

ANAL DYNAMIC GRACILOPLASTY IN THE TREATMENT OF INTRACTABLE FECAL INCONTINENCE

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Abstract *Background.* In patients with intractable fecal incontinence, conventional treatment is not always successful. Dynamic graciloplasty (transposition of the gracilis muscle to the anus with the implantation of stimulating electrodes) was developed to provide such patients with functional neosphincters. We evaluated the clinical results of this new surgical approach and the effects on quality of life.

Methods. We treated 52 patients with dynamic graciloplasty. The clinical results of treatment were evaluated in an interview, by anal manometry, and by enema testing. The degree of continence was scored. To assess quality of life, four questionnaires were administered (parts 1 and 2 of the Nottingham Health Profile, the State-Trait Anxiety Inventory, and the Self-rating Depression scale).

Results. Among the 52 patients, 38 (73 percent) were

continent after a median follow-up of 2.1 years. At 52 weeks the patients' condition had improved with respect to the median frequency of defecation (from five to two times per 24 hours, $P < 0.001$), the median time defecation could be postponed (from 9 seconds to 19 minutes, $P = 0.012$), and the median time an enema could be retained (from 0 to 180 seconds, $P = 0.005$). Patients in whom the technique was successful became less anxious than those in whom it failed ($P = 0.002$) and improved with regard to effectiveness in their occupations, ability to perform tasks around the home, personal relationships, sexual function, and social life ($P = 0.01$). They also became less isolated socially ($P = 0.05$).

Conclusions. Dynamic graciloplasty is a safe and reliable technique in patients with severe incontinence and may result in a better quality of life. (N Engl J Med 1995; 332:1600-5.)

SEVERE fecal incontinence is a problem that may substantially diminish a person's quality of life.^{1,2} The prevalence of persistent fecal incontinence in the United States has been reported to be 2.3 percent.³ Treatment methods such as a change of diet, the use of constipating agents or daily enemas, and training in biofeedback can often be effective.⁴ If conservative treatment fails, several surgical treatments, including the creation of a colostomy, have been used with varying success.

One surgical treatment is the construction of a neosphincter around the anal canal with the gracilis muscle.⁵ The results of this procedure have been disappointing,⁶ mainly because this muscle is dependent on volition, and thus a sustained contraction is not possible. Because of muscle fatigue due to a preponderance of type II muscle fibers, this skeletal muscle can provide forceful contractions for only a short time.⁷ The reported success of conventional transposition of the gracilis muscle can probably be explained by a tightening of the anal canal that results in outlet obstruction.^{8,9} Studies in animals and clinical trials have shown that the clinical results of graciloplasty were improved by electrical stimulation administered after the implantation of electrodes and a pulse generator.¹⁰⁻¹² The stimulator replaces voluntary contraction and exerts a sustained contraction^{13,14} that leads to the transformation

of type II, fatigue-prone muscle fibers into type I fatigue-resistant fibers.^{15,16} Electrical stimulation gives the transposed gracilis muscle the properties required to function as a sphincter.^{17,18}

To assess the clinical and social effects of this new technique, we designed a prospective, longitudinal clinical study to assess whether patients could be given well-functioning neosphincters and how this therapy affected their quality of life.

METHODS

Patients

From November 1986 through January 1994, 52 patients (37 women and 15 men) were treated by anal dynamic graciloplasty (transposition of the gracilis muscle to the anus with the implantation of stimulating electrodes). Their mean age was 44 years (range, 18 to 71), and the mean duration of incontinence was 15 years (range, 1 to 40). All the patients had previously received the maximal conservative treatment, and 39 patients had had one or more unsuccessful incontinence-related operations (Table 1).

The causes of fecal incontinence were anal atresia (12 patients), perineal trauma (24), cauda equina syndrome (2), and pudendal-nerve lesions (14) (Table 1). Perineal trauma was due to vaginal delivery, sphincter surgery, or direct trauma.

