

Third-party prospective evaluation of patient outcomes after dynamic graciloplasty

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Background: Dynamic graciloplasty (DGP) is a complex procedure designed to improve bowel function in patients with end-stage faecal incontinence. Outcomes of DGP were examined in comparison with stoma formation or continued medical management.

Methods: This third-party evaluation comprised a prospective case-comparison study of patient-based and clinical outcomes at a London hospital. Forty-nine patients who underwent DGP during 5 years from 1997 were compared with 87 patients with similar bowel disorders who did not undergo DGP. Outcome measures were quality of life (QoL), symptoms, anxiety and depression.

Results: At 2 years after surgery, bowel-related QoL and continence had improved by more than 20 per cent compared with the preoperative status for two-thirds of patients who had DGP ($P < 0.001$). Two-thirds were continent all or most of the time, although one-third experienced disordered bowel evacuation. Large deteriorations on the Nottingham Health Profile pain score occurred in 11 of 34 patients who had DGP, compared with seven of 57 patients in comparison groups ($P = 0.027$). Patients in comparison groups experienced no significant changes in measured outcomes over the 2 years of follow-up.

Conclusion: Although DGP is associated with a high level of morbidity, it deserves consideration as an alternative to life with severe and refractory faecal incontinence or stoma formation in people in whom conventional treatments have failed.

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Introduction

Living with faecal incontinence can cause devastating physical, mental and social problems¹⁻⁵. First-line treatments for faecal incontinence include dietary modification, constipating drugs, biofeedback therapy, injection of bio-materials and anal repair operations. A newer technique, sacral nerve stimulation, appears to be a promising and relatively non-invasive treatment for patients with intact or mildly disrupted anal sphincters⁶.

Although these treatments are effective for the majority of patients who seek help, there remain a number for whom these have failed or are not appropriate, and for whom stoma formation is the remaining alternative.

Not only may stoma formation be associated with severe psychological problems⁷⁻¹², but immediate and long-term physical complications are also frequent¹³⁻¹⁵.

Dynamic graciloplasty (DGP) is a procedure designed to improve bowel continence or to restore bowel continuity in patients who are living with a stoma. It involves the transposition of the gracilis muscle from the inner thigh to form a neoanal sphincter. The transposed muscle is then electrically stimulated via an electronic pulse generator (or 'stimulator') implanted beneath the skin of the abdomen to form a potentially continent neosphincter¹⁶.

Although DGP has been performed in a number of centres worldwide since the late 1980s, good quality, objective

evidence regarding long-term outcomes is lacking¹⁷. There are significant ethical and practical difficulties in utilizing randomized controlled trials for procedures such as DGP, where alternative procedures and expected outcomes are very different. A third-party evaluation is an alternative method of evaluation that increases confidence in the observed findings. This paper reflects the findings of such a prospective evaluation, undertaken at the Royal London Hospital (RLH). The aims of the study were to test the hypothesis that DGP leads to a better quality of life (QoL) than either continued medical management of refractory anal incontinence or the formation of a permanent stoma, and to describe short- and long-term clinical outcomes of surgery.

Patients and methods

Patients were included if they had undergone DGP at the RLH after 1 April 1997 with completion of treatment by 31 December 2002, and they were already living with a stoma or were suffering from faecal incontinence that was not amenable to other conventional medical or surgical treatments. Forty-nine of a total of 50 patients who underwent DGP participated in the study (DGP group).

Patients in comparison groups had similar bowel disorders to those in the DGP group, but had not undergone DGP. They were recruited from two sources: patients who had never been referred to the RLH but who had been received specialist surgical advice at other centres in England and Wales for a bowel disorder (the 'not offered surgery' group), and patients who were offered DGP at the RLH, but who decided not to proceed with the operation (the 'refused surgery' group). Forty-five of 70 patients in the 'not offered surgery' group and 42 of 68 in the 'refused surgery' group agreed to participate.

Response rates for questionnaires were high in the DGP group. Four patients underwent DGP before the start of the evaluation and had no baseline measures of QoL or symptoms. Response rates were high in the two comparison groups over the first year, but tailed off to 32 of 45 and 29 of 42 at 2 years (*Table 1*).

Main outcomes were symptoms, bowel-related and general QoL, anxiety, depression, and 'survival' of the neosphincter.

