difference in outcome between overlapping and direct apposition repairs. [10] Sometimes edema, swelling, and contamination may delay acute repair for 1-2 weeks. [11] In patients with severe tears, waiting for scars to form (months) may be unacceptable, because patients are frankly fecally incontinent while they are recovering after delivery; such patients may best be managed by debridement, apposition of the severed ends of the sphincter, and reposition and diversion.

Repair of anal sphincter disruption (third degree tear) is an operation performed most often by junior residents in the milieu of a just completed delivery. It may not be surprising then that the results of such operations are poor. Up to 50 percent of women experience some degree of sphincter incontinence after anal sphincter repair. [12-14] Pinta et al [9]

found that 75 percent of women who had been repaired at delivery after an obstetrical tear had persistence of a defect in the anal sphincter musculature fifteen months (median) after a repair, and 60% were incontinent. [9] It is most often patients with worsening fecal incontinence presenting for evaluation years following delivery who are found to have an anterior defect by direct inspection and ultrasound; these patients are ideal candidates for a sphincteroplasty. Whether a colon and rectal specialist or staff obstetrician should repair obstetric-related anal sphincter defects acutely is controversial. [11] The importance of accurate expert repair in the acute setting is becoming more and more recognized. Hematoma formation, wound infection, faulty technique, and unrecognized inaccurate apposition of tissues may all lead to poor outcome requiring a second repair (sphincteroplasty) in a number of these patients. [11]

The acutely injured anal sphincter is repaired by pulling the severed ends of the muscle together in the anterior midline using a direct apposition technique. Such an approach is associated with a good outcome in 50 to 100% of patients reported. [15] If the injury is very severe, particularly when there is loss of tissue, severe contamination, multiple associated injuries or a prolonged delay before surgery, it is better to divert the fecal stream and return for a secondary repair when the inflammation and infection clear entirely. Results of primary repair of the acutely damaged anal sphincter are shown in **Table 1**. [10, 16-34]

The term *sphincteroplasty* is reserved for reconstruction of the sphincter musculature, which has never healed or healed incorrectly after acute disruption. These operations are performed at a time remote from the original injury.

Anterior sphincteroplasty is the most common anal sphincter reconstruction performed. The sphincter muscle and perineal body have healed with a defect after disruption. Indeed, the vagina and anus may actually present as a cloaca, with only the thinnest of anovaginal septum present. This loss of anterior sphincter mass coupled with an absent perineal body is very common and prompts a more complex repair. At its simplest, sphincteroplasty entails an overlapping repair of the sphincter mechanism in the anterior midline. Many authors include plication of the puborectalis at the cranial aspect of the repair to lengthen the anal canal. [35] Some surgeons favor individual repair of the internal and external sphincter muscles, but there is no evidence to support this. [36-38]

Authors	Year	Country	Ν	Follow-up Months	Anal Incontinence
Haadem et al [16]	1988	Sweden	62	3	44%
Sorensen et al [17]	1988	Denmark	25	78	42%
Bek & Laurberg [18]	1992	Denmark	121	?	50%
Nielsen et al [19]	1992	Denmark	24	12	29%
Crawford et al [20]	1993	USA	35	12	23%
Sorensen et al [21]	1993	Denmark	38	3	24%
Sultan et al [22]	1994	UK	34	2	41%
Fornell et al [23]	1996	Sweden	51	6	40%
Tetzschner et al [24]	1996	Denmark	72	24-48	42%
Walsh et al [25]	1996	UK	81	3	20%
Gjessing H et al [26]	1998	Norway	38	12-60	57%
Go & Dunselman [27]	1998	Netherlands	20	6	30%
Goffeng et al [28]	1998	Sweden	27	12	59%
Poen et al [29]	1998	Netherlands	117	56	40%
Wood J et al [30]	1998	Australia	84	31	17%*
Kammerer-Doak et al [31]	1999	New Mexico	15	4	43%
Sander et al [32]	1999	Denmark	48	1	21%
Zetterstrom et al [33]	1999	Sweden	46	9	41%
Fitzpatrick et al [10]	2000	Ireland	154	3	53%
Sangalli et al [34]	2000	Switzerland	177	13 years	15%

Table 1. Prevalence of anal incontinence following primary repair of acute obstetric anal sphincter rupture

\*Includes 2 with secondary sphincter repair

Complications of fistula-in-ano, fissure, or hemorrhoidal surgery may also cause disruption of the anal sphincter in positions other than the anterior one, but this is relatively uncommon in the general population; the number of patients with sphincter defects and fecal incontinence caused by obstetric-related sphincter disruption exceeds those caused by surgical misadventures by 3 to 1. [39] Simple sphincteroplasty is performed, incorporating any associated scar into the repair.

Sphincteroplasty can be performed repeatedly (2-3 times) in an attempt to eliminate a persistent defect in the anal sphincter mechanism. [40] Success of the repair is related to whether the sphincter defect is finally eliminated. [5, 40-42] Failure is nearly always associated with a persisting defect on ultrasound. [40,

43] Combining pelvic floor retraining (biofeedback) and sphincter repair for patients who demonstrate poor or absent squeeze pressures, in addition to a defect in the sphincter musculature, may be an approach for patients with such combined etiologies presenting years after the inciting obstetrical event. [44]

The results of sphincteroplasty are shown in **Table 2**. [2, 3, 12-14, 37, 39, 45-61] In general, good results (defined as control of solid and liquid stools) are achieved in about 70 percent of patients. However, recent data from several centers have indicated that successful results are often not durable and the degree of continence initially achieved may frequently deteriorate with time. Control of flatus is very problematic at best and may reflect concomitant injury to the IAS. The role rectal and anal canal sen-

Table 2. Sphincteroplasty

Authors	Year	No. of Patients	Obstetric Related (%)	Results Excellent to Good (%)
Pezim et al [45]	1987	40	58	62
Stern et al [46]	1987	11	90	100
Christiansen & Pedersen [47]	1987	12	100	80
Laurberg et al [48]	1988	19	100	47
Yoshioka & Keighley [49]	1989	27	70	74
Abcarian et al [50]	1989	53	40	74
Fleshman et al [51]	1991	55	87	72
Wexner et al [37]	1991	16	100	95
Londono-Schimmer et al [39]	1994	94	60	50
Engel et a l[52]	1994	55	100	79
Simmang et al [53]	1994	14	79	100
Nikiteas et al [14]	1996	42	62	67
Oliveira et al [54]	1996	55	100	71
Felt-Bersma et al [55]	1996	18	55	72
Sitzler & Thomson [56]	1996	31	64	100
Gilliland et a l[57]	1998	77	69	100
Young et al [58]	1998	54	91	86
Karoui et al [12]	2000	74		51
Osterberg et al [59]	2000	51	61	58
Malouf et a l[2]	2000	55	100	91
Morren et al [13]	2001	55	84	56
Halverson & Hul 1[3]	2002	49	63	49
Pinta et al [60]	2003	39	100	67
Bravo Gutierrez et al [61]	2004	191	91	40 (3 yr) 23 (10 yr)

sation plays in the outcome of sphincteroplasty is unknown.

