Surgical Treatments for Incontinence

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Introduction

Faecal incontinence results from an impaired ability to control gas or stool to allow evacuation at a socially acceptable time and place. Normal continence depends on the consistency of the stool, capacity of the rectum, anorectal sampling reflex, and normal resting anal tone. It is maintained by the integrated action of the anal sphincters, the pelvic floor muscles, and intact neural pathways. Incontinence may result whenever any of these mechanisms malfunction without adequate compensation. Treatment for faecal incontinence can be either medical or surgical. The aim of medical therapy is to alter stool consistency through dietary changes and antidiarrhoeal medications, with a concurrent or subsequent course of biofeedback. The multiple surgical alternatives range from minimally invasive procedures, such as injection of bulking agents and sacral nerve stimulation, to complete replacement of the sphincter mechanism with an artificial bowel sphincter or stimulated graciloplasty. We group currently available surgical alternatives into five categories: Repair, Augmentation, Replacement, Stimulation and Diversion/Bypass. However, despite the plethora of exciting advances, a stoma may be the most suitable option for certain patients.

Conservative Management

Conservative medical management is the initial therapy for faecal incontinence. Even when a surgical procedure is being contemplated, it is important to begin treatment with conservative management; this approach helps to optimize the outcomes of the impending procedure. Conservative management focuses on stool consistency. Thus, the goal is to deliver a soft, well-formed stool bolus to the rectum. The Bristol Stool Chart is useful for helping patients understand the different degrees of stool consistency. The chart can also be used to evaluate and guide therapies [1]. The validated Wexner Incontinence score is widely used for assessment of continence,

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R. Cohen, A. Windsor (eds.), *Anus*,
DOI 10.1007/978-1-84882-091-3_12, © Springer-Verlag London 2014

with a score of 0 for perfect continence and 20 for complete incontinence [2].

Patients with faecal incontinence commonly have diarrhoea or loose bowel movements. In a study of older adults, 50 % of patients with chronic diarrhoea also had faecal incontinence [3]. Patients with diarrhoea should be evaluated for infectious and inflammatory causes, malabsorption, and endocrinopathies such as diabetes and hyperthyroidism. A full discussion of diarrhoea and its causes is beyond the scope of this chapter. If treating the underlying cause of diarrhoea and ceasing all laxative abuse does not improve the patient's continence, treatment can begin with bulking and anti-motility agents. The most commonly used bulking agents are natural and synthetic fibre. Soluble fibres include psyllium and gum arabic. Insoluble fibres include methyl cellulose and the synthetic calcium polycarbophil. An open-label randomized trial conducted by Bliss et al. demonstrated that, compared with a placebo group, patients with loose or liquid stools who increased their fibre intake experienced a 50 % reduction in the number of incontinent episodes [4]. Fibre has also been shown to increase stool frequency in patients with constipation, which contributes to faecal incontinence by creating overflow.

The most commonly used anti-motility agents are loperamide, codeine, tincture of opium, diphenoxylate plus atropine, and amitriptyline. Clinical trials in patients with diarrhoea and faecal incontinence demonstrate that more patients who are treated with these agents achieve full continence than those treated with placebo [5]. Loperamide, codeine, and tincture of opium are opioids that exert their effects via opioid receptors in the bowel. Diphenoxylate plus atropine and amitriptyline exerts their effects via anticholinergic pathways. Elderly patients may not tolerate the anticholinergic side effects of these medications; thus, caution should be taken accordingly. In a small double-blinded crossover trial of loperamide, codeine, and diphenoxylate, the authors concluded that loperamide was at least as effective as, or better than, the other two agents and had fewer side effects [6].

Diet therapy usually consists of increasing fibre and water intake and avoiding caffeine and alcohol. Patients are advised to consume 20–35 g of fibre and 8–10 glasses of water per day. This regimen is difficult to follow for most patients, and many will require a fibre supplement to achieve >20 g of daily fibre. Caffeine, alcohol, and certain foods may cause diarrhoea, leading to worsening of incontinence symptoms.

Repair Sphincteroplasty

Repair of a sphincter injury due to obstetric, iatrogenic, or other traumatic causes is the most traditional and widely available therapy for faecal incontinence. Obstetric injury is the most common indication for sphincteroplasty. Primary repair at the time of vaginal delivery is almost exclusively performed by obstetricians. Midline episiotomy, prolonged second stage of labour, and a forceps delivery increase the risk of sphincter injury. Studies of women evaluated with endoanal ultrasound after vaginal delivery have revealed sphincter defects in 26.9 % of primiparous women and new sphincter defects in 8.5 % of multiparous women [7]. Approximately 30 % of women with a sphincter defect will have faecal incontinence.

Endoanal ultrasound remains the primary tool for identification of sphincter injuries. The role of preoperative physiologic testing remains controversial. Gilliland et al. reviewed the outcomes of 77 patients who underwent preoperative physiologic testing followed by anterior overlapping sphincteroplasty [8]. Age, parity, prior sphincteroplasty, duration of incontinence, size of defect on endoanal ultrasound, and manometric parameters did not correlate with outcomes. Seventy-one patients underwent preoperative pudendal nerve terminal motor latency (PNTML) testing. Among patients with either a unilateral or bilateral pudendal neuropathy, only 16.7 % had a successful outcome compared with 62 % of patients who had a normal study. The authors concluded that all patients with faecal incontinence and an external sphincter defect should be offered anterior overlapping sphincteroplasty. A further recommendation was that patients should be informed that the integrity of the pudendal nerves is the most important predictor of success.

Goetz and Lowry identified 16 papers in which the influence of pudendal neuropathy was assessed [9]. Five papers concluded that neuropathy predicted outcomes after sphincteroplasty. In contrast, 11 studies that included more than 700 patients reported no such relationship. The authors

concluded that PNTML does not predict postoperative function and should not be used to exclude patients from surgery; clearly no consensus exists.

It is generally agreed that unless repair is attempted immediately after injury, it should be delayed until the wound has healed and inflammation has subsided. Studies on primary overlapping sphincter repair from the gynaecology literature have had mixed results [10].

Preoperatively, all patients who undergo sphincteroplasty are given a bowel prep of polyethylene glycol. Patients receive preoperative antibiotics in accordance with guidelines of the National Surgical Quality Improvement Program (NSQIP) of the American College of Surgeons. After general anaesthesia, the patient is placed in the prone jackknife position. The buttocks are separated with tape, and the anus and perineum are prepped with a povidone iodine solution. A transverse curvilinear incision is made overlying the external anal sphincter, approximately 0.5 cm caudal from the anal verge. The external sphincter is then dissected both from the internal anal sphincter and the posterior wall of the vagina. The anterior scar is sharply divided, but not excised. Care is taken to preserve the scar, which helps to hold the sutures. Interrupted long-term absorbable sutures are placed along the internal anal sphincter to plicate the sphincter. The desired effect is to place an index finger through a snug, but not tight, repair. An anterior levatorplasty can also be undertaken at this point. The ends of the external sphincter are overlapped and sutured to each other with a series of interrupted absorbable sutures in a mattress fashion. The wound is then partially closed in a Y-fashion to further separate the anus from the vagina. The central portion of the wound should be left open. It is not necessary to routinely use faecal diversion or bowel confinement [11, 12].

Studies with less than 3 years of follow-up have demonstrated promising results for anterior overlapping sphincteroplasty. In 55 patients treated with overlapping sphincteroplasty, Fleshman et al. reported that 28 (51 %) had complete continence and 12 (22 %) were only incontinent to gas at 1 year of follow-up [12]. Similarly, Wexner et al. found that in 16 patients with a mean follow-up of 10 months, 72 % reported excellent or good functional results postoperatively [13]. Engel et al. performed ultrasound and physiology testing pre- and postoperatively [15]. At a median of 15 months of follow-up, they found that 76 % of patients had improvement after the repair. These researchers also observed that a larger increase in squeeze pressure (20 vs 5 cm H_2O, $p=0.05$) and an intact external anal sphincter after repair (32 of 35 vs 5 of 11, $p=0.003$) correlated with success.