Standardized measures were used wherever possible (*Table 2*). At the start of the study it was not known whether the generic measures – EuroQol (EQ-5D)¹⁸ and the Nottingham Health Profile (NHP)¹⁹ – would be sufficiently sensitive to detect changes in QoL that might occur after bowel surgery; hence a condition-specific measure was also required. In the absence (at

Table 1 Numbers of participants at each stage of follow-up and questionnaire response rates

| | Length of follow-up (months) | | | | | | |
|------------------------------------|------------------------------|-----|-----|----|----|-----|-------|
| | Baseline | 3–5 | 6–9 | 12 | 24 | 36 | 48 60 |
| DGP group | | | | | | | |
| No. of patients | 49 | 49 | 47 | 45 | 40 | 31 | 23 12 |
| No. returning questionnaire | 45* | 45 | 44 | 44 | 39 | 29† | 19 8 |
| 'Not offered surgery' group | | | | | | | |
| No. of patients | 45 | – | 45 | 45 | 45 | – | – – |
| No. returning questionnaire | 41 | – | 39 | 36 | 32 | – | – – |
| 'Refused surgery' group | | | | | | | |
| No. of patients | 42 | – | 42 | 42 | 42 | – | – – |
| No. returning questionnaire | 40 | – | 35 | 36 | 29 | – | – – |

*Four patients underwent dynamic graciloplasty (DGP) before the start of the outcomes assessment study. †Two patients dropped out.

the start of the evaluation study) of an adequately tested incontinence- or stoma-specific QoL measure, the RLH bowel questionnaire was developed. This new measure was found to be sensitive to changes following successful and unsuccessful bowel surgery, and was able to discriminate between the patient groups at baseline²¹.

Data were collected by means of self-completion questionnaires. Patients in the DGP group completed questionnaires before operation and at regular intervals after surgery until the end of the study period. Patients in the comparison groups completed questionnaires on recruitment to the study and on three further occasions during a 2-year follow-up (*Table 1*). All patients were aware that their responses would not be revealed to any health professional involved in their medical care.

Ethical approval for the study was granted by East London and City Health Authority Research Ethics Committee. London Multi-Centre Research Ethics Committee and local research ethics committees gave permission for the recruitment of patients to the 'not offered surgery' group.

Statistical analysis

Statistical analyses were carried out using SPSS[®] version 11.0 software (SPSS, Chicago, Illinois, USA). Statistical significance was accepted at less than 5 per cent.

Average baseline scores for each questionnaire measure were compared between groups using means or medians, as appropriate for the distributions. Within-person changes in scores at 1 and 2 years of follow-up were compared between groups, and are shown for the DGP group

Table 2 Main outcome measures

| Questionnaire | Description | Domains | Population or normative values |
|---|---|---|---|
| EQ-5D (EuroQoL) ¹⁸ | Generic Quality of life Standardized | Five single domains of health status: mobility, self-care, anxiety/depression, pain/discomfort and usual activities Population-based single index of health status and a self-rated score for health status | Sample of 3395 UK adults |
| Nottingham Health Profile ¹⁹ | Generic Measure of distress Standardized | 38 single yes/no items give scores in six domains: emotional reaction, energy, pain, physical mobility, sleep and social isolation. Main domains chosen: pain, social isolation | Sample of 6506 UK adults |
| Hospital Anxiety and Depression Scale ²⁰ | Domain specific Standardized | 14 items give scores on scales for anxiety and depression | Scales can be categorized as normal, mild, moderate or severe |
| Royal London Hospital bowel questionnaire | Disorder specific (suitable for people with stomas or faecal incontinence) Locally devised and tested | 16 items of daily living give scores on two scales of impact of the bowel disorder: psychosocial and lifestyle | Validated within this study population ²¹ |
| Symptoms | Disorder specific, locally devised, contains questions based on the Cleveland Clinic Incontinence Scale ²² | Questions on frequency and severity of faecal incontinence and evacuatory difficulties. For dynamic graciloplasty group, questions on use of stimulator, pain and other postoperative symptoms Can be used to generate the Cleveland Clinic Incontinence Score ²² | — |

alone at 3 years. An increase or decrease of 20 per cent or more was considered to represent a large improvement or deterioration on each scale. Tests of statistical significance were chosen to compare groups and to assess within-group changes according to the distribution of each variable.

Clinical success was defined by survival of a functioning neosphincter with intact electrical circuitry and stimulator at the end of the study period. Cumulative survival was plotted using the Kaplan–Meier method.

Sample size calculations indicated that for the main outcome measures there were sufficient patients to detect between-group differences of 20–30 per cent at 2 years of follow-up and within-DGP group changes of 20 per cent at 3 years of follow-up (at a minimum of 80 per cent power and significance level of 5 per cent).

Results

The median length of follow-up for patients who underwent DGP was 43 (range 4–71) months. Both comparison groups were followed for 2 years.