All the patients were interviewed, underwent a physical examination, and were evaluated by anal manometry, electromyography, defecography, and enema testing. Patients were accepted into the study if they had grade 5 incontinence as classified on a scale of 1 to 5 according to a standardized scoring method (Table 2)¹⁴ and if there was no other therapeutic option than the construction of a colostomy. Patients who already had a colostomy retained their stoma until the dynamic graciloplasty was successfully completed.

Treatment and Evaluation

The gracilis muscle was mobilized down to its insertion into the tibial tuberosity, and the distal tendon was divided. Proximally, the neurovascular bundle was left intact, and the muscle was transposed around the anal canal and fixed to the ischial spine (according to the method of Pickrell et al.,⁵ with slight modifications¹⁷). Six weeks later, intramuscular electrodes (model SP 5566, Medtronic, Kerkrade, the

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Table 1. Characteristics of the Patients with Severe Fecal Incontinence before Dynamic Graciloplasty, According to the Cause of Incontinence.*

VARIABLE	CAUSE OF FECAL INCONTINENCE				
	ANAL ATRESIA	TRAUMA	CAUDAL LESION	PUDENDOPATHY	ALL
No. of patients	12 (23.1)	24 (46.2)	2 (3.8)	14 (26.9)	52 (100)
Age (yr)	27±7.6	48±11.0	44±30.4	52±10.2	44±14.0
Male sex	8 (15.4)	4 (7.7)	1 (1.9)	2 (3.8)	15 (28.8)
Duration of incontinence (yr)	27±9.5	11±11.6	13±13.4	14±11.7	15±12.0
No. with previous procedure					
Colostomy	2	3	0	1	6
Graciloplasty	4	1	0	1	6
Surgery	12	16	0	11	39
Biofeedback	6	7	0	5	18
Rectal sensitivity (ml)	50±17.8	35±14.3	100±70.7	40±19.3	40±18.5
Rectal capacity (ml)	175±72.1	150±78.3	—	130±46.8	150±69.0

*Plus-minus values are means ±SD. Numbers in parentheses are percentages of the group.

Netherlands) were implanted at the site of nerve entry and connected through a subcutaneous tunnel to the neurostimulator (Itrel II, model 7424, Medtronic), which was placed in the abdominal wall (Fig. 1).

With an external magnet, the patient can switch the neurostimulator on (causing the transposed gracilis muscle to contract) and off (causing the muscle to relax). The amplitude, rate, pulse width, polarity, and duty cycle of the stimulation can be programmed telemetrically by the physician. Before continuous stimulation was applied, the transposed gracilis muscle was trained for eight weeks according to a stimulation protocol.¹⁷ All 52 patients received systemic antibiotic prophylaxis for 24 hours at the times of transposition and implantation. In the last 37 patients to be treated, local antibiotics (gentamicin, Sulmycin Implant, Essex Pharma, Munich, Germany) were administered with the implant.

The number and characteristics of the episodes of incontinence, the frequency of bowel emptying, and the length of time for which defecation could be postponed were recorded. In the evaluation of continence, only patients with scores of 1 or 2 were considered to be continent.¹⁴

Anal manometry was performed before and after graciloplasty with a catheter (Königsberg Instruments, Pasadena, Calif.) that was connected to a computer-assisted polygraph (Synectics Medical, Stockholm, Sweden). The highest basal pressure and the constriction pressure were measured with a standardized stationary pull-through technique. With the repeated inflation of a balloon, intrarectal sensitivity and capacity were assessed in milliliters.¹⁹ Defecography was performed according to established methods.²⁰ Electromyography of the external sphincter, the pelvic floor,²¹ and both gracilis muscles was performed with a Viking electromyography apparatus (Nicolet, Madison, Wis.).

The length of time during which a 250-ml phosphate enema could be retained was assessed before and after the muscle transposition and again after eight weeks and one year of electrical stimulation. The enema was given with the patient in a left lateral position, and the time of first leakage was recorded.

