Dynamic Graciloplasty

Complications and Management

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PURPOSE: Patients with intractable fecal incontinence, in whom all other treatment failed, can be treated by dynamic graciloplasty. Good results have been reported, but this technique involves specific problems. All problems that occurred over an eight-year period are presented, and management is discussed. METHODS: Dynamic graciloplasty was performed in 67 patients with a mean follow-up of 2.7 years. All patients were monitored by physical examination, anal manometry, defecography, and electromyography at fixed intervals. All complications were noted and treated. Continence was defined as being continent to solid and liquid stools. RESULTS: The technique was successful in 52 patients (78 percent), whereas failures occurred in 15 patients (22 percent). Complications resulted from technical problems, problems with infection, and problems attributable to an abnormal physiology of the muscle or an anorectal functional imbalance. In total, 53 complications were identified in 36 patients. Most technical problems, concerning the transposition and stimulation of the gracilis muscle, could be treated. Failures were attributable to a bad contraction of the distal part of the muscle (n = 4) and perforation of the anal canal during stimulation (n = 1). In eight patients, infection of the stimulator and leads required explantation. Three patients did not regain continence after reimplantation. Apart from moderate constipation, physiologic complications were very hard to treat and resulted in failures in five patients because of overflow incontinence, soiling, a nondistending rectum, strong peristalsis, and strong constipation. In two patients, the technique failed despite a well-contracting graciloplasty; no clear reason for the failure was found. CONCLUSION: Complications associated with the technique of dynamic graciloplasty such as loss of contraction, infection, bad contraction in the distal part of the muscle, and constipation can often be prevented or treated. Difficulties related to an impaired sensation and/or motility, attributable to a congenital cause or degeneration, are impossible to treat, and this signifies that a good selection of patients is essential to prevent disappointment. [Key words: Idiopathic fecal incontinence; Dynamic graciloplasty; Technical complications; Infection; Physiologic complications]

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When a permanent colostomy is the only option that remains in treatment of intractable fecal incontinence, the patient could be treated by dynamic graciloplasty; however, the results of conventional graciloplasty are disappointing.[1] Dynamic graciloplasty entails implantation of leads and a pulse generator to give continuous electrical stimulation to a gracilis muscle, which is wrapped around the anal canal according to Pickrell *et al.*[2] Continuous stimulation improves the function of the graciloplasty because it enables a prolonged contraction, something which is impossible to perform by voluntary action and because stimulation induces a transformation of Type II, fatigue-prone, muscle fibers into Type I, fatigue-resistant, muscle fibers.[3]

Results have been encouraging;[4–6] however, application of the technique involves specific problems. In this study, complications during an eight-year period are analyzed.

PATIENTS AND METHODS

Between November 1986 and April 1995, 67 patients (48 female, 19 male) were treated with anal dynamic graciloplasty for fecal incontinence. Etiology of the disabling incontinence was anal atresia (n = 13), trauma (n = 34), and pudendopathy (n = 20). Median age was 44 (range, 18–71) years, and median duration of incontinence was 13.1 (range, 1–40) years.

All patients underwent preoperative anorectal manometry, defecography, and electromyography. Anorectal manometry was performed using a Konigsberg™ catheter (Konigsberg Instruments Inc., Pasadena, CA), which was connected to a computer-assisted polygraph (Synectics Medical, Stockholm, Sweden). By repeated inflation of a rectal balloon, sensation, urge capacity, and rectoanal inhibitory reflex were measured. Electromyography was performed of the external sphincter, pelvic floor, and both gracilis muscles. Both pudendo-anal reflex and pudendal nerve terminal motor latency were determined using a Nicolet Viking I™ electromyographic apparatus (Nicolet, Madison, WI). Patients were se-

lected for this treatment modality when electromyography showed moderate to severe damage to the pudendal nerve.