The major problem with determining *prognostic factors* associated with a successful surgical outcome is the heterogeneity of the patient populations reported throughout the literature.

The effect of age at operation on long-term function is controversial. Oliveira et al [54] and Simmang et al [53] found no correlation between the two while Sitzler and Thomson, [56] Nikiteas et al, [14] Rasmussen et al, [62] and Bravo Gutierrez et al [61] found that increased patient age was associated with a lower rate of successful outcomes.

Whether clinical data and *physiologic testing* might serve as prognostic indicators for outcomes is controversial. It has been suggested that preoperative data as well as preoperative clinical data (manometry), as well as electrophysiologic data (pudendal nerve terminal motor latency (PNTML), EMG) may have predictive value, but this is not conclusive. [54, 57] PNTML [37, 39, 48, 53, 54, 57, 58, 63, 64] is perhaps the most controversial of the associations and there are as many proponents of the importance of PNTML in predicting outcome as there are opponents. [14, 56, 58, 65]

#### **2. POSTANAL REPAIR**

Postanal repair was first reported by Sir Alan Parks in 1975. [4] This procedure was designed to increase the length of the anal canal, restore the anorectal angle and recreate the flap valve mechanism, which at the time was thought essential for maintaining fecal continence. Success rates ranged from 38% to 80%, depending on the definition of the success, the length of follow-up and possibly the cause of incontinence. [66-72] The results of postanal repair are shown in **Table 3.** [4, 52, 66-82]

Subsequent observational studies with a median follow-up of more than 5 years showed that continence deteriorated with time. Despite 60% to 80% of patients reporting persisting improvement, only onethird were actually continent to liquid or solid stool. [75, 80, 81] Possible explanations for deterioration of continence following initial improvement included unrecognized denervation and/or muscular injury of the sphincter and pelvic floor musculature, and the presence of occult anal sphincter disruption, particularly in the studies reported before endoanal ultrasonography or magnetic resonance imaging were available. Moreover, physiological and radiological evaluations before and after postanal repair have not demonstrated consistent changes in anal canal length, resting pressure, voluntary contraction pressure, anorectal sensitivity and movement of the anorectal angle. [67, 71, 72, 74, 83] These reports of increasingly poor outcome have diminished the popularity of this procedure significantly.

Deen et al [73] in a randomized controlled trial, comparing three procedures in 36 women with neuropathic fecal incontinence, found that complete continence was achieved in 42% of patients after post anal repair, 33% after anterior levatoroplasty, and 67% after total pelvic floor repair. In contrast, van Tets et al [74] conducted a randomized controlled trial comparing postanal repair and total pelvic floor repair in 20 women with neurogenic fecal incontinence . Complete continence to solid or liquid stool was achieved in 27% of patients after post anal repair and in 22% after total pelvic floor repair

In conclusion, postanal repair may lead to improvement in a variable percentage of patients with neurogenic incontinence, but results deteriorate with time (level C).

#### 3. NON-STIMULATED MUSCLE TRANSPOSITION

A variety of muscle transposition procedures have been devised for the treatment of fecal incontinence. Early efforts focused upon the use of transposed skeletal muscle to supplement the function of a weak or disrupted anal sphincter. Early in the 20<sup>th</sup> century, a number of surgeons utilized gluteus maximus muscle, transposed in a variety of configurations, to create a neosphincter. [84, 85] In 1952, Pickrell and associates described the use of transposed gracilis muscle to create a neosphincter for incontinent children. [86]

Published series of gracilis transposition are uncontrolled and demonstrate variable success rates. [87-96] One study reviewed the functional results of graciloplasty longitudinally in 22 patients followed for a median 63 months. [97] 18 patients (81%) were improved at 6 months, though only one regained normal continence. Results deteriorated in 5 patients during subsequent follow up. Bilateral gracilis transposition has been used successfully in several small series. [88, 98]

Success rates following gluteus transposition have likewise been variable. [99-103] A prospective randomized trial in women with post-obstetric neuropathic incontinence showed similar significant degrees of improvement following both gluteus maximus transposition and total pelvic floor repair. [104]

				Outcom	ies
Authors	year	Number of patients (female)	Median or mean follow-up: months (range)	Continent to Solid and Liquid (%)	Symptomatic improvement
Parks[4]	1975	75 (68)	ns (180 or less)	83%	ns
Browning and Parks [67]	1983	42 (36)	ns (1or less)	81%	ns
Keighley and Fielding [66]	1983	40 (ns)	ns (ns)	68%	83%
Ferguson [68]	1984	9 (8)	ns (ns)	67%	ns
Henry and Simson [69]	1985	242 (193)	11 (0.5 - 27)	60%	ns
Habr-Gama et al [70]	1986	42 (39)	12 (12)	52%	ns
Womack et al [71]	1988	16 (14)	26 (15 or more)	38%	88%
Scheuer et al [76]	1989	39 (ns)	ns (ns)	15%	70%
Yoshioka and Keighley [75]	1989	124 (111)	60 (ns)	ns	81%
Rainey et al [78]	1990	42 (37)	42 (6 - 95)	31%	71%
Scott et al [77]	1990	62 (56)	ns (ns)	45%	82%
Orrom et al [72]	1991	17 (ns)	15 (ns)	59%	ns
Deen et a l [73]	1993	12 (12)	24 (22 - 28)	42%	42%
Engel et al [52]	1994	38 (34)	43 (15 - 126)	21%	50%
Jameson et al [79]	1994	36 (33)	6 (6) 25 (6 - 72 )	50% 28%	83% 53%
Setti-Carraro et al [80]	1994	34 (34)	73 (61 - 95)	26%	82%
Rieger et al [81]	1997	19 (ns)	96 (24 - 120)	37%	58%
van Tets et al [74]	1998	11 (11)	3 (3)	27%	45%
Matsuoka et al [82]	2000	20 (20)	36 (12 - 90)	35%	35%

ns: not stated

Several unique approaches to pediatric fecal incontinence have been reported in small series with reasonable success rates. These include autogenous transplantation of denervated palmaris longus muscle, [105] transposition of vascularized but denervated gracilis, [106] and use of a reversed autogenous smooth muscle cuff [90] None of these techniques have gained widespread acceptance (Level D).