Quality-of-Life Evaluation

The quality-of-life study started later in the study period and included 30 patients. This subgroup did not differ substantially from the overall group of 52 patients with respect to sex, age, and duration and cause of incontinence. This study was performed prospectively, with the measurements obtained 2 months preoperatively compared with three postoperative measurements (at 3, 6, and 12 months).

Four questionnaires were used to assess quality of life: parts 1 and 2 of the Nottingham Health Profile,²² the State-Trait Anxiety Inventory,^{23,24} and the Self-rating Depression scale (Zung scale).^{25,26} Part 1 of the Nottingham Health Profile is designed to measure perceived health in six specific areas, whereas part 2 is related to the following

five areas of "task performance" that are most affected by health: effectiveness in one's occupation, ability to perform tasks around the home, personal relationships, sexual function, and social life. These questionnaires have been validated and translated into Dutch.

A disease-specific questionnaire was constructed for this study that included items addressing the patient's problem with fecal incontinence in relation to sports, holidays, visiting, and eating. This questionnaire was tested in a pilot study.²⁷ To determine the success or failure of the dynamic graciloplasty, the disease-specific questionnaire was used together with the continence scale.¹⁴

In addition, patients were stratified according to whether their incontinence had lasted a long or a short time in relation to their age, in order to investigate a potential relation of this variable with their adaptation to their condition. Duration was considered to be long if years of incontinence divided by years of age equaled 0.9 or more. The groups thus defined were compared on the basis of their preoperative scores on part 2 of the Nottingham Health Profile, which were used as proxies for their degree of adaptation; lower scores indicated better adaptation.

Statistical Analysis

Data on the patients were expressed as medians and ranges in the case of categorical measurements and otherwise as proportions. Since the duration of follow-up varied, we estimated the percentages of successful treatments with the product-limit method, much as the Kaplan-Meier method is used to study survival data.²⁸ In these calculations, patients with stomas were considered to be incontinent at week 0 (after graciloplasty but before neurostimulation). In the case of quantitative data, the normality of the distributions was determined from histograms. When distributions were not normal and normality could not be obtained by transformation of the data, medians were presented, and Wilcoxon signed-rank tests were used to evaluate differences between groups. In the case of normally distributed data, mean values were estimated by a repeated-measures procedure that allowed for missing data.^{29,30} In this analysis, we tested whether the changes from week 0 to weeks 26 and 52 were significant. To avoid multiple testing, data obtained at other times were not tested. To determine correlations, the Spearman rank-correlation coefficient was used.

The quality-of-life data were also tested nonparametrically, with the Wilcoxon signed-rank test used to compare groups of patients. These data were expressed as the medians and interquartile ranges of the differences between the preoperative and postoperative measurements. A P value of 0.05 or less was considered to indicate statistical significance.

The studies were approved by the medical ethics committee of Maastricht University Hospital, and informed consent was obtained from all patients.

RESULTS

Clinical Results

After a median follow-up of 2.1 years (range, 12 weeks to 7.4 years) after the implantation of the electrical stimulator, 38 of the 52 patients (73 percent) were continent. In 14 patients (27 percent) only partial,

Table 2. Scoring System for Fecal Incontinence.*

SCORE	SYMPTOMS
1	Continence with regard to solids, liquids, and flatus
2	Continence with regard to solids and liquids, but not to flatus
3	Continence with regard to solids, but occasional incontinence of liquids
4	Occasional episodes of incontinence of solids
5	Frequent episodes of incontinence of solids and liquids

*Adapted from the classification system of Williams et al.¹⁴

if any, improvement in continence could be achieved; these patients had continence scores of 3, 4, or 5 after follow-up (Fig. 2). The treatment failures were partly due to problems with the dynamic graciloplasty — i.e., inadequate contraction of the distal part of the gracilis muscle (in four patients) or infection around the neurostimulator and leads that necessitated their removal (four patients). Six patients had no improvement even though each had a well-functioning dynamic graciloplasty. In four, this was due to very strong peristalsis, the presence of a nondistending rectum, perforation of the anal canal by the graciloplasty, and overflow incontinence (one patient each). In the remaining two patients no objective reason for the treatment failure could be found. Among the 12 patients with anal atresia, 6 (50 percent) were treated successfully, as were 22 of the 24 patients with trauma (92 percent), 9 of the 14 with pudendal-nerve lesions (64 percent), and 1 of the 2 with caudal lesions (50 percent).