Results of overlapping sphincteroplasty in the long term are far less encouraging. Halverson and Hull reviewed the experience from the Cleveland Clinic [16]. With a median follow-up of 62.5 months, 49 patients were contacted and Fecal Incontinence Severity Index (FISI) and Fecal Incontinence Quality of Life Scale (FIQL) scores were calculated. Thirty-one patients had an injury due to obstetric causes, 7 were iatrogenic, 3 were from trauma, and 3 were not documented. Four patients had subsequent permanent faecal diversion after repair. More than 50 % of the patients were incontinent to liquid and solid stool, and only 14 % reported perfect continence. The median patient-rated and surgeon-rated FISI score was 20 [16]. This group of researchers published a subsequent study with a median follow-up of nearly 11 years [17]. At the study end point, none of the patients reported perfect continence, and the patient-rated and surgeon-rated FISI score increased to 39.4 and 39.9, respectively. These results indicate a significant decline in function as compared with the prior study.

Postanal Repair

Sir Alan Parks developed the posterior anal repair, which now bears his name, in the late 1960s and early 1970s. The repair was designed for patients with idiopathic faecal incontinence with the intention to restore the acute angulation of the anorectal junction. The repair initially showed promising results through the 1980s with reported success rates up to 86 % [18]. The results of these early studies may have been limited by a lack of standardization in grading of faecal incontinence. With the advent of anorectal ultrasound, the identification of anterior sphincter injuries became more common, and it is postulated that some of the patients initially treated with a posterior repair for "idiopathic" faecal incontinence indeed likely

had an anterior sphincter defect. Matsuoka et al. reported the results of 21 patients who underwent posterior repair after thorough preoperative evaluation [19]. None of the patients had a sphincter defect and 13 had prolonged pudendal nerve terminal latencies. Thirty-five percent of patients reported improvement in their symptoms. In this group, the Wexner faecal incontinence score improved from a mean of 16.5 preoperatively to 2.6 postoperatively, which was statistically significant. The remaining patients who reported no improvement had a minimal change in their incontinence score, from 16.5 preoperatively to 13.3 postoperatively (not statistically significant). The most recent series, reported by Mackey et al., evaluated 57 patients [20]. Postoperative incontinence was rated by patients as *none* to *minimal* (26 %), moderate (26 %), and severe (48 %).

Technique

The Parks' postanal repair is performed with patients under general anaesthesia in the prone jackknife position. A posterior angulated or curvilinear incision is made 1–2 cm distal to the anal verge. An intersphincteric dissection is then undertaken to above the level of the levators and into the presacral space. The ischiococcygeus and puborectalis are then approximated in layers with interrupted absorbable suture. The external sphincter is similarly plicated, and a finger is introduced into the anal canal to assess the repair. The wound is closed in layers, often over a closed suction drain.

Augmentation Radiofrequency Therapy

The Secca® procedure, which was approved by the US Food and Drug Administration (FDA) for treating faecal incontinence, involves the delivery of radiofrequency energy to the anal canal. The basis for such therapy comes from experience in applying radiofrequency energy to the lower oesophageal sphincter in treating gastroesophageal reflux disease. The Mederi RF generator (Mederi Therapeutics, Inc., Greenwich, CT) delivers radiofrequency energy at 465 kHz to the muscle below the mucosa through a set of four needles (Fig. 12.1). The power output is varied to achieve a target temperature of 85 °C. The mucosa is protected with water irrigation. The lesions are delivered from 1.5 cm above the dentate line to 0.5 cm below the dentate line. 16 to 32 applications are delivered, with each set comprising 4 individual lesions.

The results of various series of the Secca® procedure reported in the literature are summarized in Table 12.1. The first reported experience with the Secca® procedure was by Takahashi et al. in 2002 [21]. In a pilot study of 10 patients with 12 months of follow-up, these researchers demonstrated a significant reduction in Wexner faecal incontinence scores, from 13.5 to 5.0. At 24 months of follow-up, the average Wexner score in this same cohort was 7.8 [23]. This was still a significant decrease from baseline but not as large as that seen at 1-year of follow-up. A multicenter, prospective, manufacturer-sponsored study in the United States conducted by Efron and colleagues included 50 patients who were followed for 6 months. The results of this study demonstrated a more modest decrease in Wexner scores from 14.5 to 11.1 [22]. However, the authors noted an improvement in all four components of the FIQL score as compared with baseline. Ruiz et al. noted a similar modest decrease in Wexner scores from 15.6 to 12.9 at 12 months in patients treated with the Secca® procedure [26]. Lefebure et al. reported a minimal change in Wexner scores in a series of patients followed for 12 months [25].

Because the device was unavailable for several years, recent data are limited. However, the Secca® procedure remains a viable option. It is a minimally invasive procedure that can be performed under local anaesthesia, and it has few associated complications. In patients with incontinence who do not have a known sphincter defect, the number of surgical options is limited. Further studies may help elucidate which of these patients may benefit most from the Secca® procedure.

Injectables

The symmetry and anatomy of the anal canal have been recognized as important components in the maintenance of continence. The use of injectable

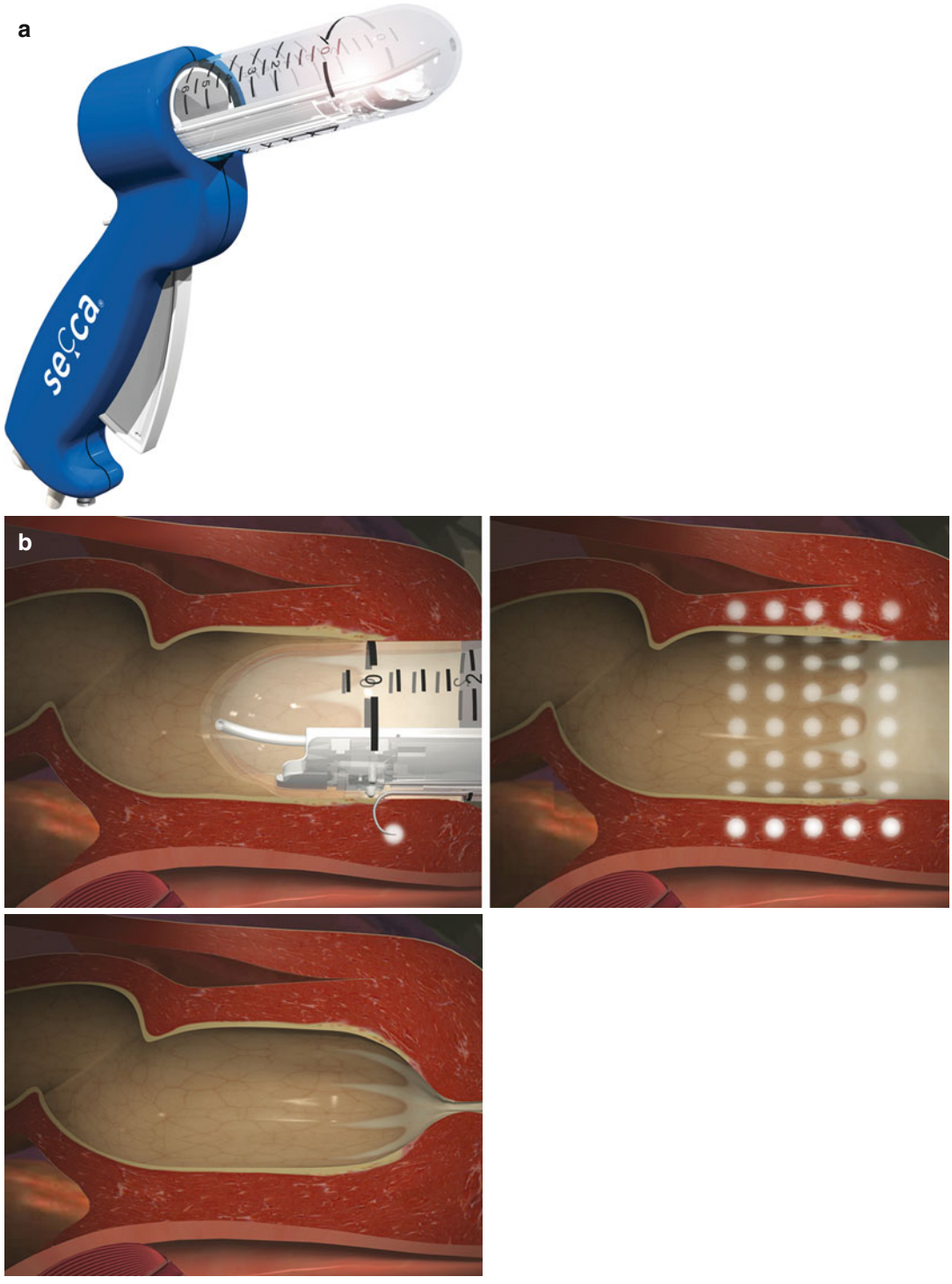

Fig. 12.1 Schematic illustration of (**a**) the applicator, (**b**) four quadrant electrode deployment sites (© 2012 Mederi Therapeutics Inc.)