### **II. NOVEL SURGICAL THERAPIES**

#### **1. STIMULATED MUSCLE TRANSPOSITION**

Even after successful muscle transposition, functional outcomes are limited by two physiological factors. First, patients are unable to consciously maintain tonic contraction of their neosphincters over long periods of time. Furthermore, even if patient volition were not a problem, gracilis muscle is poorly suited to tonic contraction. While the external anal sphincter comprises predominantly slow-twitch, fatigue-resistant type I fibers, the gracilis muscle comprises predominantly type II, fast-twitch fibers that are rapidly fatigable. [107] Graded electrical stimulation transforms type II into type I muscles fibers,[108] and use of an implantable electrical pulse generator has been shown to convert transposed gracilis to a muscle with predominantly type I fibers. [107, 109, 110] The results of stimulated graciloplasty are shown in **Table 4.** [110-127]

Successful electrical stimulation of a previously transposed gracilis muscle was first reported in 1988,[128] and case series from 2 independent centers were simultaneously reported in 1991. [109, 110] Encouraging additional investigation, Baeten et al [109] showed improved continence in 8 of 10 patients; Williams et al,[110] in 12 of 20. Several

Authors	year	No. of pts	Percentage continent*
Mercati et al [111]	1991	7	
Williams et al [110]	1991	20	60
Baeten et al [112]	1995	52	73
Geerdes et al [113]	1996	67	78
Mander et al [114]	1996	12	42
Geerdes et al [115]	1997	15	53
Cavina et al [116]	1998	31	85
Christiansen et al [117]	1998	13	77
Madoff et al [118]	1999	131	66
Mander et al [119]	1999	64	69
Rouanet et al [120]	1999	9	56
Sielenzneff et al [121]	1999	16	81
Baeten et al [122]	2000	123	74
Rullier et al [123]	2000	12	58
Matzel et al [124]	2001	121	
Bresler et al [125]	2002	24	79
Wexner et al [126]	2002	129	56
Rongen et al [127]	2003	200	72

Table 4. Dynamic Graciloplasty: General measures of continence

\* variable definitions; does not necessarily denote perfect continence.

issues of divergence in technique arose from these studies, each of which has seen increasing consensus in the literature despite a lack of randomized trial data. Thus, intramuscular (vs. epineural) electrodes are now universally employed, and diverting stomas and 'vascular delay' prior to muscle transposition are no longer utilized.

In 1995, Baeten reported his results in 52 patients, with 38 (72%) becoming continent after surgery. [112] In a subsequent paper, 200 patients followed for a median of 261 weeks were reported. [127] The overall success rate was 72%. Patients with incontinence due to trauma had the best results (82% success), while patients with incontinence due to congenital anorectal malformation had the worst results (52% success). 138 complications were reported, including disturbed evacuation in 32 patients (16%), infection in 24 (12%), pain in 16 (8%) and pulse generator displacement in 12 (6%). Ten patients (5%) had anorectal perforations, 7 of whom eventually obtained a successful outcome.

Rosen et al [129] reported restoration of continence

in 9 of 10 patients treated by dynamic graciloplasty using a "split-sling" wrap configuration. Sielezneff et al [121] treated 16 patients and 13 had improved continence. However, 8 patients suffered morbidity, resulting in 33 subsequent admissions and 23 reoperations.

Three multicenter prospective trials of dynamic muscle plasty have been performed to date. [118, 119, 122] In each of these studies, patients served as their own controls. No randomized prospective trials have been performed.

Madoff et al studied 139 patients from 12 centers, 128 of whom had gracilis wraps and 11 gluteus wraps. [118] Of those patients, 104 were treated for fecal incontinence, and 35 underwent total anorectal reconstruction following abdominoperineal resection for cancer. Success rates for graciloplasty were 71% for patients with acquired incontinence and 50% for those with incontinence due to a congenital abnormality. There were a total of 138 complications for the entire group. Wound complications (41 major and 35 minor) were both the most prevalent and the most consequential. Other complications included pain in 28 patients (22%), hardware problems in 14 (11%) and tendon detachment in 4 (3%). Centers with significant prior experience with the procedure had substantially fewer major wound complications (17.4 vs. 33.1%) and significantly higher success rates (80% vs. 47%).

Mander et al [119] reported the results of dynamic graciloplasty in 64 patients with refractory fecal incontinence treated at 7 centers. There were 24 infectious complications, 5 of which involved perineal wound breakdown and 3 of which required reoperation. 44 (69%) patients became continent to solid stool 1 month following stoma closure. Evacuation problems developed in 16 patients (25%), and this lead to failure in 14. At a median of 10 months follow-up, 29 patients had a good functional result.

Baeten et al [122] reported the results of dynamic graciloplasty in 123 patients treated at 20 centers. 189 adverse events occurred in 91 patients, including one death due to pulmonary embolism. There were 18 major and 31 minor infectious complications. There were 42 instances of therapy-associate pain, occurring variably in the donor leg, at the anal canal, or at the device site. There were 11 lead dislodgements but no problems with lead breakage or pulse generator malfunction. A follow-up study showed full or partial recovery from these complications in 87% of patients. [124]

This study, in contrast to others, was based upon data from daily continence diaries. A successful result (defined as a 50% or greater decrease in incontinent events in patients without pre-existing stomas) was achieved in 63% of patients after one year. Followup of this patient cohort demonstrated stable success rates at 18 months (55%) and 24 months (56%). [126] Statistically significant improvements in the physical and social function scales of the SF-36 were recorded at 12 months.

Chapman et al [130] performed a systematic review of dynamic graciloplasty for fecal incontinence on behalf of the Australian Safety and Efficacy Register of New Interventional Procedures- Surgical (ASER-NIP-S). The authors reviewed 37 original articles published between 1991 and October 2000. All of the papers were judged to be of low-evidence quality, as all but one paper were case series, and the sole comparative study utilized historical controls. Mortality excluding cancer deaths was 1% (95% confidence interval 1-3%) and morbidity 1.12 (95% CI 0.14 - 2.08) events per patient. Success was variably defined between studies, but was reported as ranging from 42-58%. The ASERNIP-S Review Group determined that "the safety of the procedure cannot be determined at the present time due to an incomplete and/or poor-quality evidence base" and that "efficacy is established." Thus, a grade C recommendation can be given to stimulated muscle transposition.

