

## DYNAMIC GRACILOPLASTY: A SMALL AND SALUTARY EXPERIENCE

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**Background:** The Colorectal Unit at the King Faisal Specialist Hospital and Research Centre was one of 12 centers involved in the first international multicenter trial of dynamic graciloplasty. Some complications and problems related to the procedure were specific to Saudi Arabia, and this paper documents this experience in more detail.

**Patients and Methods:** Patients with a generalized anal sphincter weakness were offered dynamic graciloplasty. Prior to surgery, patients underwent manometric examination of their sphincters. A right gracilis transposition was undertaken. After six weeks, a pulse generator was implanted and electrodes were inserted. The stimulation program commenced four weeks later. The neosphincter was magnetically controlled to allow defecation. Patients were followed at 3-monthly intervals to assess clinical progress.

**Results:** Five patients (3 males and 2 females) were considered to be suitable for the procedure. One patient developed an infection of the thigh wound which resolved without drainage. There was no other surgical morbidity. Mean resting (26.4 mm Hg) and "squeeze" (51.4 mm Hg) pressures prior to surgery were low. Following implantation, mean resting and "squeeze" pressures rose during training in 4 patients (48.5 and 100.8 mm Hg, respectively). Two patients maintained satisfactory clinical and manometric function at 6 and 5 years' follow-up. One patient ceased to have any function in the transposed muscle and refused a further graciloplasty four years after graciloplasty. Another patient avulsed the leads and the transposed tendon on two occasions, and failed to heed advice given regarding posture and sitting. The final patient had an unsatisfactory wrap because of massive peri-rectal fibrosis. There was a 50% reduction in bowel frequency in the two patients in whom the procedure was successful.

**Conclusion:** The technique requires a high level of patient cooperation, but should be available in specialized centers for the management of patients with refractory anal incontinence.

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**Key Words:** Dynamic graciloplasty, anal incontinence.

The Colorectal Unit at the King Faisal Specialist Hospital and Research Centre (KFSH&RC) was one of 12 centers initially involved in the first international multicenter trial of dynamic graciloplasty in patients suffering from anal incontinence.<sup>1</sup> The procedure involves detaching one gracilis muscle from its distal tibial attachment, wrapping the mobilized muscle around the anus, and attaching the wrapped tendon to the contralateral ischial tuberosity. The neosphincter is controlled by an implanted stimulator placed in an abdominal subcutaneous pouch and switched externally by a magnet.<sup>2</sup>

The combined results from the multicenter trial have been published recently in the form of a general overview.<sup>1</sup> Some complications and problems, however, were specific to Saudi Arabia, and this paper documents this experience in more detail.

### Materials and Methods

Following discussions with the Backen Research Institute, Maastricht, Holland, who originally organized the trial, and approval of the KFSH&RC research ethics committee, patients referred to the colorectal clinic at KFSH&RC suffering from anal incontinence were considered for dynamic graciloplasty. Both authors attended training sessions in relation to patient assessment and operative technique in Maastricht, and Professor C. Baeten, who pioneered the technique in Maastricht, spent time in Riyadh.

Patients with anal incontinence were evaluated clinically, and those who obviously had a discrete sphincter defect were offered overlapping sphincter repair.<sup>3</sup> Patients with a generalized weakness were considered for dynamic graciloplasty. It was decided that in the initial period of study, no patients over 45 years would be offered the operation. After explaining the technique to patients, it was stressed that since the operation was still in the trial phase, there could be no guarantee of success. The risks, benefits and alternative treatments were discussed with the patient before seeking consent. If the patient wished to

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proceed

with graciloplasty, arrangements were made for the patient's admission for surgery.

Prior to surgery, all patients underwent electromyographic examination of their anal sphincters and the gracilis muscle to be used for the graciloplasty. Pressure measurements were made with a solid state, four transducer, Synectics Medical PC Polygraph HR (Synectics Medical AB, Stockholm, Sweden) during pull through. Pressures were measured in triplicate at rest and during maximum squeezing. Rectal compliance was measured with an intrarectal balloon during gentle filling with saline. The recto-anal inhibitory reflex was tested in all patients. A 200 mL warm saline enema was administered to each patient to determine how long the enema could be retained.