Table 12.1 Summary of trials on radiofrequency energy therapy (Secca® procedure)

Author (year)	*n*	Follow-up (months)	Wexner score		Comments
			Before	After	
Takahashi (2002) [20]	10	12	13.5	5	Four bleeding complications, 3 resolved, 1 required suture control
Efron (2003) [21]	50	6	14.5	11.1	18 % had prior overlapping sphincteroplasty; 4 % had prior artificial bowel sphincter
Takahashi (2003) [22]	10	24	13.7	7.8	No significant difference between 1- and 2-year follow-up
Takahashi (2008) [23]	19	60	14.4	8	Sustained benefit
Lefebure (2008) [24]	15	12	14.1	12.3	No long-term complications. No change in FIQL scores except in the depression subscale
Ruiz (2010) [25]	16	12	15.6	12	No long-term complications

Table 12.2 Summary of trials on injectable materials

Author (year)	*n*	Material used	Follow-up (months)	Wexner score		*P* value
				Before	After	
Shafik (1993) [26]	11	PTFE	24	63 % improved		–
Shafik (1995) [27]	14	Autologous fat	24	85 % improved		–
Malouf (2001) [28]	10	Bioplastique®	6	30 % improved		_
Davis (2003) [29]	18	Durasphere®	28.5	11.8	8	0.002
Tjandra (2004) [30]	82	Silicone (US guided)	12	14.5	3	<0.001
Chan (2006) [31]	7	PTQ®	14	9–14	1–5	0.016
Stojkovic (2006) [32]	73	Contigen®	12	10	6	<0.001
de la Portilla (2008) [33]	20	PTQ®	24	13.5	9.4	0.127
Maeda (2008) [34]	10	Bulkamid®	19	15	12	<0.05
Maeda (2008) [34]	10	Permacol®	19	16	15	<0.05
Soerensen (2009) [35]	33	Silicone	12	13	11	–
Tjandra (2009) [36]	20	PTQ®	12	12	4	<0.001
Graf (2011) [37]	206	NASHA/Dx	12	14.3	10.9	<0.001

bulking agents for the treatment of faecal incontinence stems from similar technology in the field of urinary incontinence. Table 12.2 lists several of the early and more recent trials on injectable agents. Use of these agents is attractive due to their minimally invasive nature. First described for faecal incontinence by Shafik and colleagues in 1993, submucosal injection of polytetrafluoroethylene (Teflon or Polytef™; DuPont, Wilmington, NE) and autologous fat yielded successful short-term outcomes. Other injected agents include carbon-coated beads, silicone, collagen, nonanimal stabilized hyaluronic acid stabilized in dextranomer microspheres, polyacrylamide, and porcine dermal collagen.

The Cochrane Collaboration reviewed the available literature on injectable agents in 2010. Based on four randomized trials involving 176 patients, the authors observed a high risk for bias, which precluded definitive conclusions [39]. They did note, however, that most trials showed an improvement in patients' symptoms in short-term follow-up. A small randomized trial comparing silicone biomaterial and carbon-coated beads showed a greater proportion of patients in the silicone group having a 50 % reduction in incontinent episodes at 12 months of follow-up [37]. The injection method employed in each of the reported studies is highly variable. In a study including 82 patients who underwent injection

of silicone, Tjandra et al. reported significantly improved functional and quality of life outcomes with ultrasound-guided injections compared with non-guided injections [31].

Noting the relative lack of high-quality, randomized data, the NASHA Dx Study Group conducted a manufacturer-sponsored, international, multicenter, randomized, double-blinded controlled trial at 8 US centres and 5 European centres [38]. Patients with a Wexner score of greater than 10 and who had failed conservative management were randomized in a 2:1 fashion to transanal submucosal injection with nonanimal stabilized hyaluronic acid stabilized in dextranomer microspheres (Solesta®, Salix Pharmaceuticals, Raleigh, NC) or sham therapy, which consisted of mimicking the procedure without injection of any substance. The primary end point was a response to treatment as defined by a reduced number of incontinent episodes by 50 % or more compared with baseline. Fifty-two percent of patients in the treatment group achieved this end point at 6 months compared with 31 % of patients in the sham arm (odds ratio 2.36, 95 % CI 1.24–4.47, $p=0.009$). There was no difference in the median decrease in number of incontinent episodes or change in Wexner scores from baseline between the treatment and sham groups. There was a significant difference between the treatment and sham groups in the mean increase in number of incontinence-free days at 6 months (3.1 vs 1.7, $p=0.016$) [38].

The role of injectable materials for faecal incontinence has not yet been fully defined. However, their demonstrated efficacy, minimally invasive nature, and low complication rates are certainly advantageous attributes that may support the use of this therapy, either as a primary treatment of faecal incontinence or as an adjunct. The long-term results, optimal dose, and site of injection are all issues that remain to be clarified.

Replacement Muscle Transposition: Non-stimulated Gluteoplasty

Gluteus maximus muscle transposition was described in the early twentieth century as a treatment for faecal incontinence [40]. The gluteus maximus muscle is suitable for transposition due to its large bulk, proximity to the anal canal, and single proximal neurovascular pedicle. In addition, buttock contraction is a standard response to impending incontinence [41].

Technique

In the prone jackknife position, the lower portion of the gluteus maximus muscles and the fascia are individually mobilized from their origins on the ileum and sacrum. The neurovascular bundle is identified near the ischial tuberosity and preserved. The muscle strips are tunnelled underneath the skin and anchored to the contralateral gluteus maximus muscle on each side so that the anus is fully encircled [41].

Outcomes

Devesa et al. reported the largest series of bilateral gluteoplasties for faecal incontinence, in which 9 of 17 patients achieved normal control and the most common reported morbidity was infection of the perianal wound [42]. However, with the introduction of gracilis transpositions, enthusiasm for the gluteoplasty diminished [41].

Muscle Transposition: Non-stimulated Graciloplasty

In 1952, Pickrell described a novel surgical approach to treating children with faecal incontinence caused by neurologic and congenital disorders [43]. The advantages of transposition of the gracilis muscle include its superficial location, ease of mobilization, and lack of requirement for strength or range of motion [41].

Technique

The technique entailed removing the gracilis muscle from the thigh, wrapping it around the anus, and attaching the free end to the contralateral ischial

tuberosity. Patients underwent training to gain voluntary control of muscle contraction and relaxation.

Outcomes

Corman reported long-term outcomes of non-stimulated graciloplasty; 11 of 14 patients in this study had fair to excellent results [44]. Christiansen et al. reported a series of 16 patients who underwent unstimulated gracilis transpositions, with over 80 % improvement [45]. In an attempt to improve outcomes, Kumar et al. performed bilateral gracilis transpositions in 10 patients. They observed a 90 % improvement in continence maintained for 2 years [46].

Muscle Transposition: Stimulated Graciloplasty

The non-stimulated graciloplasty technique suffered from faced with certain long-term limitations. Namely, the chronic contraction of the transplanted gracilis muscle caused fatigue and thereby compromised the patient's sustained control of continence. The gracilis muscle is naturally composed of fast-twitch type II fibres that are easily fatigable. An approach to resolving this limitation became available in the early 1980s, when researchers demonstrated that the application of low-frequency electrical stimulation could, over time, transform type II fibres into slow-twitch, fatigue-resistant type I fibres [47]. In 1988, Baeten and coworkers used this technology to advance the procedure of stimulated graciloplasty. Their approach, which is also called dynamic graciloplasty, involved stimulating the gracilis muscle with a pulse generator. Tested on patients with fatigue-related suboptimal control following transposition, this stimulation was demonstrated to engender a neosphincter characterized by involuntary resting tone [41, 48].