#### 2. ARTIFICIAL ANAL SPHINCTER

Artificial sphincters have been used for the treatment of urinary incontinence since 1973. [131] A success rate of 79% with a mean follow-up of 7.2 years has been reported. [132] The device (AMS Sphincter 800<sup>™</sup> Urinary Control System, American Medical Systems, Minnesota, USA) and its subsequent modifications is a totally implantable system consisting of 3 parts: an inflatable occlusive cuff that is implanted around the native sphincter, a pressure-regulating balloon that is implanted in the prevesical space, and a control pump that is implanted in the labia majora or the scrotum. In 1987, Christiansen & Lorentzen [133] applied this device to a patient with fecal incontinence. The patient had an excellent result with no complications at a follow-up of three months.

Early promising results[134] prompted the modifications of the AMS Sphincter 800<sup>™</sup>, which eventually culminated in the development of Acticon<sup>™</sup> Neosphincter (American Medical Systems, Minneapolis, USA) that was specifically designed for fecal incontinence and became available in May 1996. The results of the artificial anal sphincter are shown in **Table 5.** [133-157]

Lehur et al [137] and Wong et al [149] reported early results and demonstrated the feasibility of the technique with 77% and 75% of patients retaining a functioning device after a median 20-month and a mean 58-month follow-up, respectively. The success rate (defined as continence to liquid and solid stool) in patients with a functioning device was 90% and 86%, and the intention-to-treat success rate was 69% and 67%, respectively in the two studies.

With a longer follow-up period (median 7 years [range 5 to 10 years]), Christiansen et al [151] reported a poorer result. Forty-one percent of patients had their devices explanted due to infection, mechanical malfunction, or obstructed defecation (n=1). Only 47% of patients retained a functioning device. The success rate at a median 7-year follow-up was

Authors (ref)	year	No of pts	mean or median Follow-up (mo)	No (%) of functioning device	Overall Complication	"Success" in patients with a functioning device	"Success" in intention to treat
Christiansen et al[133]	1987	1	c	1	none	success	success
Christiansen et al[154]	1989	5	0.5 - 14	4	80%	50%	40%
Weston et al[155]	1991	1	1	0	yes	failure	failure
Christiansen et al[134]	1992	12	19	10 (83%)	58%	50%	42%
Lehur et al[137]	1996	13	20	10 (77%)	38%	%06	69%
Wong et al[149]	1996	12	58	9 (75%)	33%	86%	67%
Gelet et al[156]	1997	1	24	1	yes	success	success
Vaizey et al[139]	1998	9	10	5 (83%)	su	100%	83%
Lehur et al[138]	1998	13	30	11(85%)	15%	82%	%69
Michot[150]	1998	10	Su	8 (80%)	30%	88%	70%
Christiansen et al[151]	1999	17	84	8 (47%)	41%	50%	24%
Medical services							
advisory committee[136]	1999	60	1 - 84	43 (72%)	ns	71%	52%
Lehur et al[141]	2000	24	20	20(83%)	42%	90%	75%
Dodi et al[142]	2000	×	10.5	6 (75%)	38%	67%	50%
O'Brien et al[152]	2000	13	ns	10 (77%)	9%69	90%	%69
Savoye et al[140]	2000	12	16	12 (100%)	ns	67%	67%
Malouf et al[157]	2000	18	26	6 (33%)	SU	us	ns
Altomere et al[153]	2001	28	19	21 (75%)	32%	67%	50%
Devesa et al[143]	2002	53	26.5	26 (49%)	58%	65%	53%
Wong et al[145]	2002	115	12	75 (65%)	87%	85%	54%
Ortiz et al[144]	2002	22	28	15(68%)	77%	60%	41%
Lehur et al[146]	2002	16	25	12 (75%)	31%	92%	69%
Parker et al[147]	2003	37	12	17 (46%)	43%	49%	47%
Michot et al[148]	2003	25	34.1	20(80%)	20%	79%	960%
Ortiz et al[135]	2003	×	44	5 (63%)	7500	CCF-FI score: $16 \rightarrow 8$	

CCF-FI: Cleveland Clinic Florida Fecal Incontinence; ns: not stated "Success" is defined as "continence to solid and liquid stool without significant obstructed defecation, otherwise defined in each study"

50%, while the intention-to-treat success rate was just 24%.

The Department of Health and Aged Care in Australia conducted a systematic review to assess the safety and effectiveness of artificial bowel sphincters in the management of fecal incontinence, and reported their results in 1999. [136] The authors identified 7 case-series involving 60 patients that satisfied their criteria. [139, 149-151, 155, 156] Mortality was zero, but 18% of patients had surgical site infections and 5% had erosion of the adjacent skin. Twentyeight percent of patients had their devices explanted. Only 60% of patients had adequate follow-up. Of these, 94% were continent to solid stool, 72% to solid and liquid stool, and 36% were completely continent. On the basis of these analyses, it was recommended that public funding not be approved for artificial anal sphincters because there were insufficient data to assess the safety profile of the device and because the effectiveness of the device in fecal incontinence had not been demonstrated due to the lack of rigorous studies.

There have been 9 non-randomized interventional studies [139, 141-148] and 2 observational studies [152, 153] evaluating the safety and effectiveness of newest sphincter systems (Acticon<sup>TM</sup> Neosphincter). No mortality was reported, but the overall complication rate varied between 20 and 87%. Surgical site infections (9 to 58%) and erosion of the adjacent skin (6 to 25%) were common. Up to 46% of patients underwent revisional surgery and the proportion of patients with a functioning device at the time of evaluation after follow-up of up to 34 months ranged between 46 and 83%, with 17 to 40% patients having their devices explanted.

Almost all of the patients (93 to 100%) with a functioning device were continent to solid stool, 60 to 95% were continent to solid and liquid stool, and 27 to 67% were completely continent. The success rate in patients with a functioning device was 49 to 100% and the intention-to-treat success rate was 41 to 83%.

Wong et al [145] has reported the largest multicenter prospective trial to date. Of 115 patients, 75 patients (65%) retained a functioning device after a median follow-up of 12 months. The overall complication rate was 87%. Forty-six percent of patients underwent revisional operations and device explantation was required in 37%. Thirty patients (40%) experienced obstructed defection with 21 reporting to have been impacted. A successful outcome was achieved in 85% of the 61 patients with a functioning

device. The intention-to-treat success rate was 54%.