The baseline characteristics of the groups differed significantly by cause of disorder: there were more patients with a stoma as a result of previous cancer treatment in the 'not offered surgery' group than in the DGP and 'refused surgery' groups. Patients in the DGP group had significantly higher (worse) baseline scores on both scales of the RLH bowel-specific measure. One patient in the DGP group and one in the 'refused surgery' group reported that

they were never incontinent at baseline; both described their incontinence as staining and difficulty cleaning after defaecation rather than frank incontinence (*Table 3*).

Clinical outcomes and symptoms

During the study period, DGP failed in 15 of 49 patients (*Fig. 1*). Events leading to clinical failure were usually multiple and included evacuation difficulty in eight of the

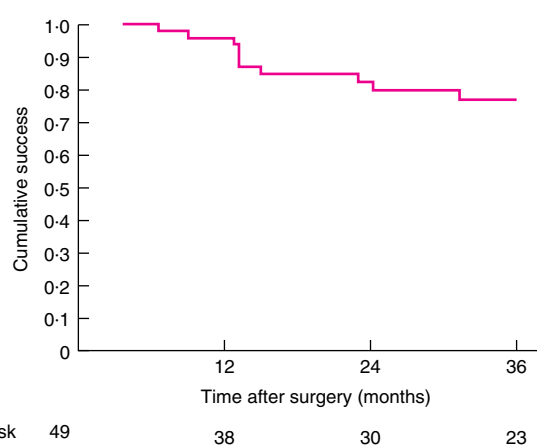


Fig. 1 Kaplan–Meier success curve for the 49 patients who underwent dynamic graciloplasty at the Royal London Hospital. Success was defined as a functioning neosphincter and no stoma. The procedure failed completely in 15 patients

Table 3 Baseline characteristics for the three patient groups

| | DGP group | 'Refused surgery' group | 'Not offered surgery' group | P |
|--|------------------|-------------------------|-----------------------------|-----------|
| No. responding on at least one occasion after baseline | 48 | 38 | 40 | |
| Mean (range) age at recruitment (years) | 42 (15–71) | 44 (17–81) | 49 (16–81) | 0.524** |
| Sex ratio (M:F) | 12:36 | 8:30 | 10:30 | 0.891†† |
| Cause of disorder | | | | 0.011††† |
| Congenital | 6 | 11 | 9 | |
| Cancer | 1 | 4 | 8 | |
| Obstetric trauma | 24 | 18 | 12 | |
| Other trauma or neuropathic or idiopathic | 17 | 5 | 10 | |
| Median time with disorder (years) | | | | |
| Congenital | 20 | 25 | 20 | 0.360‡‡ |
| Acquired | 5 | 7 | 5 | 0.903‡‡ |
| Previous incontinence-related surgery (non-stoma patients) | | | | 0.961†† |
| Yes | 14 | 13 | 6 | |
| No | 16 | 13 | 7 | |
| Not asked | 0 | 2 | 6 | |
| Frequency of incontinence to solid or liquid stool | n = 48 | n = 37 | n = 40 | 0.092††¶¶ |
| Never | 1 | 1 | 0 | |
| < 1/month | 0 | 12 | 2 | |
| < 1/week | 3 | 6 | 6 | |
| ≥ 1/week | 6 | 9 | 5 | |
| Daily | 20 | 9 | 6 | |
| Stoma | 18 | 10 | 21 | |
| EuroQoL (EQ-5D) weighted index of health status* | n = 43¶¶ | n = 38 | n = 40 | 0.169‡ |
| Median (i.q.r.) | 0.69 (0.59–0.81) | 0.76 (0.66–1.00) | 0.69 (0.62–0.85) | |
| NHP pain scale† | n = 44 | n = 35 | n = 39 | 0.541‡‡ |
| Median (i.q.r.) | 0 (0–23) | 0 (0–23) | 0 (0–24) | |
| NHP social isolation scale† | | | | 0.596‡‡ |
| Median (i.q.r.) | 20 (0–44) | 0 (0–40) | 0 (0–42) | |
| HADS‡ | n = 44 | n = 37 | n = 40 | |
| Median (i.q.r.) anxiety score | 9.0 (6.8–10.9) | 8.0 (4.8–13.0) | 8.0 (4.3–11.0) | 0.482‡‡ |
| Median (i.q.r.) depression score | 6.8 (2.3–10.9) | 3.5 (2.0–9.0) | 4.0 (2.3–9.8) | 0.150‡‡ |
| RLH bowel-specific measure§ | n = 41 | n = 38 | n = 39 | |
| Median (i.q.r.) psychosocial impact score | 4.8 (2.9–7.3) | 2.3 (0.3–5.6) | 3.3 (0.3–6.5) | 0.011‡‡ |
| Median (i.q.r.) lifestyle impact score | 7.3 (5.3–7.9) | 4.7 (2.5–6.9) | 4.1 (1.9–6.8) | 0.002‡‡ |