Technique

Depending on whether a diverting stoma is created, the procedure of stimulated graciloplasty is carried out in two or three phases. In the first phase, the gracilis is removed from the thigh and wrapped around the anus to form a skeletal muscle ring; the severed distal portion is anchored to the contralateral ischial tuberosity (Fig. 12.2). The stimulator (Medtronic Inc, Minneapolis, MN) is implanted in the abdominal wall (Fig. 12.2c), with leads placed on the main trunk or in the intramuscular portion of the gracilis muscle, close to the nerve. The second phase of the procedure involves conditioning the muscle through the application of low-frequency neuromuscular stimulation, delivered at increasing levels over a period of 8 weeks. This process gradually changes the contractile properties of the gracilis muscle, transforming its easily fatigable fast-twitch fibres into fatigue-resistant slow-twitch fibres. In this phase, the patient also learns to use an external magnet in order to turn the stimulator on and off, thereby causing muscle contraction and relaxation, which facilitates the control of continence [41, 49]. If a diverting stoma must be created, additional operative interventions are required for its creation and subsequent closure.

Outcomes

Stimulated graciloplasty was a widely applied transposition procedure for treating faecal incontinence. Success rates generally range between 57 and 93 % [41, 49]. As reported in a prospective series including 17 patients, our initial experience with the procedure at Cleveland Clinic Florida indicated its feasibility despite a steep learning curve [50]. In an initial report of a multicenter trial, the Dynamic Graciloplasty Therapy Study Group (DGTSG) found that 60 % of patients who underwent the procedure had significant improvements in continence and quality of life [51]. Wexner et al. reported the long-term results of this multicenter trial, including outcomes of 129 patients who underwent stimulated graciloplasty from 1993 to 1999 [52]. Overall success, defined as a 50 % or greater reduction in the number of faecal incontinence episodes, was achieved in 62 and 56 % of patients at 1 and 2 years, respectively. These rates demonstrate the durability of the earlier, short-term DGTSG results. The authors of a systematic review

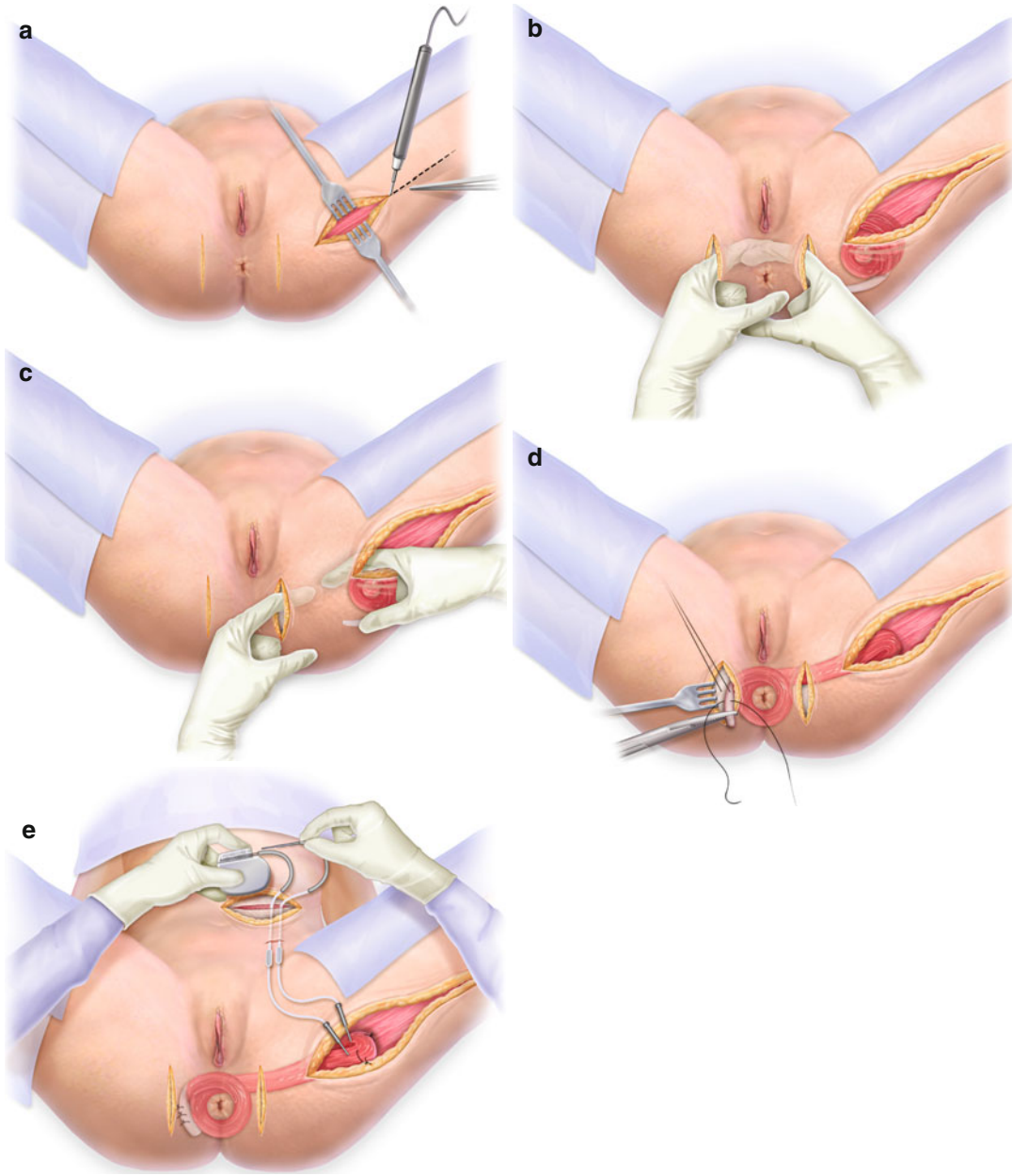

Fig. 12.2 (**a**) Incisions for harvesting the gracilis muscle. (**b**) Incision at the anus. (**c**) Incisions for tunneling the gracilis muscle from the leg to the anus. (**d**) Wrapping the gracilis muscle around the anus. (**e**) The stimulator that is implanted in the abdominal wall. With permission from Wolters Kluwer copyright 2012

reported that the efficacy of stimulated graciloplasty, as measured by patient reports of satisfactory continence, ranged from 42 to 85 % [53].

Many series have demonstrated that stimulated graciloplasty is effective in treating faecal incontinence; however, relatively high rates of complications and surgical revision have also been observed (Table 12.3). As reported by the DGTSG in the original trial, rates of complications and reoperations were 74 and 40 %, respectively [41, 57]. We observed a variety of complications associated with this procedure and its associated technology, including lead fibrosis, seroma of the thigh incision, excoriation of the

Table 12.3 Outcomes of stimulated graciloplasty

Author (year)	*n*	Follow-up (months)	Morbidity (%)	Revision surgery (%)	Success (%)
Christiansen (1998) [53]	13	17	–	–	84
Sielezneff (1999) [54]	16	20	50	43.7	81
Mavrantonis (1999) [55]	21 IM	21	–	–	93
	6 DS	12.5			10
Mander (1999) [56]	64	10	–	–	56
Madoff (1999) [57]	128	26	41	–	66
Konsten (2001) [58]	200 IM	–	–	2.7	74
	81 DS			26	57
Bresler (2002) [59]	24	–	42	46	79
Wexner (2002) [51]	129	24	–	–	62
Rongen (2003) [60]	200	72	–	69	72
Penninckx (2004) [61]	60	53	77	77	61

IM intramuscular, *DS* direct stimulation

skin above the stimulator, rotation of the stimulator, premature battery discharge, fracture of the lead, perineal skin irritation, perineal sepsis, rupture of the tendon, tendon erosion, muscle fatigue during programming sessions, electrode displacement from the nerve, and fibrosis around the nerve [50]. In addition, some patients who underwent the procedure had faecal impaction, anal fissure, and parastomal hernia. Other studies have reported instances of hardware failures, infections, muscle detachment, device malfunction and migration, postoperative evacuatory dysfunction, and severe unresolved pain that resulted in hospitalization and reoperation in numerous cases [53]. Some of these complications led to stoma creation or death.