In conclusion, a grade C recommendation can be made regarding the safety and effectiveness of artificial anal sphincters for the treatment of fecal incontinence.

#### **3. SACRAL NERVE STIMULATION**

Sacral nerve stimulation (SNS) was proposed for the treatment of patients with urologic symptoms in 1967,[158] but not used in urology until 1981. [159] SNS was first used for the treatment of fecal incontinence in 1995 by Matzel et al. [160] The authors treated 3 patients, all of whom improved (2 became totally continent).

SNS is a minimally invasive technique with low morbidity. The surgical technique can be divided into two stages. The first stage, percutaneous nerve evaluation, is used to confirm a satisfactory nerve response and then evaluate the clinical response before permanent device implantation. Screening is performed for a one to three-week period after which the electrode is removed and a permanent electrode and neurostimulator may be implanted if the response is satisfactory. [161]

The second stage is implantation of a permanent electrode and neurostimulator if screening is successful. The test and screening stage can be done with either a temporary, percutaneously placed test stimulation lead or by operative placement of a permanent quadripolar lead close to the target nerve. Those with the temporary, percutaneously placed test stimulation lead require simultaneous implantation of the pulse generator and the quadripolar lead by either an open or a percutaneous technique, while those with a lead already in place will undergo removal of the percutaneous extension before placement of the pulse generator. The pulse generator is placed subcutaneously in the abdomen or gluteal area. [162] The impulse generator can be modified by external telemetry and is activated the day after surgery. The results of sacral nerve stimulation are shown in **Table 6.** [160, 162-170]

Vaizey et al [171] evaluated 12 women with an intact anal sphincter with percutaneous nervous evaluation. Seven of nine patients without lead displacement had complete cessation of incontinence for solid and liquid stool. In a different study by Ganio et al,[172] 28 patients with fecal incontinence underwent the peripheral nerve evaluation test. 25 patients completed the test period. Out of the 25 patients with incontinence, 22 had a successful test-period.

Table 6.	Sacral Nerve	Stimulation fo	r Incontinence

Authors	Year	Patients	Before stimulation	After stimulation
Matzel et al [160]	1995	3	52 % of bowel movements were involuntary	6 % of bowel movements were involuntary
Malouf et al [163]	2000	5	18 (2-58) episodes of incontinence / 7 days	2 (0-8) episodes of incontinence / 7 days
Malouf et al [164]	2000	3	10.3 episodes of incontinence / 7 days	0 episodes of incontinence / 7 days
Matzel et al [165]	2001	6	40.2 % incontinent bowel movements	2.8 % incontinent bowel movements
Leroi et al [166]	2001	6	3.2 <sup>+</sup> / <sub>-</sub> 2.6 episodes of incontinence / 7 days	0.5 <sup>+</sup> /_0.6 episodes of incontinence / 7 days
Ganio et al [167]	2001	5	3 episodes of incontinence / 7 days	0 episodes of incontinence / 7 days
Rosen et al [168]	2001	16	6 (3-15) episodes of incontinence / 21 days	2 (0-5) episodes of incontinence/ 21 days
Ganio et al [169]	2001	16	11.5 <sup>+</sup> / <sub>-</sub> 4.8 (2-20) episodes of incontinence / 14 days	0.6 <sup>+</sup> / <sub>-</sub> 0.9 (0-2) episodes of incontinence / 14 days
Kenefick et al [170]	2002	15	11 (2-30) episodes of incontinence / 7 days 0	(0-4) episodes of incontinence / 7 days
Matzel et al [162]	2004	34	16.4 episodes of incontinence / 7 days	2 episodes of incontinence / 7 days

Several studies have investigated the effects of SNS in the longer term, after permanent implantation of the neurostimulator. Malouf et al [163] reported marked improvement in 5 of 5 patients followed for a median of 16 months. Matzel et al [165] reported improvement in 6 of 6 patients followed for 5-66 months. Two devices had to be removed due to intractable pain. Leroi et al [166] studied nine of eleven patients who progressed from temporary to permanent stimulation. Eight out of nine experienced improvement in their incontinence. Rosen et al [168] performed test stimulations in 20 patients; 16 had a positive response and underwent device implantation. The median number of incontinent events/21 days dropped from 6 to 2. Kenefick et al [170] reported the results of SNS in 15 consecutive patients. All patients were improved and 11 were fully continent at a median follow up of 24 months.

Matzel et al [162] published a multicenter prospective trial of SNS in 37 patients, 34 of whom underwent neurostimulator implantation. The median number of incontinent episodes/week dropped from 16.4 at baseline to 3.1 at 12 months and 2.0 at 24 months. Patients reported an improved ability to defer defecation and decreased pad use. FIQL was significantly improved in all 4 scales. SF-36 scores improved in 7 of 8 scales, but only reached statistical significance in social functioning.

The mechanism of action of SNS is uncertain. Some studies have demonstrated increased resting anal pressure, [167, 168, 170, 172] but others have not. [163, 173] Several studies have documented an increase in anal squeeze pressure. [167, 168, 170, 172] SNS appears to increase rectal sensitivity. [168, 170, 172] In one short-term study, SNS was found to decrease rectal contractile activity and reduce episodes of spontaneous anal relaxation. [171]

Kenefick et al [174] investigated the effect of sacral nerve stimulation on rectal blood flow as a measure of autonomic nerve function. Sixteen patients were recruited and examined with a laser Doppler flowmeter to measure changes in red cell flux. The study provided evidence of an effect of sacral nerve stimulation on the autonomic innervation of the lower gut, as the flux increased as a function of voltage. The change in flux happened within seconds in all patients, suggesting modulation of extrinsic neural activity.

SNS has been a safe procedure with a relatively low complication rate. Complications include pain, infection and lead dislodgement. The explanation rate is reported to be 4%. [161]

Based on numerous small prospective trials, SNS for fecal incontinence is recommended at a grade C level.

#### 4. INJECTABLE BIOMATERIALS

Injection of bulk-enhancing agents to increase urethral resistance at the level of the bladder neck is a successful treatment for patients with urinary incontinence. [175] This concept has now been utilized in a number of trials to improve fecal continence.

Shafik[176] treated 11 patients with "partial" fecal incontinence with perianal injections of polytetra-fluoroethylene paste with improvement or cure in all patients. Shafik[177] subsequently treated 14 patients with "partial" fecal incontinence with autologous fat injections. All patients became continent. There were no complications using either agent.