The sensitivity of the rectum was influenced by the cause of incontinence (Table 1). The median value for sensitivity was 30 ml for patients with a continence score of 1, 40 ml for those with a score of 2, and 50 ml for those with a score of 5. At 26 weeks there was a significant association ($P=0.003$) between sensitivity and the outcome of treatment. No significant correlation was found between capacity and the outcome of treatment ($P=0.09$). No correlation ($r=-0.07$) was found between the outcome of treatment and the interval (range, 44 to 4734 days) that elapsed between the transposition of the gracilis muscle and the implantation of the stimulation device.

The median voltage needed for a good contraction (Table 3 and Fig. 3) increased from 1.26 V when stimulation was first used to 2.04 V at 8 weeks (measured in 52 patients, $P<0.001$) and 2.40 V at 26 weeks (in 47 patients, P not significant). Thereafter, it increased very little, and even after 156 weeks the median voltage needed was below 3 V. After eight weeks the frequency

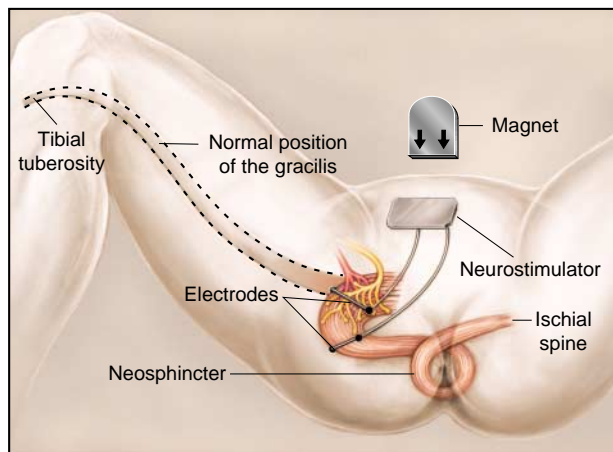


Figure 1. Configuration of the Anal Dynamic Graciloplasty, Showing the Transposed Gracilis Muscle, the Electrodes, the Neurostimulator, and the External Magnet.

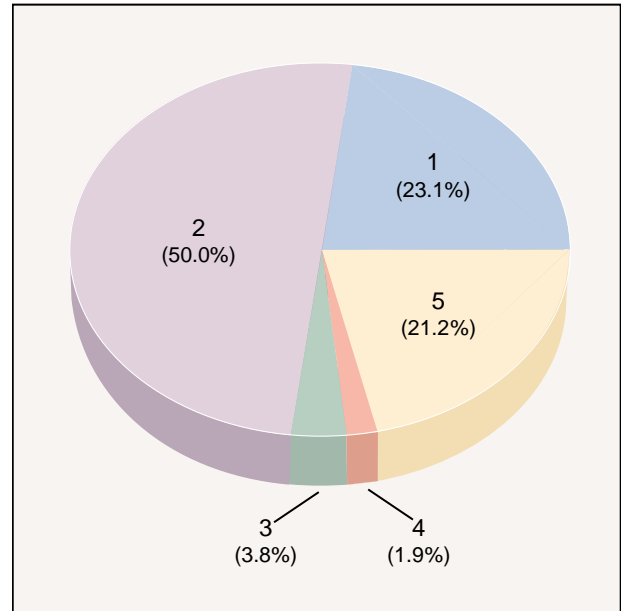


Figure 2. Outcomes of Treatment, According to the Patients' Continence Scores at Follow-up.