In 93 cases of dynamic graciloplasty, Matzel et al. reported 211 complications [63]. Although 42 % of patients in this study had severe complications, 92 % achieved recovery following treatment. With the exception of major infections, most of the complications did not adversely affect outcomes. In a systematic review of adverse events associated with the procedure, the most common complications observed were infection (28 %), device malfunction (15 %), and leg pain (13 %) [49, 53]. The mean morbidity rate was 1.12 per patient (range 0.14–2.08).

Risks of morbidity associated with stimulated graciloplasty have been reduced through selected modifications of the procedure. For example, rates of infectious complications have been lowered as a result of improved infection control measures [41, 61]. Complications caused by nerve fibrosis, lead displacement, and high impedance have been virtually eliminated by placing the leads adjacent to the intramuscular portion of the nerve rather than directly on the exposed portion of the nerve trunk [59, 61]. This method of stimulation is the only factor that has been identified as a significant predictor of successful outcomes of stimulated graciloplasty [59]. However, it is evident that surgical experience strongly impacts outcome [41, 58].

Despite evidence for the positive influence of stimulated graciloplasty on patient function and quality of life, Medtronic Inc. abandoned pursuit of FDA approval for the neurostimulator in the United States in 1999. This unfortunate decision was attributed partly to the relatively high rates of associated morbidity. Currently, surgeons in many other countries perform the operation to treat faecal incontinence. In addition, the technique of stimulated graciloplasty has been adapted for performing total anorectal reconstruction for anal atresia and following abdominoperineal resection. In the United States, sphincter muscle loss is currently treated with unstimulated graciloplasty. In the era of FDA approval for sacral nerve stimulation (SNS), graciloplasty still has a role in the treatment of

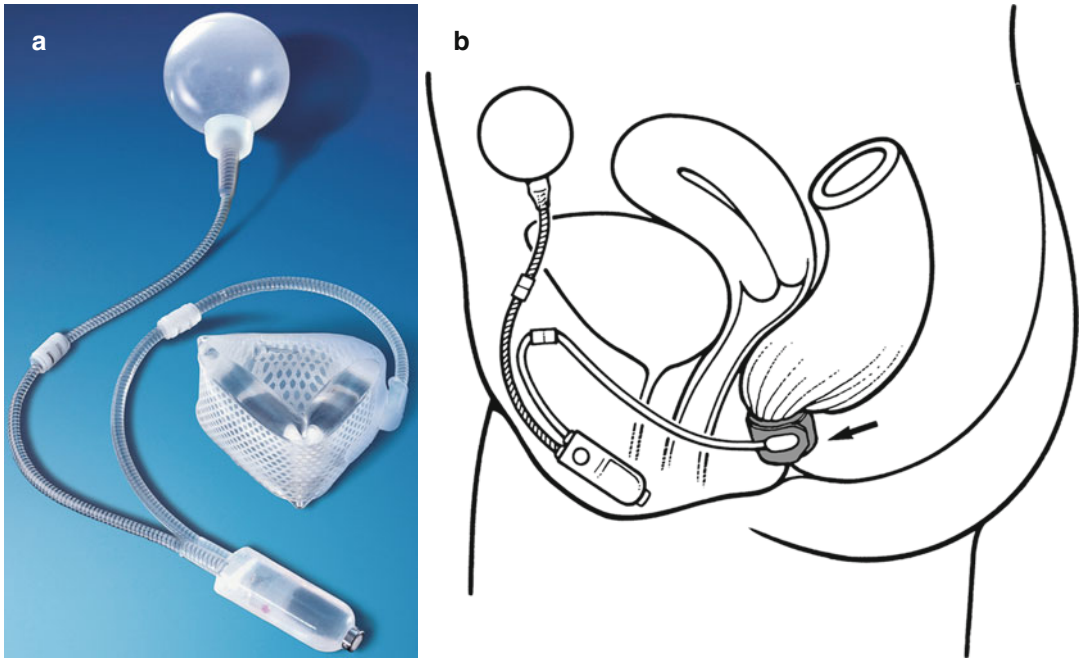

Fig. 12.3 (**a**) Artificial bowel sphincter system, (**b**) schematic of ABS placement for faecal incontinence in a female patient (Courtesy of American Medical Systems, Inc.)

faecal incontinence secondary to large sphincter defects or in patients with rectoanal atresia who are not likely to benefit from SNS and will continue to depend on sphincter replacement. Perhaps successful outcomes for this subgroup of patients might be best achieved with an artificial bowel sphincter preceded by a nonstimulated graciloplasty.

Artificial Bowel Sphincter

This approach to treating faecal incontinence involves implanting a prosthesis that simulates normal anal sphincter function. The Acticon® Neosphincter (American Medical Systems, Minnetonka, MN), which was approved by the FDA in 2001, is an implantable, fluid-filled artificial bowel sphincter (ABS) made of solid silicone rubber. The prosthesis comprises three parts that are connected with kink-resistant tubing: a perianal occlusive cuff, implanted around the anal canal; a pressure-regulating balloon, implanted in the abdomen; and a control pump with a septum, implanted in the labium majus or scrotum (Fig. 12.3) [31, 64, 65]. In response to the patient's control of the pump mechanism, the Acticon® Neosphincter facilitates the opening and closing of the anal canal, simulating normal anal sphincter function. Continence is maintained as adjustments of the fluid-filled cuff compress the anal canal to a pressure approximating physiological resting values.

In order to evacuate, the patient squeezes and releases the pump mechanism between 5 and 15 times. Each pump moves fluid from the cuff to the pressure-regulating balloon, thereby emptying and collapsing the cuff, which releases the compressive force around the anal canal. Due to residual pressure within the balloon, fluid passively flows back into the cuff, usually refilling it within 2–3 min. Continence is re-established as the refilled cuff compresses the anal canal again. Pressure in the occlusive cuff is maintained by the pressure-regulating balloon. The ABS device is available in different cuff lengths (8–14 cm), widths (2.0–2.9 cm), and balloon pressure ranges (80–120 cm H_2O).

Table 12.4 Outcomes of artificial bowel sphincters

Author (year)	*n*	Follow-up (months)	Infection (%)	Device explant/reimplant	Functional (%)
Wong (1996) [65]	12	58	25	7/4	75
Lehur (1998) [66]	13	30	8	4/2	85
Vaizey (1998) [67]	6	10	33	1/0	83
Christiansen (1999) [68]	17	60	18	7/0	53
Lehur (2000) [69]	24	20	4	8/4	83
O'Brien (2000) [70]	13	–	23	3/0	77
Altomare (2001) [71]	28	19	18	5/0	75
Lehur (2002) [72]	16	25	0	6/1	75
Devesa (2002) [73]	53	26.5	21	12/2	49
Ortiz (2002) [74]	22	28	9	9/2	68
Wong (2002) [75]	112	12	38	41/7	67
Michot (2003) [76]	25	34.1	12	5/0	76
Parker (2003) [77]	37	12	19	27/7	49
Casal (2004) [78]	10	29	10	3/2	90
Ruiz-Carmona (2008) [79]	17	68	29	11/3	53
Wexner (2009) [80]	47	39	41	18/4	65

Technique

Because infection is a major complication of the ABS procedure, meticulous aseptic technique is imperative. Preoperatively, patients undergo a full bowel preparation and receive appropriate intravenous antibiotic prophylaxis. A modified lithotomy position is preferred in order to allow a combined perineal and abdominal approach. An anterolateral circumanal incision in the rectovaginal or rectourethral septum is created, and dissection proceeds in a cephalad direction. The ischiorectal fossae are entered on both sides, and a circumferential tunnel around the rectum is created, ideally proximal to the anococcygeal ligament, to minimize the chance of erosion through the perianal skin. This incision must be made very carefully to avoid injuring either the rectum or the vagina, as injury would preclude implantation of the artificial sphincter. A cuff sizer is passed around the anal canal to allow correct selection of the cuff width and length. The cuff itself is passed around the anus and fastened. A low transverse abdominal incision is made and a pocket in the space of Retzius is created. The cuff tubing is then tunneled up from the perineal incision towards this pocket. The balloon is inserted in the pocket. The control pump is implanted in the subcutaneous tissues of the scrotum in men and the labium majus in women on the ipsilateral side of the patient's dominant hand. The balloon is filled with fluid and connected to the cuff tubing for 30 seconds to allow for pressurization of the cuff. The balloon is then drained and refilled with the appropriate amount of fluid. The final step is implantation and pressurization of the pump, tubing, and cuff via a colour-coded tubing system. The device is kept in the deactivated state until the surgical wounds have healed, generally over a period of 6 weeks after which it is activated in the outpatient setting.