Kumar et al [178] reported of the use of glutaraldehyde cross-linked collagen injections in 17 patients with fecal incontinence. The collagen was injected submucosally in one to three positions either until a gutter deformity was corrected or adequate symmetrical anal cushions were raised. Following injection, 11 out of 17 patients showed marked symptomatic improvement, one some improvement, two minimal improvement and three no improvement. The mean follow-up was 8 months. There was a trend towards an increase in resting pressures, but squeeze pressures were not altered.

Malouf et al [179] studied 10 patients with passive incontinence. The patients were either injected circumferentially or at a single site with a siliconebased product Bioplastique. Patients who failed to show improvement after the first injection were offered a second injection six weeks after the first injection. At six weeks, 6 of 10 patients showed either marked improvement or complete cessation of leakage. Three patients were not improved. However, after six months, only 2 of 7 had maintained marked improvement. Complications occurred in five of the first six patients including infection and pain.

Kenefick et al [180] reported upon six patients with fecal incontinence related to "poor internal anal sphincter function" treated with silicone Bioplastique. The median follow-up was 18 months .There was a marked improvement in symptoms in five of six patients, as well as improvement in the physical and social function scales of the SF-36. Fecal incontinence score improved from a median of 14 before the procedure to 8 after the procedure on a scale where 24 is the worst score and 0 the best score. Davis et al [181] assessed the efficacy of a larger molecule, bulking agent (Durasphere) over the short and long-term in 18 patients with an internal anal sphincter defect refractory to conservative management. It was injected in the submucosal plane at the site of the defect until adequate anal sphincter symmetry was restored. The mean follow-up was 28.5 months. Fifteen of eighteen patients reported improvement in their incontinence. Interestingly, patients who predominantly have mucus leakage as their main presenting symptom were not helped by this treatment.

In summary, most series of injectable biomaterials report reasonable success rates. However, each of these series is uncontrolled and involves small numbers of patients. Very few long term outcomes data have been reported, so the longevity of therapeutic efficacy is unknown. Numerous injectable agents have been employed and no comparative data are available. Injection technique has not been standardized. Accordingly, perianal injection therapy for fecal incontinence can be recommended at a grade C level.

## 5. RADIOFREQUENCY ABLATION (SECCA® PROCEDURE)

Radiofrequency ablation is a novel but unproven invasive management option for fecal incontinence that has recently been introduced into the literature. [182] The potential usefulness of this approach was first established in patients with gastroesophageal reflux disease (Stretta® procedure), where intraluminal radiofrequency energy was used to treat the lower esophageal sphincter. However, the utility of the Stretta® procedure for gastroesophageal reflux has been called into question[183] because a shamcontrolled trial showed no decrease in esophageal acid exposure post-treatment. [184] It was hypothesized that delivery of radiofrequency energy to the anal canal (termed the Secca® procedure) could potentially improve the barrier function of the anal sphincter complex. This hypothesis was based on histologic animal data generated by studies of Stretta® technique; no human histologic data exist for the effect of radiofrequency energy in the esophagus or the anal canal. [183] Radiofrequency heating apparently causes "tissue tightening" with concomitant collagen contraction, focal wound healing, and tissue remodeling. This approach has also been used to "tighten tissue" in other clinical situations, such as sleep apnea, snoring and BPH. [182]

The first study of ten patients was reported by Takahashi et al in 2002. [182] The authors reported a decrease in the Cleveland Clinic Florida Fecal Incontinence score from 13.5 to 5 and both the FIQL and SF-36 were improved as well. Two-year follow-up showed persistence of these results. [185]

A multi-center study then commenced. [186] On an outpatient basis using local anesthesia, radiofrequency energy was delivered via an endoscopic device with multiple needle electrodes to create thermal lesions in the mucosa of the anal canal. Forty-three women and seven men (50 patients total, mean age 61) were treated. Patients had had fecal incontinence for a median of 15 years. At six months after treatment, the Cleveland Clinic Florida Fecal Incontinence score dropped from 14.5 to 11 and the SF-36 parameters improved from 64 to 76. These improvements were substantially smaller than those reported in the original single-center study. [182] Physiologic parameters, including PNTML, anal ultrasound, and anorectal manometry, were not changed.

It is of critical importance to emphasize that the effectiveness of the Secca® technique remains unknown as no comparative trial data has been generated. Long-term results will need to be documented in order to determine the place this management technique might have in the armamentarium of surgical approaches used to treat fecal incontinence. A randomized trial between this approach and simple biofeedback and medical management needs to be done. The technique is recommended at a grade D level.

#### **III. COLOSTOMY**

A permanent colostomy is usually formed as a last resort for severe fecal incontinence when all other interventions have failed. Because colostomy is generally regarded as a failure of treatment, its effectiveness, perioperative complications, and impact on the quality of life have never been properly evaluated. Importantly, however, colostomy is a frequently successful management strategy for fecal evacuation that restores dignity to many patients and allows them to regain social function.

No systematic reviews, randomized controlled trials or non-randomized interventional studies have been reported regarding colostomy for incontinence, and only one observational study (level 4 evidence) and one non-experimental study (level 4 evidence) were identified.

Catena et al [187] reported a retrospective chart review of 44 patients (35 women) who underwent elective end sigmoid colostomy for fecal incontinence of various etiologies. After colostomy formation 19 patients (43%) were asymptomatic, while the other 25 experienced such problems with their rectal stump as diversion colitis and mucus leakage. Of the 25 patients, 12 (27% of the total) underwent a secondary proctectomy due to the rectal stump problems sufficient to warrant the operation. Histological examination revealed diversion colitis in 6 patients. The sole factor associate with proctectomy was age, with younger patients being more likely to require rectal excision. The authors concluded that data are insufficient to recommend primary proctectomy in patients with severe fecal incontinence warranting permanent end sigmoid colostomy.

Norton et al [188] examined patients' view of a colostomy by conducting a questionnaire study of patients who had a colostomy created to manage their fecal incontinence. Sixty-nine individuals (58 women) responded. When patients were asked to rate their ability to live with their stoma on a scale of 0-10, the median score was 8 (range 0 - 10). The majority (83%) felt that the stoma, within the past month, restricted their life "a little" or "not at all." Eighty-four percent answered that they would "probably" or "definitely" choose to have the stoma again. When they were asked the question "compared to when you were incontinent, how much change has having a stoma made to your overall quality of life?" on the scale of -5 (much worse) to +5 (much better), the median rating was +4.5 (range -5 to +5). The authors concluded that health care professionals should discuss the option of a stoma with incontinent patients because of the overwhelmingly positive outcomes.