Scores of 1 and 2 were considered to indicate successful treatment, and scores of 3, 4, and 5 to indicate unsuccessful treatment.

of stimulation could be lowered from 25 to 15 pulses per second in 70 percent of the patients who had preservation of smooth contraction.

The resting pressure of the anal sphincter increased from a mean of 38 mm Hg before the muscle transposition to 49 mm Hg after eight weeks of stimulation (P not significant) and remained constant thereafter (Table 3). After the muscle transposition, the mean constriction pressure improved significantly, from 50 to 72 mm Hg. During stimulation, this pressure was 69 mm Hg after 8 weeks and 75 mm Hg after 26 weeks ($P=0.001$). It then remained constant through week 156 of stimulation (Table 3).

The median frequency of defecation decreased from five times per 24 hours (i.e., a state of incontinence) before the muscle transposition to four times per 24 hours before stimulation and to two times per 24 hours ($P<0.001$) after eight weeks of stimulation. It then remained constant at two times per 24 hours through week 156 (Table 3). The median time defecation could be postponed increased from 9 seconds (0.15 minute) before stimulation to 11 minutes at 8 weeks (in 51 patients, $P=0.016$) and to 19 minutes at 52 weeks (in 32 patients, $P=0.012$) (Table 3). Because patients with a stoma cannot postpone defecation, they were not included in this analysis. The median time the 250-ml phosphate enema could be retained was 0 seconds before transposition, 60 seconds at 8 weeks of stimulation (measured in 51 patients, $P<0.001$), and 180 seconds at 52 weeks (measured in 11 patients, $P=0.005$) (Table 3).

In seven patients infection around the neurostimula-

Table 3. Estimated Clinical Results over a Three-Year Period for 52 Patients with Anal Dynamic Graciloplasty, Based on Data on the Study Patients.*

VARIABLE	BEFORE SURGERY	AFTER SURGERY	WEEKS OF NEUROSTIMULATION					
			WK 0	WK 8	WK 26	WK 52	WK 104	WK 156
No. studied	52	52	52	52	47	39	18	11
Sphincter pressure (mm Hg)								
At rest	38	42	42	49	50	48	52	51
During stimulation	50†	72†	61	69	75‡	76‡	77	77
Voltage (V)	—	—	1.26	2.04§	2.40	2.59	2.91	2.96
Defecation frequency (times/day)	5	4	4	2§	2	2‡	2	2
Ability to postpone defecation (min)	0.15	—	0.5	11¶	—	19	—	—
Enema retention (sec)	0	3	—	60§	—	180**	—	—

*Data with a normal distribution (pressure at rest and during stimulation, and voltage) are estimated clinical results, and data with a nonnormal distribution (defecation frequency, ability to postpone defecation, and enema retention) are medians. †Values denote constriction pressure.

‡P=0.001. This and the P values listed below are for the comparison with the value before surgery.

§P<0.001.

¶P=0.016.

||P=0.012.

**P=0.005 (measured in 11 patients at week 52).

tor and leads necessitated their removal, and four of these patients remained incontinent even after the implantation of a second neurostimulator. Five infections occurred among the first 15 patients who were treated, whereas there were only two infections among the next 37 patients. This varying infection rate may have been due to modifications in the perioperative regimen of antibiotics.

Quality of Life

The results of the quality-of-life evaluation of a subgroup of 30 patients are shown in Table 4. Treatment was successful in 22 patients and unsuccessful in 8. These 30 patients did not differ significantly from the overall group with respect to the outcome of treatment. There was good correlation ($r=0.76$, $P<0.001$) between the clinical results as scored by the patients' physicians¹⁴ and the results obtained by the independent quality-of-life-researcher who scored the questionnaires the patients completed at home.