Outcomes

Since Christiansen et al. first reported on ABS as a treatment for faecal incontinence in 1987, numerous case series have been published on the efficacy and safety of the procedure (Table 12.4) [31, 64, 82]. Wong et al. reported a large multicenter, prospective trial including 112 patients [76]. The findings demonstrated that the ABS is effective, achieving a continence rate of 85 % and a significant improvement in quality of life in patients with functioning devices. However, on an intention-to-treat basis, success was achieved in only 53 % of patients.

Similar to stimulated graciloplasty, limitations to the ABS are attributable to its high rate of complications; most of these are related to infections of the foreign material and subsequent need for surgical revision and explantation. A systematic review of ABS case series reported a statistically and clinically significant improvement in Wexner and AMS scores after ABS implantation [83]. Six studies reported quality of life outcomes, which were also significantly improved compared with preoperative assessment. However, preoperative and postoperative functional and quality of life outcomes were not assessed by an intention-to-treat analysis in any of these studies; studies only compared outcomes in patients with a functional device. Thus, any negative impact of implantation followed by explantation of a failed ABS device was not assessed, possibly biasing the results. Ruiz-Carmona et al. reported long-term outcomes of ABS in 17 patients with a median follow-up of 5 years [80]. Only 9 of 17 (53 %) cases had an activated functional ABS by the end of the study period. However, those nine patients had significantly improved continence, with significant improvement in Wexner scores from 17.5 preoperatively to 9, 5.5 and 10 at 6, 12 months and at the end of follow-up, respectively. In addition, there was a significant improvement in quality of life.

Unfortunately, rates of postoperative complications of ABS have remained very high, ranging from 19 to 100 % [31, 64]. A systematic review including 14 studies reported explantation rates between 17 and 41 % and surgical revision rates between 13 and 50 % [83]. Wong et al. reported 117 postoperative complications in 114 cases [76]. The most common complications include infections, erosions or ulcerations of the rectum or surrounding skin, device malfunction such as cuff rupture, balloon and pump leaks, and device migration [76, 80, 81, 83, 84]. Fecal impaction, dehiscence of the perineal wound, pain, discomfort, and patient dissatisfaction are less common but also significant problems [81, 83, 84]. Among these complications, infection is the most common, resulting in explantation in 4–38 % of cases [76, 80, 81, 83, 84]. Ruiz-Carmona reported 5-year follow-up data in 17 patients with an ABS [80]. All patients suffered from at least one complication, and 65 % required at least one reoperation. After the first implant, 11 devices had to be removed (65 %) and 7 patients eventually underwent a second implantation.

ABS infection can be divided into two groups: early-stage infection, defined as infection prior to ABS activation, and late-stage infection, defined as infection after ABS activation [81, 83]. In a study from our institution, 21 of 51 patients (41.2 %) developed infection at a mean follow-up period of 39 months [81]. Eighteen (35.3 %) cases developed infection before ABS activation (early-stage infection), a result similar to other reports; all 18 cases required ABS explantation. A bowel movement prior to the third postoperative day and a history of perianal infection prior to ABS implantation were risk factors for early-stage ABS infection. In a study by Winslett et al., secondary procedures were necessary in up to 32 % of the patients treated for perianal abscess, either because of inadequate examination under anaesthesia for drainage or undefined occult fistula-in-ano [85].

Late-stage complications after ABS device activation can also result in ABS explantation. The incidence of these complications may increase with device use over time [78, 86]. In a series from our institution, the most common late-stage complication was device malfunction, followed by erosion of device, persistent perianal pain, migration of device, constipation, and hematoma over the labium majus [81]. This was similar to the other reports [74, 76, 78, 83, 84, 86]. Thirteen of 33 patients (32.0 %) required ABS explantation. In the late stage, device malfunction was the most common reason for explantation (46.1 %). All of the ABS devices that required explantation functioned satisfactorily after activation, but the function deteriorated with time. Four of 9 malfunctioned ABS devices were due to leakage of the system, which implied that the present design may be inadequate for longer-term function. Erosion of the rectum or skin was the second most common reason for explantation (38.5 %). Five patients had erosions through the skin and one had erosion through the rectum with associated rectovaginal fistula. Five patients had associated infection that resulted in explantation [81]. Tejirian et al. reported intra-abdominal erosion of artificial bowel sphincter reservoir [87].

Devesa et al. attempted to identify risk factors of erosion, but they found no association with pre-existing fibrosis, perianal wound closure method, tension of the wound, and soiling or straining during evacuation [74]. Similarly, we did not find erosion to be associated with any important patient-related factors [81]. Erosions were found only after ABS activation. The rate of explantation increased with the time after ABS implantation; the longer the ABS was in use, more complications occurred and the risk of ABS explantation increased. The 1-year and 2-year cumulative risks of ABS explantation were 9.7 and 13 %, respectively. After 2 years, the risk of ABS explantation sharply increased, and in the third and fourth year, risk increased to 43 and 48 %, respectively [81]. A similar explantation rate of 44 % at 48 months was also reported by Ortiz et al. [75].

Despite these shortcomings, ABS is an effective method of achieving continence in patients with debilitating faecal incontinence who might otherwise require a permanent colostomy. It certainly requires a motivated, healthy patient who is technically able to operate the device and is willing to potentially undergo multiple operations in order to achieve continence.

Stimulation: Sacral Nerve Stimulation

Initially developed in 1989 to treat urinary incontinence, SNS is a promising approach for patients with faecal incontinence. In 1995, Matzel et al. reported initial success with this treatment for faecal incontinence in three patients [88]. Since that time, extensive experience with SNS has been gained in Europe and Australia, and the technique has been refined [89, 90]. Most recently, after a large multicenter trial [91], this procedure was FDA approved for faecal incontinence in the United States.

Technique

We evaluate all SNS candidates by a physiological assessment and by obtaining a Wexner faecal incontinence score, in addition to completing a 2-week bowel diary. SNS is performed in two stages. The first stage involves the placement of a tined lead in the third sacral foramen under fluoroscopic guidance. The patient is awake for the beginning of this procedure but is given intravenous sedation and local anaesthesia as needed. Once the needle is placed in the third sacral foramen, the patient's motor and sensory response is tested by connecting the needle to a temporary pulse generator. A successful sensory response includes any sensation (such as tapping or tightening) in the perineum, vagina, scrotum, rectum or pelvis, and the desired motor response is plantar flexion of the great toe and a bellows response in the perineum. Once both responses are elicited, the tined lead is placed using a Seldinger technique with fluoroscopic guidance (Fig. 12.4). Once again, fluoroscopic images are obtained, and sensory and motor testing are performed to ensure proper positioning. Low-voltage stimulation is desired in order to achieve the longest possible battery life. A subcutaneous pocket is then created in a preoperatively marked location in the upper buttock, and the quadripolar lead is attached to a temporary extension that is tunneled into this pocket. The temporary extension is attached to an external pulse generator for the duration of the 2-week test period. The patient is monitored for 2 weeks with a re-evaluation of the Wexner score and maintenance of a bowel diary. Assuming a 50 % or greater improvement in symptoms, the patient returns after 2 weeks for implantation of the permanent stimulator. Because a sensory response is not elicited during this second stage operation, a deep intravenous sedation may be employed. The incision is reopened, the temporary connection is removed, and the lead is placed into the stimulator.