In conclusion, a grade C recommendation regarding the role of permanent colostomy to manage fecal incontinence can be made on the basis of only two studies of level 4 evidence as well as the consensus of expert opinion.

### IV. SURGERY FOR CHILDHOOD INCONTINENCE

Incontinence in childhood can be either functional or organic. Functional incontinence is usually associated with severe constipation. It is a self-limiting problem that usually disappears at puberty, while organic incontinence is caused by congenital malformations affecting the anorectum, anal sphincters or the spinal cord. [189] Between 40% and 70% of affected patients have one or more additional congenital defects, more likely in patients with higher malformations. Anomalies of the sacrum and genitourinary tract are the most common associated anomalies. [190]

A commonly accepted figure for the incidence of anorectal malformations in Europe and North America is around 1 in 4000-5000 live births. [191-194] The overall male to female ratio is approximately 1.4:1. [195-197]

Posterior sagittal anorectoplasty is the most frequently performed surgical procedure in the reconstruction of anorectal malformations. It was developed and popularised by Peña in 1982. [198] A critical determinant for functional outcome is the type of anorectal malformation. Poor prognostic factors are high malformations[197] and presence of a sacral defect. [199, 200] Fecal incontinence is a frequent postoperative sequela after surgery for anorectal malformations. [201-203]

Patients with fecal incontinence due to conditions such as myelomeningocele or persisting incontinence after surgery for anorectal malformations are mainly treated with the antegrade continence enema (ACE) procedure. Since Malone et al [204] reported their initial experience with this method it has become widely performed and accepted as the most successful treatment for intractable fecal incontinence in young patients. [205] It is believed that ACE offers over 70 % of patients with neuropathic bowel or anorectal malformations a chance to be clean. [205]

The ACE procedure can be made by using an ileal segment or the appendix. Tackett et al [206] presented their results with an ileal segment or the appendix in 45 children (29 with myelomeningocele, 7 with imperforate anus) in a retrospective review in 2002. The appendix was used to create the continent cecostomy in 28 patients and ileum in 17 patients. In 16 patients who underwent simultaneous construction of appendiceal Mitrofanoff neourethra, the appendix was split and used for the cecostomy and neourethra in 11. No significant difference was noted in the rate of continence or complications between the two groups. Acceptable continence was achieved in 87 % (39 patients) of the patients and total continence in 69 % (31 patients). Complications that required reoperation related to the continent cecostomy occurred in 10 patients, including stomal stenosis in 8 (6 with an appendicostomy) and stricture in 2 (1 with an appendicostomy).

It is possible to perform the antegrade continence enema procedure laparoscopically. Lynch et al [207] compared the results of their experience with the laparoscopic appendicostomy with the published results of previously described open ACE procedures. [208-210] 30 children have had laparoscopic appendicostomy procedures at Lynch's institution and two required conversion to open procedure, because of difficulty locating the appendix. The stoma is being used for regular antegrade colonic washouts in 29 of the 30 patients, compared with 19 of 31 in Malone's series and 16 of 20 in Pena's. Improvement in soiling has been achieved in 27 (90 %), 15 of whom are completely clean. This rate is similar to that of the other types of procedures. Stenosis of the stoma occurred in 8 (27 %), compared with rates of 10 % - 33 % in other series. Stomal leakage has been troublesome for 2 (6.7 %), compared with leak rates between 5.6 % and 15 % in other series. From these data it appears that that laparoscopic appendicostomy is a simple and safe alternative to previously described methods. There is a minimal morbidity, a long-term viability rate and improved control of soiling in 90 % of the children.

Yerkes et al [211] objectively determined outcomes after the ACE to refine patient selection and maximize the quality of perioperative counselling and teaching. An anonymous questionnaire was mailed to all ACE patients within the last four years. 71 %~(65patients, 57 with myelodysplasia) returned the questionnaires. Complete or near complete fecal incontinence was achieved by 77 % of the patients, while the other 23 % reported improved continence with the ACE. All responses indicated that the ACE was superior to medical management and 91 % rated ACE as significantly better than medical management. 9 patients (14 %) required revisions due to stenosis at skin level. For overall satisfaction on a 5point Likert scale 89 % were very satisfied, 9 % satisfied and 1.5 % very dissatisfied.

Based upon consistent results from case series and consensus expert opinion, the antegrade continent enema (ACE) procedure can be recommended at a grade of C.

To reduce the risk of stomal stenosis in antegrade continence enema, Tam[212] reported about a virtually complication-free simple modification: the Yappendicoplasty in 1999. Twelve children underwent the Y-appendicoplasty and orthopic appendicostomy and none experienced stomal complication that required intervention and the control of fecal continence ranged from excellent to good.

Peña et al [213] described sigmoid resection with

preservation of a rectal reservoir in three children suffering from fecal incontinence, intractable constipation and a dilated rectosigmoid after anorectal malformation repairs. The dilated colonic segment was resected in all three cases. Proximally, the resection line was immediately above the upper limit of the dilated bowel and the distal line above the level of the peritoneal reflection. An end-to-end anastomosis was performed between the descending colon and the dilated rectum. The follow-up period was 6 months to 3 years. No fecal impaction and full continence was achieved.

Powell et al [214] and Cloutier et al [215] also described megarectum and megasigmoid occurring after anorectal malformation repairs. In these cases a resection of the dilated bowel, including the rectum, with a pull-through technique was performed. The constipation was relieved, but incontinence remained a problem in most patients.

Graciloplasty has also been used for children with fecal incontinence. [216, 217] Sonnino et al [216] reported 7 patients (5 with imperforate anus) aged 6.5 to 19 years who underwent a modified Pickrell procedure with the gracilis muscle transposed subcutaneously, without constructing a pulley through the median raphe as originally described. All patients were continent at a mean follow-up of 4.4 years. None of the patients had evidence of fibrosis of the muscle or anal canal, and tension in the transposed muscle was maintained. Han et al [217] reported similar results following graciloplasty in sixteen children (12 with imperforate anus) with uncontrollable fecal incontinence. Only 11 patients were followed-up over a mean period of 5.6 years; 10 of these had nearly normal continence. There were no evidence of fibrosis in the transposed muscle and the tension was maintained. In contrast, Baeten et al [218] reported that incontinent adults treated with dynamic graciloplasty were less likely to achieve successful results than those with acquired incontinence.

Hakelius et al [105] have used free muscle transplantation in the treatment of anal incontinence in children for several years. They transpose a striated muscle, usually the palmaris longus, two weeks after denervation, to the perirectal area as a U-sling around the rectum corresponding to the location of the puborectalis muscle. 26 children had been operated by this method during more than 15 years and at follow-up after an average of 11 years and 4 months, 60% of the cases were regarded as good, 16% as fair, 8% as improved and 16% as failures.