The State-Trait Anxiety Inventory questionnaire administered at 52 weeks showed that the patients who were successfully treated were less anxious than the unsuccessfully treated patients ($P=0.002$). Part 2 of the Nottingham Health Profile questionnaire revealed significant improvement in the successfully treated group at 52 weeks ($P=0.01$). These patients also had significant improvement at 26 weeks ($P=0.05$) with regard to social isolation, a dimension analyzed in part 1 of the Nottingham Health Profile that is of particular importance in this population. No significant changes were found in the other areas analyzed, except for mobility ($P=0.016$) (Table 4). No significant changes were found in either group in the results of the Zung questionnaire. There were no significant changes in any area of any questionnaire in the unsuccessfully treated group.

The relation between the duration of fecal inconti-

nence and the adaptability of the patients was investigated preoperatively in part 2 of the Nottingham Health Profile. Significant differences were found between the patients with a short duration of incontinence and those with a long duration (i.e., patients with anal atresia) ($P=0.01$). Patients with anal atresia scored very well preoperatively on all questionnaires (with scores similar to those of healthy persons), unlike those who had a short history of incontinence.

DISCUSSION

Since 1952, conventional graciloplasty has been performed to replace a dysfunctional or absent external anal sphincter, but contradictory results have been reported.^{5,6,8,9,31-33} The basic problem has been that the patient cannot achieve sustained contraction of the transposed muscle. This problem can be solved by stimulating the gracilis muscle electrically with implanted electrodes.^{17,18} Gradually increasing the duty cycle gives the muscle the opportunity to adjust to its new function. The ongoing electrical stimulation causes fast-twitch, fatigue-prone type II fibers to be transformed into slow-twitch, fatigue-resistant type I fibers.^{34,35} In this process the histochemical composition of the gracilis muscle comes to resemble that of the external anal sphincter.⁷

A normal anal sphincter achieves fecal continence with only a moderate degree of contraction, produced by the alternating activation of a limited number of motor units. Through electrical stimulation, however, continence is achieved by the continuous activation of all motor units involved. The results of this study show that in a majority of cases the transposed muscle can

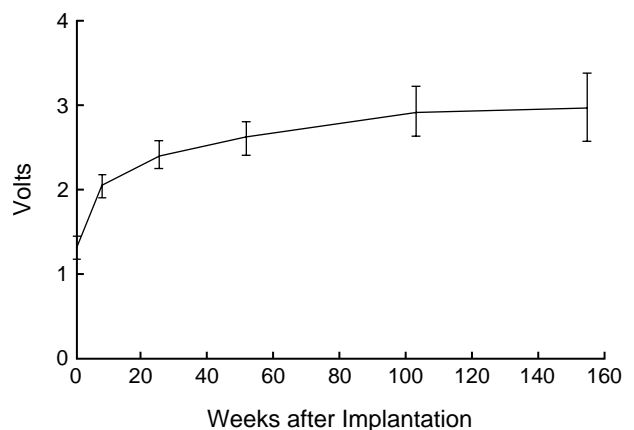


Figure 3. Estimated Mean (\pm SD) Voltage Needed to Achieve Continence in the 52 Study Patients at Various Periods after the Implantation of the Stimulation Device.

Table 4. Results of the Quality-of-Life Evaluation in 30 Patients Who Underwent Anal Dynamic Graciloplasty, According to Whether Their Treatment Was Successful or Unsuccessful.*