The gracilis muscle was transposed around the anal canal, leaving the neurovascular bundle intact, and six weeks later the neurostimulator (Itrel® II, model 7424, Medtronic, Kerkrade, The Netherlands) and the intramuscular electrodes (model 4300–35, Medtronic, Kerkrade, The Netherlands) were implanted.[7] Stimulation was started three days later using a pulse width of 210 ms, a stimulation frequency of 25 pulses per second, and a cyclic mode with an "on" time of 0.1 second and an "off" time of 1.2 seconds, yielding a duty cycle of 8 percent (the time during which the muscle is actually contracting). Subsequently, the duty cycle was increased over the next six weeks to 14 percent (0.2 seconds on and 1.2 seconds off) after two weeks, 36 percent (0.4 seconds on and 0.7 seconds off) after four weeks, and 67 percent (1 second on and 0.5 seconds off) after six weeks. At eight weeks, continuous stimulation is started. Continence was defined as being continent to solid and liquid stools and eventually to flatus.[5]

Postoperatively, all patients were monitored closely at fixed intervals (2, 4, 6, 8, 16, 26, and 52 weeks, 1.5, 2, and 3 years, *etc.*). Physical examination, anal manometry, and defecography were repeated. All complications were noted and treated.

Patient data are expressed as median and the range; correlation was tested with Spearman's correlation coefficient. Results were considered significant if $P < 0.05$. Studies were approved by the medical ethical committee of Maastricht University Hospital. Informed consent was obtained from all patients.

Table 1.
Patients in Whom Dynamic Graciloplasty Failed with Pathogenesis of Fecal Incontinence and Cause of Failure

Patient	Group	Cause
1	1	Nondistending rectum with good function of graciloplasty. Colostomy
2	1	Bad contraction distal end of gracilis. Colostomy
3	1	Infection. Incontinent after reimplantation. Colostomy
4	1	Bad contraction distal end of gracilis
5	1	Severe constipation after closure stoma. Colostomy
6	1	Very strong peristalsis with good function of graciloplasty
7	2	Soiling with moderate function of graciloplasty
8	2	Incontinent with good function of graciloplasty. Colostomy
9	2	Incontinent with good function of graciloplasty. Colostomy
10	3	Perforation of anal canal by graciloplasty. Colostomy
11	3	Infection. Incontinent after reimplantation
12	3	Overflow incontinence because of fecal impactation. Colostomy
13	3	Bad contraction distal end of gracilis. Colostomy
14	3	Infection. Incontinent after explantation
15	3	Bad contraction distal end of gracilis

1 = anal atresia; 2 = trauma; 3 = pudendopathy.

RESULTS

With a mean follow-up of 2.7 years after implantation of the neurostimulator (range, 14 weeks-8.7 years), 52 patients (78 percent) were continent. No patient was continent after graciloplasty alone. Mean preoperative resting pressure (n = 67) was 36 mmHg (standard deviation (SD) = 22), and mean squeeze pressure was 55 mmHg (SD = 32). Resting and squeeze pressures one year after implantation of the stimulator (n = 53) are 57 mmHg (SD = 23) and 90 mmHg (SD = 37) and remain stable thereafter.

In 15 patients, results are regarded as unsuccessful (Table 1). Of these, 11 were among the first 30 patients treated whereas in next 37 patients only 4 failures occurred. Complications resulted from technical problems, problems with infection, and problems attributable to an abnormal physiology of the muscle or an anorectal functional imbalance. In total, 53 complications were identified in 36 patients. Complications, actions taken, and outcome are summarized in Table 2.

Technical problems were encountered 25 times in 21 patients. In five patients, this led to eventual failure of the procedure. In four patients, insufficient contraction of the distal part of the gracilis muscle caused a failure of the graciloplasty (6 percent). In one patient, perforation of the anal canal during stimulation required the creation of a permanent colostomy.