The operation has been described in detail previously.<sup>4,5</sup> Our patients were all given prophylactic antibiotics. A single longitudinal incision was made over the gracilis muscle instead of making three separate incisions as originally described, and the thigh wounds were drained for 24 hours. An implantable pulse generator (IPG), the Medtronic Itriel II (Medtronic, Minnesota, USA), was inserted and the electrodes implanted six weeks after the graciloplasty, under general anesthesia without muscle relaxation, and the stimulation program commenced four weeks later. The IPG was programmed at two-weekly intervals so that at the end of eight weeks, the stimulator was "on" continuously. The neosphincter could be switched "on" and "off" to allow defecation at an appropriate time. At the end of training, patients were seen at three-monthly intervals to assess IPG function and programming, and to assess the clinical progress of the patient.

Five patients (two females and three males, Table 1) were considered on clinical assessment to be suitable for dynamic graciloplasty. The right gracilis muscle was used for graciloplasty in all patients. One patient, a diabetic male, developed an infection of his thigh wound which resolved with antibiotics and without drainage. There was no other surgical morbidity.

All patients had low resting and squeeze pressures prior to surgery (Table 2), and with the exception of patient number 5, all patients improved during training. Patients numbers 1 and 3 maintained satisfactory clinical and manometric function at six and five years' follow-up, respectively, but the first patient did not seem to use his magnet, and the other patient continued to complain of pelvic pain despite reassurance from surgeons in Cleveland and Maastricht (Table 2). Despite repeated instruction, this patient never seemed to know whether her IPG was "on" or "off." Patient number 2 had a loop ileostomy at the end of training and further testing was halted. This patient had her stoma closed, and seemed to improve for some time, but four years after the graciloplasty, she ceased to have

any function in the transposed muscle. A second graciloplasty was refused by the patient, who requested that the IPG be removed. Patient number 4 avulsed the leads during training, had them reinserted, was counseled with regard to sitting and



FIGURE 1. Resting, squeeze and stimulated pressures in patients who had a satisfactory result from dynamic graciloplasty.



FIGURE 2. Resting, squeeze and stimulated pressures in patients whose graciloplasty failed.

TABLE 1. Patient demographics.

| Patient # | Sex    | Age | Occupation   | Reason for incontinence     | Stoma | Complication                       |
|-----------|--------|-----|--------------|-----------------------------|-------|------------------------------------|
| 1         | Male   | 33  | Teacher      | RTA                         | No    | Lost magnet                        |
| 2         | Female | 18  | Student      | Congenital                  | Yes   | Late necrosis of muscle            |
| 3         | Female | 28  | Prison guard | Hemorrhoid surgery          | No    | Vaginal pain                       |
| 4         | Male   | 60  | Businessman  | Hemorrhoid, fistula surgery | No    | Avulsed lead and 2x avulsed tendon |
| 5         | Male   | 51  | Businessman  | RTA                         | Yes   | Loose wrap                         |

RTA=road traffic accident.

excessive activity, avulsed his gracilis tendon on two subsequent occasions, and failed to obey all advice given. Patient number five had an unsatisfactory wrap because of massive peri-rectal fibrosis secondary to his original

trauma. The original wrap was found to be too loose and was tightened, but the patient's sacral wound broke down and his colostomy was not closed.