ASSESSMENT INSTRUMENT AND GROUP OF PATIENTS	DIFFERENCE FROM PREOPERATIVE SCORE		
	AT 2 MO	AT 6 MO	AT 12 MO
	median (25th to 75th percentile)		
State-Trait Anxiety Inventory			
Treatment successful	-4 (-12 to 6)	-6 (-10 to 1)	-6 (-8 to 1)†
Treatment unsuccessful	-5 (-9 to -1)	-1 (-5 to 3)	5 (7 to 8)
Zung Scale			
Treatment successful	-1 (-6 to 7)	-1 (-6 to 2)	-2 (-4 to 3)
Treatment unsuccessful	1 (-6 to 7)	-2 (-7 to 1)	7 (-3 to 9)
Nottingham Health Profile, part 1			
Treatment successful			
Mobility	0 (-9 to 0)	0 (-11 to 0)‡	0 (-12 to 5)
Pain	0 (0 to 26)	0 (-1 to 21)	0 (-11 to 21)
Energy	0 (0 to 0)	0 (0 to 0)	0 (0 to 19)
Sleep	0 (0 to 13)	0 (0 to 2)	0 (-4 to 6)
Social isolation	0 (0 to 0)	0 (-23 to 0)§	0 (-21 to 0)
Emotional reaction	0 (-14 to 12)	0 (-10 to 0)	0 (-21 to 1)
Treatment unsuccessful			
Mobility	0 (-17 to 0)	0 (0 to 11)	0 (-27 to 31)
Pain	0 (-10 to 0)	-2 (-8 to 0)	0 (-12 to 7)
Energy	0 (0 to 2)	0 (-28 to 0)	0 (-13 to 24)
Sleep	0 (-22 to 0)	0 (-17 to 0)	0 (0 to 17)
Social isolation	0 (-19 to 19)	0 (-52 to 0)	0 (-43 to 22)
Emotional reaction	1 (-9 to 7)	-6 (-16 to 0)	0 (-6 to 9)
Nottingham Health Profile, part 2			
Treatment successful	-2 (-3 to 0)¶	-1 (-4 to 0)¶	-2 (-6 to -1)**
Treatment unsuccessful	1 (0 to 3)	-2 (-7 to 1)	-1 (-3 to 4)

*Negative values indicate improvement, positive values deterioration, and 0 no change. Treatment was successful in 22 patients and unsuccessful in 8.

†P=0.002. This and the P values listed below are for the comparison with the corresponding group unsuccessfully treated.

‡P=0.016.

§P=0.05.

¶P=0.005.

¶P=0.04.

**P=0.01.

cope with this nonphysiologic level of activation. The increase in pressure during stimulation, reaching 75 mm Hg after 26 weeks, resulted in continence in the majority of patients.

For good continence, several anatomical and physiologic entities are considered to be essential. These are the muscle wall of the anorectum, the internal and external anal sphincters, the transitional epithelium of the anal canal, and a rectum with sufficient capacity. Physiologically, the bowel should have a normal pattern of motility, whereas the anorectum should be able to sense its contents, to relax on filling, and to distinguish among flatus, liquid stools, and solid stools. Restoring the anal sphincter alone is therefore no guarantee of continence. In patients with impaired sensitivity (which is more common in patients with anal atresia, the cauda equina syndrome, or pudendopathy), good closure of the anal canal is achieved, but inability to sense extensive filling can lead to overflow incontinence.

We observed no difference in outcome between groups in which different intervals elapsed between the transposition of the gracilis muscle and the implantation of the electrical stimulator. Even when stimulation is begun years after the muscle transposition, there can still be improved function of the graciloplasty. This

strategy can therefore benefit many patients who have had unsuccessful graciloplasty.

Because dynamic graciloplasty requires lifelong stimulation of the transposed muscle in order to maintain a tetanic contraction, the increasing voltage needed for stimulation remains a source of concern. Insufficient contraction that requires an increase in voltage may be due to the transformation of muscle fibers from type II to type I, progressive fibrosis around the electrodes, or displacement of the electrodes. An increase in the stimulation voltage was needed until 26 weeks after the start of stimulation, but the further increase up to a period of 2 years was minimal. At the present settings for stimulation, the expected longevity of the stimulator would be seven years.

The patients in whom the technique was successful became less anxious and improved in areas such as effectiveness in their occupations, ability to perform tasks around the home, personal relationships, sexual function, and social life. The patients became less socially isolated after 26 weeks of stimulation. Patients with long-standing incontinence (i.e., those with anal atresia) seemed before the operation to be very well adapted to their incontinence.

Patients in whom the operation failed remained at their preoperative level with regard to quality of life.

We conclude that dynamic graciloplasty is an excellent technique for replacing the anal sphincter in patients for whom no other treatment is effective. Dynamic graciloplasty is safe and reliable and leads to a better quality of life.

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