Two transposed gracilis muscles could not be stimulated afterwards (3 percent), and a second graciloplasty had to be performed. The anal canal was per-

Table 2.
Complications That Occurred with Dynamic Graciloplasty Divided in Technical, Infectious, and Physiologic Complications

	Incidence (%)	Result/Therapy
Technical complications		
Insufficient contraction of distal gracilis	4 (6)	Failure
Perforation of anal canal during stimulation	1 (1.5)	Failure
Transposed muscle cannot be stimulated	2 (3)	Second graciloplasty
Perforation anal canal during transposition	1 (1.5)	Temporary ileostomy
Anal wrap too loose	3 (4.5)	Tendon shortened
Transient edema leg	2 (3)	Elastic stockings
Lead problems	5 (7)	Revision of the lead
Displacement stimulator	6 (9)	Repositioning stimulator
Off-switching problem stimulator	1 (1.5)	Replacement stimulator
Infectious complications		
Infection neurostimulator and leads	8 (12)	Reimplantation (n = 6), failure (n = 3)
Perianal infection	2 (3)	Removal of suture
Infection lead	1 (1.5)	Exchange lead
Physiological complications		
Overflow incontinence	1 (1.5)	Failure
Soiling	1 (1.5)	Failure
Nondistending rectum	1 (1.5)	Failure
Strong peristalsis	1 (1.5)	Failure
Severe constipation	1 (1.5)	Failure
Moderate constipation	12 (18)	Biofeedback, laxatives, enemas
No clear reason found	2 (3)	Failure

forated during transposition in one patient, requiring creation of a temporary ileostomy. In three patients, the tendon had to be shortened because the wrap was performed too loosely (4 percent). In two patients, there was transient edema of the leg after transposition of the muscle.

Revision of a lead had to be performed in five patients (7 percent), twice for a bad connection to the stimulator and three times because of dislocation. Because of displacement, the stimulator had to be repositioned in six patients (9 percent). In one patient, there was spontaneous off-switching of the stimulator; after replacement of the stimulator, the patient did well. Apart from this, no hardware problems (concerning stimulator or leads) occurred.

Complications by infection were encountered 11 times in ten patients. In three patients, this led to eventual failure of the technique. Infection of implanted neurostimulator and leads occurred in eight patients (12 percent). Two patients remained continent without reimplantation; the other six patients had a reimplantation of a neurostimulator and leads. Three of these patients did not regain continence.

In two patients, a perianal infection occurred after transposition of the muscle. Instead of the usual prolene sutures, silk sutures were used to anchor the gracilis tendon. Both patients recovered well after removal of the suture. One patient had an infection of one of the leads, which was successfully replaced.

Finally, complications related to physiologic imbalance occurred 17 times in 17 patients. The technique failed in five patients because of overflow incontinence, soiling, nondistending rectum, strong peristalsis, and severe constipation. Twelve patients complained of constipation (18 percent) of a mild nature.

Analyses of the success rate in connection with the pathogenesis of incontinence reveal that in the anal atresia group only 7 of 13 patients (54 percent) were treated successfully, whereas in the trauma group 31 of 34 (91 percent) were continent after treatment. In the pudendopathy group, this was 14 of 20 (70 percent).

Assessment of the threshold for sensation in the anal canal revealed a median of 50 ml in the anal atresia group (n = 7; range, 10–100), 30 ml in the trauma group (n = 29; range, 8–70), and 40 ml in the pudendopathy group (n = 18; range, 12–180). Sensation associated well with the outcome of treatment ($P = 0.003$). Capacity of the rectum appeared to be similar in all three groups, 150 ml on average. Two patients (3 percent) remained incontinent despite a well-functioning graciloplasty. No obvious cause for this failure was found.

DISCUSSION

A steep learning curve was experienced with the application of the dynamic graciloplasty, and these data confirm a previous report.[8] Dealing with the reported complications requires a profound understanding of all three categories involved (technical, infectious, and physiologic).

In understanding the technical problems, both the

background of muscle transposition and muscle stimulation should be considered. After the gracilis muscle is transposed around the anal canal, the whole muscle should be well vascularized to guarantee viable, contracting muscle tissue. Minor or no contraction of the distal part of the gracilis with a good contraction of the proximal part can be attributed to several reasons. Ligation of the peripheral arteries may cause insufficient blood supply to the distal part of the muscle, inducing necrosis or fibrosis. No evidence of necrosis was observed, but fibrosis has been demonstrated in one occasional patient and may, therefore, have occurred in more patients with a failure. Division of the distal vascular pedicles four to six weeks before transposition of the muscle (vascular delay) is suggested[5] to improve outcome by allowing formation of sufficient collaterals, but further investigation is needed.