TABLE 2. Preoperative and post-training measurements.

| Timing                         | Measurement                    | Patient #1      | 2      | 3      | 4        | 5         |
|--------------------------------|--------------------------------|-----------------|--------|--------|----------|-----------|
| Preoperative                   | Resting (mm Hg)                | 26              | 30     | 48     | 22       | 6         |
|                                | Squeeze (mm Hg)                | 39              | 69     | 71     | 30       | 48        |
|                                | "Full" sensation (mL)          | 120             |        | 110    | 15       | 80        |
|                                | RAIR                           | Normal          | Normal | Normal | Not done | Not done  |
|                                | Enema test (sec.)              | 0               | 0      | 30     | 30       | 0         |
|                                | Diaper use                     | For urine       | None   | None   | None     | For urine |
|                                | Bowel frequency (per day)      | 1-2             | Stoma  | 4      | 2-3      | Stoma     |
| End of training                | Resting (mm Hg)                | 81              | 32     | 43     | 38       | 15        |
|                                | Squeeze (mm Hg)                | 106             | 104    | 107    | 86       | 25        |
|                                | Stimulated (mm Hg)             | 94              | 79     | 81     | 22       | 24        |
|                                | Enema test (sec.)              | 30              | -      | -      | -        | -         |
|                                | IPG voltage                    | 2.8             | 3.0    | 1.3    | 0.9      | 2.4       |
|                                | Frequency of stimulation (pps) | 25              | 25     | 25     | 25       | 25        |
|                                | Two months                     | Resting (mm Hg) | 80     |        | 33       | *         |
| Squeeze (mm Hg)                |                                | 90              |        | 103    |          |           |
| Stimulated (mm Hg)             |                                | 92              |        | 44     |          |           |
| Enema test (sec.)              |                                | 350             |        | 60     |          |           |
| IPG voltage                    |                                | 2.6             |        | 1.3    |          |           |
| Frequency of stimulation (pps) |                                | -               |        | 15     |          |           |
| Six months                     |                                | Resting (mm Hg) | 76     |        | 39*      |           |
|                                | Squeeze (mm Hg)                | 98              |        | 89*    |          |           |
|                                | Stimulated (mm Hg)             | 81              |        | 60     |          |           |
|                                | IPG voltage                    | 2.8             |        | 2.3*   |          |           |
|                                | Frequency of stimulation (pps) | -               |        |        |          |           |
| Eight months                   | Resting (mm Hg)                | 72              |        | 20     |          |           |
|                                | Squeeze (mm Hg)                | 80              |        | 46     |          |           |
|                                | Stimulated (mm Hg)             | 74              |        | -      |          |           |
|                                | IPG voltage                    | 3.5             |        | 2.3    |          |           |
|                                | Bowel frequency                | 0.2/day         |        | 3/day  |          |           |
|                                | Frequency of stimulation (pps) | 10              |        |        |          |           |

\*IPG leads not functioning; +wrap ineffective because of fibrosis; pps=pulses/sec.; RAIR=recto-anal inhibitory reflex.

In patients who had a satisfactory result from dynamic graciloplasty, the resting, squeeze and stimulated pressures attained during training were maintained without increasing stimulator voltage (Figure 1), whereas in patients whose graciloplasty failed, both pressures fell with time despite increasing stimulator voltage (Figure 2). There was a 50% reduction in bowel frequency in the two patients in whom the procedure was successful. In the two patients who had functioning neosphincters, the time that the saline enema could be held increased from 0 to 300 sec. in patient number 1 and 30-60 sec in patient number 3. In the only patient in whom measurements were possible, the fusion frequency fell from 25 pps (pulses/sec.) to 15 pps at eight months post-training. The stimulator frequency was reduced from 25 pps post-training to 10 pps at eight months post-training.

**Discussion**

The original multicenter trial which included KFSH&RC reported 128 patients who underwent the procedure.<sup>1</sup> Two of our five patients in whom dynamic graciloplasty was performed had satisfactory results, although even they failed to use their magnets and stimulators properly. At the outset of the trial, it was realized that it would be very important to select patients for the operation with great care. We, therefore, chose patients who seemed to be educated and who would understand what they had to do themselves. Much time was spent explaining the procedure and the method of activating and deactivating the IPG. The need to avoid stretching the transposed muscle was also stressed. Detailed consent forms in Arabic were read and signed by all patients, but despite these precautions the patients themselves seemed to fail to make any real effort to facilitate the procedure.<sup>5</sup> None of our patients had had surgery for incontinence previously,<sup>2</sup> and this fact may have contributed to their poor cooperation because none of them had had past experience of operative failure.