### **V. CONCLUSIONS**

Data regarding the surgical treatment of fecal incontinence are generally weak. Randomized, controlled studies are rare, and practical considerations make the likelihood of such studies improbable. Furthermore, the quality of data reported, particularly in older studies, is frequently poor. Problems include heterogeneous patient populations; variable definitions of "continence," "incontinence," "success," and "failure"; non-standardized and non-validated continence scales; underreporting of validated symptom-specific quality of life measures; variable patient follow up and lack of independent assessment of continence outcomes. Given these realities, conclusions must be drawn with considerable care.

The spectrum of surgery for fecal incontinence is broad and expanding. Interventions range from simple outpatient procedures to major reconstructive surgery. As the reported outcomes of these various operations are often similar, a sound general principle is to proceed first with the simplest and least invasive procedure. Major operations associated with more profound morbidity should be restricted to patients who have failed simpler measures.

#### 1. GENERAL (LEVEL D)

Surgery for fecal incontinence is an acceptable treatment modality for patients with moderate or severe fecal incontinence. Surgery is not indicated for minor complaints.

Patients with moderate incontinence should undergo conservative therapy before being offered surgery. Before surgical intervention is undertaken, all patients should have anorectal physiology evaluation (including assessment of sphincter integrity by endoanal ultrasound or magnetic resonance imaging). Anal manometry is sometimes of adjunct benefit. Surgery should be performed by surgeons with specialty training and expertise in pelvic floor physiology and the management of fecal incontinence.

#### 2. Sphincter repair (Level C)

Sphincter repair is indicated for patients with acute traumatic sphincter disruption, such as following obstetrical injury. In the acute setting, direct apposition of the muscle ends is generally the most appropriate technique, but many patients experience persisting incontinence. Optimal results can be expected when the surgeon is expert and experienced and the environment is controlled.

Overlapping sphincteroplasty can be offered to patients with moderate to severe fecal incontinence who have a documented sphincter injury confirmed by endoanal ultrasound or magnetic resonance imaging. If early repair is not undertaken, repair should be delayed at least 6 months to allow resolution of local inflammation and maturation of scar tissue. A diverting stoma is not indicated except under special circumstances such as a history of Crohn's disease or multiple previous failed repairs. Most patients enjoy significant functional improvement after sphincteroplasty, but long-term results deteriorate with time.

#### 3. POSTANAL REPAIR (LEVEL C)

The popularity of the postanal repair for patients with "idiopathic" (neurogenic) fecal incontinence has diminished considerably the procedure's introduction, and the operation is now done only infrequently. Postanal repair can be offered to patients with persistent severe fecal incontinence and intact anal sphincters who have failed conservative therapies and are reluctant to have more complicated or experimental surgical procedures. Reasonable continence can be achieved in the short term in about half of the patients who undergo this operation, but the restored continence tends to deteriorate with time.

## 4. NON-STIMULATED MUSCLE TRANSPOSITION (LEVEL D)

Non-stimulated muscle transposition using either gracilis or gluteus muscle can improve continence in a variable percentage of patients. Children often have the best results. The quality of continence achieved is not well documented in many studies, and some data suggest that results may deteriorate with time. Since the advent of electrical muscle stimulation, unstimulated wraps are performed infrequently.

## 5. STIMULATED MUSCLE TRANSPOSITION (LEVEL C)

Electrically stimulated gracilis muscle neosphincters can provide improved continence for a majority of patients who undergo the procedure. However, the complication rate associated is high, particularly in the hands of inexperienced surgeons. The procedure should only be performed in dedicated specialized centers.

#### 6. ARTIFICIAL ANAL SPHINCTER (LEVEL C)

Artificial anal sphincter implantation is an effective procedure that can be offered to patients with severe fecal incontinence when other conventional treatment options have failed or are not suitable. Patients must be well motivated and both physically and psychologically skilled to manage the device. Morbidity associated with the procedure is significant and device explantation is eventually required in a third of patients. For patients who can retain a functioning device, continence, together with the quality of life, is highly likely to improve significantly. The overall intention to treat success rate is approximately 50%. The procedure should only be performed in dedicated specialized centers.

#### 7. SACRAL NERVE STIMULATION (LEVEL C)

Sacral nerve stimulation is a promising treatment for patients with fecal incontinence. The clinical benefit appears to be maintained in the medium-term without deterioration. It is not possible to give recommendations on patient selection, because such a diverse group of patients have been treated with SNS. Until now all patients treated have had an intact, partially intact or surgically repaired external anal sphincter. The effect of SNS on patients with anatomic sphincter defects is unknown. The mechanism of SNS action is uncertain.

#### 8. INJECTABLE BIOMATERIALS (LEVEL C)

There are only a few small studies published on injectable biomaterials in the treatment of fecal incontinence. The clinical results are promising, but many different injection materials and techniques have been used, the follow-up period is short and the patients highly selected. At present this technique only has a place within trials, and randomised controlled studies are needed.

## 9. RADIOFREQUENCY ABLATION (SECCA® PROCEDURE) (LEVEL D)

Available data are very limited and too sparse to draw reliable conclusions as to safety and efficacy.

## **10.** SURGERY FOR CHILDHOOD INCONTINENCE (LEVEL D)

Despite development of the Pena sagittal anorectoplasty, successful management of imperforate anus, particularly high lesions, remains challenging. Fecal incontinence is a frequent sequela of surgery for anorectal malformations, and a team approach involving specialists in incontinence management is important. For children with intractable incontinence, the antegrade continent enema (ACE) procedure is the most successful treatment. (level C) ACE can be performed using either the appendix or ileum, and laparoscopic ACE procedures are safe and simpler than open ACE procedures. Stimulated graciloplasty has been used successfully in selected children with refractory incontinence, but long-term safety and efficacy data are not available.

#### **11.** COLOSTOMY (LEVEL C)

Formation of an end colostomy is a reasonable treatment option for patients with refractory incontinence who are able to accept the associated alteration in body image. Colostomy provides restoration of a more normal lifestyle and improves quality of life. Colostomy should not be regarded as a treatment failure but rather a reasonable treatment option for patients whose lives are restricted by fecal incontinence that is not amenable to other therapy. An end sigmoid colostomy alone, without proctectomy, is recommended. The minority of patients who develop significant symptoms from their retained rectal stump may eventually require proctectomy as a secondary procedure.

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