An additional reason may be an inadequate construction of the anal wrap. A transposed muscle will adapt to the new situation by optimizing sarcomere number and length to develop optimum tension.[9] Sometimes the wrap is still too loose requiring shortening of the tendon. A transposed gracilis muscle should allow at least 270° of muscle tissue surrounding the anal canal. Continence is achieved by contraction of the muscle and not by tightness of the wrap. Too much tendon reduces the active part of the turn and can damage the bowel. In a patient with spina bifida with minor sensation in the perianal region and short muscular parts of the gracilis, the wrap was too tight and partly tendinous, resulting in late perforation of the anal canal.

So far, no randomized study has been performed to explore whether the final result depends on the type of loop. Good results have been reported with the gamma loop,[6] the epsilon loop,[5] the alpha loop[10] (Fig. 1), and the modified epsilon loop.[11] We previously used the gamma loop but switched to an epsilon loop (large muscle mass or much scar tissue in the rectovaginal septum) or an alpha loop (short muscle) when the operative situation demands this. Certainly the choice is also a matter of preference and the experience of the surgeon.

During the first months of stimulation a gradual increase of the amplitude is mandatory to preserve good muscle contraction. Type I muscle fibers become abundant after stimulation and contract less forceful than Type II muscle fiber, which diminish in quantity. To develop the same force of contraction, a higher amplitude is required (that is, more motor units are recruited to yield the same effect). Also, as is

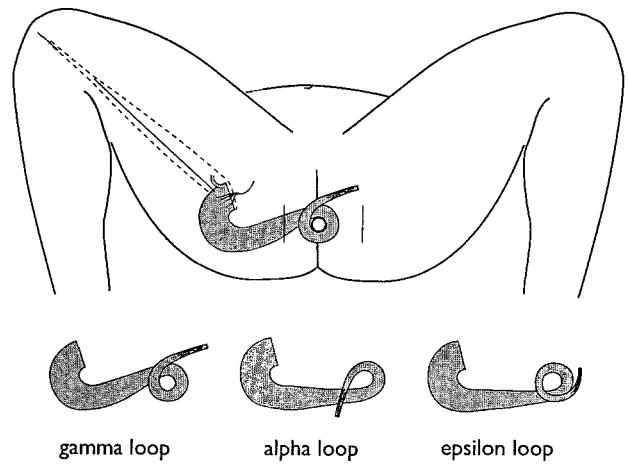

Figure 1. Configuration of the dynamic graciloplasty. The gracilis muscle is transposed from the right leg, wrapped around the anal canal and fixed to the ischial spine. The gamma loop, alpha loop, and epsilon loop are depicted. Six weeks later, a neurostimulator and leads are implanted.

customary with implanted devices, fibrosis is formed around the leads, and this is activated even more so by electrical stimulation. If the stimulation amplitude has to be strongly increased or if it exceeds 5 V and voluntary muscle contraction is good, dislocation or fracture of the lead may have occurred. Dislocation of the cathodal lead increases the electrode nerve distance requiring an elevation of the stimulation amplitude. This occurred in three patients: twice because of a trauma and once in a patient with osteogenesis imperfecta attributable to very weak muscle tissue. To optimize stability, leads have to be implanted perpendicular to the muscle fibers and need to be securely fixed to the epimysium.

In the course of treatment, patients can experience pain in the transposed and stimulated gracilis muscle, the knee, around the anal canal, and over the neurostimulator or lead. Muscular pain can be caused by muscle fatigue, this can be reduced by decreasing the stimulation amplitude or frequency, restarting intermittent stimulation to retrain the muscle, choosing an alternative electrode selections (±), or using unipolar stimulation. An inadequately low frequency can also cause pain because of insufficient pulses to induce a fused (tetanic) contraction. If pain is only experienced when the stimulator is switched on, stimulation of sensory nerves through an open circuit is possible. In one patient, an infection near the anus caused a pain sensation in the knee, probably mediated by still intact sensoric nerves. Pain over the stimulator pocket or the lead often is the result of infection or local

tissue/skin irritation. Irritation over the pocket is treated by repositioning the stimulator in a deeper pocket (under the fascia of the rectus muscle) away from bony structures. During tunneling of the leads, care should be taken to place them far enough away from the pubic bone as not to cause pain through pressure when sitting on them, *e.g.*, when biking.