Mechanism of Action

Despite the wide acceptance and application of SNS, the exact mechanisms of action are poorly understood. Fecal continence requires a complex interaction of the puborectalis muscle, internal and external anal sphincter muscles, colonic motility, and anorectal sensory function. During SNS, the

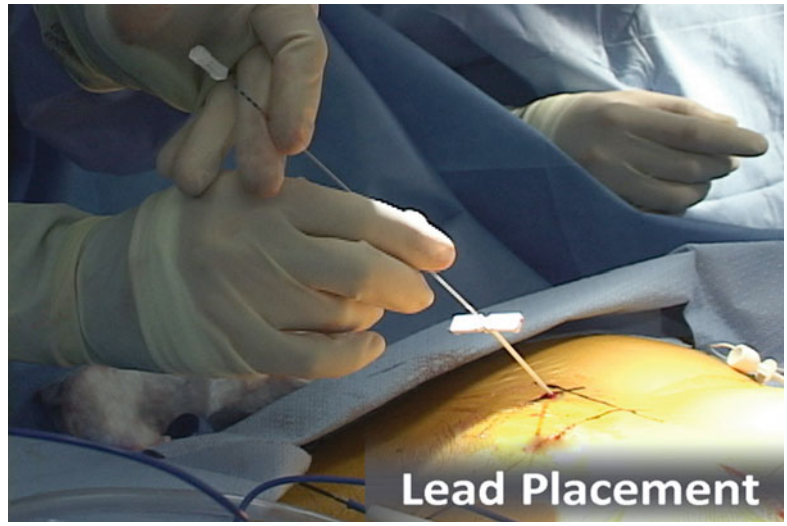

Fig. 12.4 Tined lead placement under fluoroscopic guidance in sacral nerve stimulation stage I. Courtesy of Medtronic

third sacral nerve, a mixed somatic motor and sensory nerve, is stimulated. The stimulation current is rarely set at a level that would induce external anal sphincter contraction, as this would result in continual discomfort; but rather the degree of stimulation is determined by patient sensation of the stimulation in the perineum [92]. It is therefore likely that stimulation of somatic sensory efferent nerves is an important component of the physiological effects. [92] In an animal model, Griffin et al. observed augmented sensory cortical evoked potentials from the anal canal, in addition to upregulation of cortical neural cell adhesion molecule (NCAM) expression with SNS [92, 93]. Sheldon et al. demonstrated cerebral cortical changes with temporary SNS [94]. Goonertane et al. showed normalization of mucosal substance P levels in patients who responded to stimulation [95]. Interestingly, no specific changes in anorectal physiology testing parameters have been consistently proven to be altered by SNS.

A recent prospective study from the United Kingdom included 23 patients who underwent temporary SNS, including 16 patients (70 %) who had a good clinical response to test stimulation [96]. Maximal squeeze pressure increased in all patients; however, resting pressures significantly improved only in responders. SNS did not influence rectal compliance in both responders and nonresponders. Maximal tolerated volumes were significantly increased in all patients after test stimulation; however, maximal tolerated distension significantly increased in responders only.

Otto et al. hypothesized that SNS leads to pelvic floor contraction and increased rectal perception [97]. In a prospective series of 14 patients with consecutively implanted permanent stimulators, these researchers performed endoanal ultrasound, manometry, and volumetry examinations at 6 months with the device on or off. The stimulator settings were placed at subsensory levels 1 month prior to examination so that patients were blinded to the stimulator settings (on/off) at the time of examination. Stimulator activation was associated with decreases in the diameter of the external anal sphincter (8.7–7.0 mm), the diameter of the internal sphincter (3.3–2.7 mm), and the distance between the pubic symphysis and anal mucosa (46.5–43.4 mm). Perception threshold increased from 62.1 to 86.4 mL, and the volume evoking defecation increased from 148.9 to 188.2 mL with the stimulator turned on. However, the intrarectal pressures and the corresponding volumes did not differ with the stimulator on or off [97].

Outcomes

High success rates for test stimulation and permanent SNS implantation have been reported in multiple series (Table 12.5). In a large multicenter,

Table 12.5 Outcomes of sacral nerve stimulation

Author (year)	*n*	Follow-up (months)	Scoring method	Outcome		*P* value
				Before	After	
Malouf (2000) [97]	5	16	Wexner	16	2	<0.01
Ganio (2001) [98]	16	15.5	Williams	4.1	1.25	0.01
Leroi (2001) [99]	6	6	Urgency episodes/1 week	4.8	2.3	>0.05
			FI episodes/1 week	3.2	0.05	>0.05
Matzel (2001) [100]	6	5–66	Wexner	17	2	NR
Rosen (2001) [101]	16	15	FI episodes/3 weeks	6	2	NR
Kenefick (2002) [102]	15	24	FI episodes/1 week	11	0	<0.001
Jarrett (2004) [103]	46	12	FI episodes/1 week	7.5	1	<0.001
Matzel (2004) [104]	34	24	FI episodes/1 week	16.4	2.0	<0.0001
Rasmussen (2004) [105]	45	6	Wexner	16	6	<0.0001
Uludag (2004) [106]	75	12	FI episodes/1 week	7.5	0.67	<0.01
Hetzer (2007) [107]	37	13	Wexner	16	5	<0.01
Holzer (2007) [108]	29	35	FI episodes/3 weeks	7	2	0.002
Melenhorst (2007) [109]	100	36	FI episodes/1 week	31.3	4.8	<0.0001
Tjandra (2008) [110]	53	12	Wexner	16	1.2	<0.0001
Altomare (2009) [111]	52	60	Wexner	15	5	< 0.001
Boyle (2009) [112]	13	3–6	Wexner	12	9	0.0005
			FI episodes/2 weeks	15	3	0.01
Matzel (2009) [113]	9	117.6	Wexner	17	10	<0.007
Dudding (2010) [114]	9	46	FI episodes/1 week	9.9	1.0	0.031
Michelsen (2010) [115]	177	24	Wexner	16	10	<0.0001
Vallet (2010) [116]	23	44	Wexner	16	6.9	NR
Wexner (2010) [90]	120	28	FI episodes/1 week	9.4	2.7	<0.0001
Lim (2011) [117]	41	51	Wexner	11.5	8.0	<0.001
George (2012) [118]	25	114	FI episodes/week	22	0	0.001

NR not reported

prospective, nonrandomized trial in 16 centres in North America and Australia, which was submitted to the FDA for approval of SNS in the United States, 285 patients were evaluated for potential enrollment with stringent guidelines [91]. Exclusion criteria included congenital anorectal malformations, previous rectal surgery (rectopexy, rectal resection, sphincteroplasty within 24 months), external anal sphincter defects greater than 60°, chronic inflammatory bowel disease, visible sequelae of radiation, active anal abscesses or fistulae, and neurologic diseases. Of the 285 patients assessed, 133 patients were candidates for test stimulation. Ninety percent of patients who underwent test stimulation had a successful response (≥50 % improvement) and subsequently underwent permanent implantation. At 1 year of follow-up, 83 % of patients had a greater than 50 % improvement in number of weekly incontinent episodes ($p<0.001$). Perfect continence was achieved in 40 % of patients, and an additional 30 % reported greater than 75 % improvement. These results remained consistent through 3 years of follow-up [120]. The number of weekly incontinent days and number of urgent incontinent episodes per week followed a similar pattern of improvement. In addition, scores on the FISI and on all four domains of the FIQL scale, as well as patients' use of pads, demonstrated statistically and clinically relevant improvements.

To confirm that the clinical benefit derived from SNS was not due to a placebo effect, Leroi et al. conducted a double-blinded crossover study with 27 patients who underwent permanent SNS for faecal incontinence [121]. After implantation, patients were randomized in a double-blind

crossover design to stimulation ON or OFF for 1 month periods. While still blinded, the patients chose the period of stimulation (ON or OFF) that they preferred; the stimulation corresponding to the selected period was continued for 3 months. These investigators found that the number of incontinent episodes was significantly reduced during the ON versus OFF period and the patients had a significantly greater preference for the ON versus OFF period. In the final period of the study, the number of incontinent episodes, Wexner score, ability to postpone defecation, and quality of life improved significantly in patients with the stimulator ON [121].

A recent meta-analysis comparing SNS with maximal conservative therapy included 34 studies and 790 patients, 665 (84.2 %) of whom received a permanent implant [122]. All studies reported a decrease in incontinent episodes per week, with an overall mean difference before and after treatment of −6.83 incontinent episodes (95 % CI −8.05, −5.60; $p<0.001$) with follow-up ranging from 2 to 36 weeks. In the 14 studies reporting pre- and postoperative Wexner scores, a mean difference of −10.57 (95 % CI −11.89, −9.24; $p<0.001$) was observed. All SF-36 outcomes favoured an improved quality of life after SNS implantation except bodily pain, which was not impacted by SNS; and scores on all four domains of the FIQL (lifestyle, coping/behaviour, depression/self-perception, embarrassment) also significantly improved.