Only one of our patients developed a procedure-related complication, and this compares well with the complication rate in the trial as a whole in which there were 138 complications in 128 patients.<sup>1</sup> The overall probability of developing a wound infection during the first 12 months after surgery was 17.4% at centers experienced in the technique, compared with 33.1% at centers in which the experience was less. Late atrophy of the transposed muscle has been reported before,<sup>2</sup> and in our patient may have been related to prolonged sitting with the legs widely abducted on hard floors. Other late complications we encountered included failure to use the magnet properly, inability to tell whether the stimulator was “on” or “off,” lead displacement, and tendon detachment, and these have been reported in other centers, but overall these problems were infrequent (tendon displacement 4/128, others 14/128). None of our patients developed acute muscle necrosis, anal necrosis or anal stricture.

At the end of the training period, three patients had functioning neosphincters. One patient had already avulsed his electrodes and the fifth patient still had a functioning stoma and a loose wrap. This latter patient had a loose wrap consequent upon gross post-traumatic peri-anal scarring, and with hindsight should probably not have been offered the procedure. Of the 128 patients reported in the multicenter trial, 109 (85%) achieved a successful result at some point during follow-up.<sup>1</sup> This success was maintained in 85 patients (66%), which is better than the rate reported in this paper (40%), although our numbers were comparatively small. In “inexperienced” centers, the success rate was 47% in contrast to 80% reported from “experienced” centers.

Our patients tended to be impatient, and thus many of the “optional tests” included in the trial data set were not completed. We were not able to get all patients to repeat the enema test postoperatively. The patients in whom graciloplasty was considered to be successful were able to hold their bowel contents longer following dynamic graciloplasty than prior to the procedure. Fusion frequency and the frequency of stimulation necessary to produce a sustained contraction of the neosphincter were difficult to test. In other studies, it was found that as more muscle fibers convert from fast to slow twitch,<sup>6</sup> the pulse frequency necessary to produce a smooth muscle contraction fell.<sup>5</sup> This observation was made in the one patient in whom testing was undertaken.

Unfortunately, our patients, in general, seemed to be unwilling to use their magnets to switch their stimulators, and one actually gave his magnet to his children for play and it was lost. Our patients often sat for hours on the floor with crossed legs and thighs widely abducted. This posture stretched the gracilis “wraps” and explained why we found that with time, anal pressures diminished and continence progressively failed. Despite many requests to avoid sitting with thighs abducted, one patient continued to do so and as a consequence, avulsed the tendon from its attachment to

the ischial tuberosity on two occasions. Despite re-implantation the patient continued to sit crosslegged.

It is tempting to speculate that some of our “local” problems with dynamic graciloplasty could be overcome by using a muscle such as gluteus in place of gracilis muscle to form the neosphincter.<sup>7</sup> Wide abduction of the legs during sitting would not stretch a “wrapped” gluteus, and the problems of tendon detachment and lead avulsion might be avoided. Unfortunately, dynamic gluteoplasty was not found to be as successful (45%) as dynamic graciloplasty (66%) in the multicenter trial,<sup>1</sup> and the complication rate was quite high (13/11).

We thought that we had selected our patients with care,<sup>8</sup> because we had realized the importance of the patients themselves in relation to determining the final outcome of the procedure. In retrospect, however, our selection seems to have been rather poor, because only two out of our five patients completed training with functioning neosphincters. It appears that the culture and sitting habits of most of our patients precluded successful dynamic graciloplasty. For this reason, our participation in the multicenter trial was concluded. In recent times, the operation has not been offered to patients at KFSH&RC, although it should be available in specialized centers for the management of patients with refractory anal incontinence.<sup>1</sup>

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