Severe technical complications leading to failure of the technique occurred mainly in the beginning; manageable problems of dislocation and displacement still occur. In obese patients, neurostimulators are nowadays always fixed to the musculi rectus fascia because they tended to move or to twist.

When foreign bodies are implanted, infection can be a serious cause of failure, especially in this easily contaminated area. Infection normally starts at the site of implantation of the leads and continues toward the stimulator. If infection occurs, antibiotic therapy is rarely efficacious, and removal of implanted devices is required. Majority of infections occurred in the first 15 patients. Infection rate decreased sharply after antibiotic prophylaxis had been changed into application of systemic antibiotics (24 hours of metronidazole, gentamicin, flucloxacillin intravenously) and local antibiotics (Sulmycin Implant®, Essex Pharma, Munich, Germany) and immersion of the neurostimulator and leads in a gentamicin solution before implantation. One-half of infections occurred after repositioning of a stimulator or a lead; therefore, optimum initial application is essential.

Sensory function of the anorectum is an important factor in the preservation of continence.[12–14] Patients with an impaired sensation and/or an altered peristalsis of the bowel, therefore, may benefit less from restoration of the anal sphincter. In both groups of patients with long-standing pudendal neuropathy and anal atresia, the threshold for sensation appeared to be higher than for patients in the trauma group, and this may account for the decreased success rate. According to current opinions in pediatric surgery, an infant with anal atresia is treated with creation of a stoma directly after birth. Six months later, the colon stump is exteriorized and the anorectum is reconstructed. Apart from a hypotrophic external anal sphincter, sensation and motor function may be impaired as well. Whether this is congenital or induced by six months of bowel inactivity is uncertain. In three of these patients, the technique failed because of an abnormal rectal compliance or peristalsis. These deficits can probably be prevented by immediate repair after birth[15] and not by construction of a dynamic graciloplasty afterwards.

In none of the patients with constipation was an obstruction of the anal canal attributable to a very high resting pressure found. Three patients developed a lumpy, bag-shaped rectum,[16] and they need to use enemas occasionally. Ten patients had a poor technique of straining, unable to produce enough propulsive force (n = 5) or simultaneously straining and contracting the graciloplasty (n = 5). Two patients improved without therapy, three patients regularly use enemas, and four patients were successfully treated with biofeedback training. One patient, incontinent because of a congenital origin, became severely obstipated after closure of her stoma; when all further therapy failed, a new colostomy was created. It was remarkable that of the seven patients who underwent biofeedback training only patients who were incontinent because of trauma responded well, whereas both patients with long-standing pudendopathy and the patient with anal atresia did not.

Three of five physiologic complications leading to failure of the technique are found in patients with anal atresia, although this group only represents 20 percent of the whole group. The other four failures in the anal atresia group are attributable to infections (n = 2) and technical problems (n = 2). Nine anal atresia patients were among the first 25 patients treated. Failures in this group, therefore, not only have their origins in an abnormal anorectal physiology but also suffer from the steep learning curve.

It should be noted that most patients treated so far were among the most difficult cases to deal with. Almost all had had multiple previous surgeries and/or adjuvant therapies. It is to be expected that the complication rate will decrease if patients can be treated at an earlier stage.

CONCLUSION

Complications associated with the technique of dynamic graciloplasty such as loss of contraction, infection, bad contraction in the distal part of the muscle, and constipation can often be prevented or treated. Difficulties related to an impaired sensation and/or motility, because of a congenital cause or degeneration, are impossible to treat, and this signifies that a good selection of patients is essential to prevent disappointment.

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