Long-Term Outcomes

Several recent reports have demonstrated that the improvement of symptoms and quality of life with SNS is maintained over time. Altomare et al. reported outcomes of 52 patients with more than 5 years follow-up (median, >6 years) and found that nearly 75 % of patients maintained at least a 50 % improvement [112]. Another study reported a sustained effect over a 6-year follow-up period in 10 patients who underwent permanent SNS implantation with a median Wexner score of 7 (range, 2–11) from 20 (range, 12–20) ($p<0.0001$) [116]. George et al. reported their long-term experience with SNS at St. Mark's Hospital [119]. Of 23 patients followed for a median of 9.5 months, full continence was maintained in 12 (48 %) patients; 3 (13 %) patients underwent explantation for loss of efficacy at 48–60 months after permanent implantation; and 3 (13 %) patients died because of unrelated comorbidities. In addition, 9 patients required a device battery change at a mean of 7.25 years.

SNS for Fecal Incontinence with an Associated Sphincter Defect

Considering the favourable long-term outcomes of SNS, for patients with faecal incontinence associated with a sphincter defect, there is a compelling argument for SNS to be the initial treatment instead of an overlapping sphincter repair [123]. Several reports including patients with varying degrees of internal and/or external anal sphincter defects have demonstrated successful outcomes of permanent SNS in this group, indicating that an intact anal sphincter is not a prerequisite for success with SNS. In the recent North American trial, patients with an internal anal sphincter defect had a 65 % success rate compared with 87 % among patients with an intact sphincter [91]. Nonetheless, this success was maintained over a 3-year follow-up. A recent meta-analysis reported five studies that included more than 75 % of patients with sphincter defects and 18 studies that included only patients with an intact sphincter muscle [122]. The number of incontinent episodes per week and Wexner scores improved significantly more in the sphincter intact versus sphincter defect group, whereas the ability to defer defecation was greater in patients with sphincter defects. In a series of 13 patients with sphincter defects who underwent permanent SNS, Boyle et al. observed that SNS results in positive outcomes irrespective of the degree of sphincter disruption [113]. Thus, SNS should certainly not be denied on the basis of a sphincter defect, and it can be considered as the initial treatment for appropriate SNS candidates.

Complications

Compared with the high rates of revision and device removal required for the artificial bowel sphincter and stimulated graciloplasty, the

complications following SNS are uncommon and less severe. Furthermore, even if surgical revision is required, it is a less involved procedure. In a prospective single-centre study including 87 consecutive patients who underwent permanent stimulator implantation, 36 (24.1 %) patients required surgical revision over a mean follow-up of 48.5 months [124]. Several other studies of long-term SNS outcomes report surgical revision rates ranging from 10 to 25 % [91, 93]. A recent meta-analysis reported 6 % pain or local discomfort, 3 % lead displacement or breakage, 3 % infection, and 3 % seroma formation in patients with a permanent SNS implant [90].

A report of infectious complications in the multicenter SNS trial in North America and Australia demonstrated that early infections were less severe and easier to resolve than late infections [125]. This study included 120 patients with a mean follow-up of 28 months. Thirteen (10.8 %) patients had infections, 9 had early infections (within 3 weeks of permanent implantation), and 4 had late infections (13–41 months after implantation). Most of the early infections (78 %) were treated with antibiotics without device explantation. However, all late infections necessitated device explantation, despite administration of intravenous antibiotics. Age, body mass index, and length of operative time for the temporary or permanent implantation were not significantly associated with infection. In a single-centre prospective study, Faucheron et al. reported infection in 4 (4.5 %) patients, necessitating explantation at 2–9 months post-implantation [124]. One infection started with the temporary lead site, whereas the remainder occurred only after permanent SNS implantation. All patients underwent reimplantation of an SNS device at 5–9 months following explantation.

Pain unresponsive to medical management is an uncommon complication (less than 10 %) [124]. If the pain cannot be improved by stimulator setting adjustments, surgical revision with placement of the stimulator in a deeper alternate position may be required. Electrode complications present with sudden worsening of incontinence that does not improve with stimulator setting adjustments and can be confirmed by x-ray. Electrode fracture is suspected when there is excessive impedance in the system (>4,000 Ω). Electrode displacements or fractures are infrequent [124] and require revisional surgery.

However, increased impedance and worsening of faecal incontinence have been reported in patients without electrode breakage. In Faucheron et al.'s series, 4 (5 %) patients presented in this manner, with x-rays confirming correct position and integrity of the electrodes [124]. Re-exploration confirmed an intact circuit, and implantation of a new electrode and new extension cable, attached to the previously implanted stimulator, yielded good results. The authors postulated that the increase in impedance causing failure of the device was secondary to fibrosis surrounding the tip of the electrode, as happens with the dynamic graciloplasty electrode.

Finally, changes in efficacy are addressed by stimulator reprogramming. Govaert et al. retrospectively reviewed their experience with 155 patients with permanent implants and found that 75 % of patients required reprogramming at least once during follow-up (median 28 months) [126]. The mean voltage was significantly increased at 3 months compared with 1 month of follow-up (2.0 V vs 1.8 V, $p<0.001$); however, after 3 months there were no subsequent significant increases in voltage. Fifty-one (33 %) patients required reprogramming at 1–25 % of follow-up visits, 42 (27 %) patients at 26–50 % of follow-up visits, 14 (9 %) patients at 51–75 %, and 9 (6 %) patients at 76–100 % of follow-up visits. Electrode polarity was the most frequently adjusted parameter. This study highlights the importance of close outpatient follow-up with trained clinicians for assessment and reprogramming of SNS in order to achieve optimal outcomes.

SNS is an effective treatment for faecal incontinence that has demonstrable benefits for symptom severity and quality of life outcomes. Technical problems are infrequent and can be easily managed, even when a complete substitution of the device is required. Furthermore, as this is a minimally invasive procedure, it is suitable for many patients, including those affected by severe comorbidities that would preclude other more invasive surgery.

Stimulation: Posterior Tibial Nerve Stimulation

As with SNS, posterior tibial nerve stimulation (PTNS) was first described for urinary incontinence [127]. The tibial nerve is a mixed nerve composed of L4–S3 fibres, and it originates from the same spinal segments that innervate the pelvic floor [92].

Percutaneous Technique

A fine gauge needle is percutaneously inserted, just above and medial to the ankle, next to the posterior tibial nerve, and a surface electrode is placed near the arch of the foot. The needle and electrode are connected to a low-voltage stimulator. Stimulation of the posterior tibial nerve produces a motor (plantar flexion or fanning of the toes) and/or sensory (tingling in the ankle, foot, or toes) response. Initial treatment usually consists of 12 outpatient sessions lasting 30 min each, typically 1 week apart. Treatment may be repeated if required [128].

Outcomes

In 2003, Shafik et al. first reported PTNS for the treatment of faecal incontinence [129]. Vitton et al. reported significant benefit in a cohort of 24 patients, 46 % of whom showed sustained improvement by 1 year after completion of stimulation [130]. Hotouras et al. reported the largest study to date, which included 100 patients evaluated prospectively [131]. They found that Wexner scores and quality of life were significantly improved following 12 sessions of PTNS. Although long-term results are lacking, these short-term results are promising. PTNS can be performed via percutaneous and transcutaneous routes; however, the optimal route is still debated. George et al. compared the efficacy of both approaches to sham stimulation in a randomized trial including 30 patients [132]. These investigators found that 82 % of patients who underwent percutaneous PTNS had a 50 % or greater reduction in weekly incontinent episodes, compared with 45 % of patients who underwent transcutaneous PTNS and 12.5 % of patients who underwent sham stimulation.

Conclusion

From simple, office-based procedures with low durability to sophisticated, technically demanding, and highly complicated surgical procedures, the ideal treatment for faecal incontinence requires an individualized approach. The introduction of new technology is encouraging, and it is hoped that it will advance these much needed procedures. Despite this plethora of exciting advances, a stoma still remains the best option in many patients with end-stage faecal incontinence.

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