*Scale 0–1; 1 represents best health. †Nottingham Health Profile (NHP) scale 0–100; 0 represents best. ‡Hospital Anxiety and Depression Scale (HADS): 0–7, normal; 8–10, mild; 11–14, moderate; 15–21, severe. §Scale 0–10; 0 represents best health. DGP, dynamic graciloplasty; i.q.r., interquartile range; RLH, The Royal London Hospital. ¶Statistical analysis of non-stoma patients only. **One-way ANOVA; †† χ^2 test; ‡‡Kruskal–Wallis ANOVA.

16 patients. Other causes included perianal pain, sepsis, electronic circuitry problems and ongoing faecal soiling.

At 2 years after surgery nearly two-thirds (23 of 37) of patients who underwent DGP were never or rarely incontinent to solid and liquid stool (Table 4), and 11 of 17 previously incontinent patients experienced an improvement of more than 20 per cent on the Cleveland Clinic Incontinence Scale (Table 5).

Disordered bowel evacuation was frequent and ongoing throughout the follow-up period. Five patients underwent formation of a colonic conduit in order to achieve bowel evacuation by antegrade irrigation (Table 4). Nearly half of all patients with a satisfactory continence outcome (incontinence less than once per week) experienced ongoing evacuatory difficulties once or more per week.

Significantly more patients in the DGP group than in comparison groups deteriorated by 20 per cent or more on the NHP pain scale at 2 years of follow-up ($P = 0.027$) (Table 5).

No significant changes in symptoms were observed during follow-up of the comparison groups.

Quality of life

Median scores for the main condition-specific QoL outcome measures improved following DGP; these improvements increased over the first postoperative year and began to stabilize after 12 months. The trend was most marked for the bowel-specific RLH psychosocial and lifestyle impact scales: 17 of 30 and 21 of 33 patients respectively in the DGP group experienced

Table 4 Frequency of incontinence to solid or liquid stool and frequency of disordered bowel evacuation in the dynamic graciloplasty group 6 months to 4 years after surgery (cross-sectional data)

| | Time after surgery (months) | | | | | |
|--|-----------------------------|----------|----------|----------|----------|-----------|
| | Preop. | 6-9 | 12 | 24 | 36 | 48 |
| Frequency of incontinence to solid or liquid stool | | | | | | |
| No. of respondents | 48 of 49 | 46 of 49 | 42 of 45 | 37 of 40 | 27 of 31 | 22 of 23* |
| Never or less than once per week | 4 | 25 | 27 | 23 | 17 | 13 |
| Once or more per week | 6 | 9 | 9 | 7 | 6 | 1 |
| Daily | 20 | 5 | 1 | 3 | 1 | 2 |
| Stoma | 18 | 7 | 5 | 4 | 3 | 6 |
| Frequency of disordered bowel evacuation†‡ | | | | | | |
| No. of respondents | — | 39 of 49 | 39 of 45 | 36 of 40 | 27 of 31 | 21 of 23* |
| Never or less than once per week | — | 14 | 17 | 15 | 12 | 7 |
| Once or more per week | — | 5 | 6 | 2 | 2 | 1 |
| Daily | — | 8 | 6 | 11 | 7 | 5 |
| Colonic conduit | — | 5 | 5 | 4 | 3 | 2 |
| Stoma | 18 | 7 | 5 | 4 | 3 | 6 |

*Includes three non-responders known to have a stoma at this stage. †Defined as one or more of the following required to achieve evacuation: straining for more than 20 min, use of enemas, rectal irrigation, digitation or suppositories. ‡Question not asked in early stage of study.

Table 5 Patients with large (20 per cent or greater *versus* baseline) improvement or deterioration at 2-year follow-up

| | DGP group | | | 'Refused surgery' group | 'Not offered surgery' group | P‡ |
|--------------------------------------|-------------------|------------------|--------------|-------------------------|-----------------------------|---------|
| | Clinical success* | Clinical failure | All patients | | | |
| Cleveland Clinic Incontinence Scale† | | | | | | |
| No. of patients | 15 | 2 | 17 | 15 | 13 | |
| No. with ≥ 20% improvement | 10 | 1 | 11 | 3 | 1 | 0.001 |
| No. with ≥ 20% deterioration | 0 | 1 | 1 | 2 | 3 | 0.385 |
| EQ-5D health status | | | | | | |
| No. of patients | 28 | 7 | 35 | 28 | 29 | |
| No. with ≥ 20% improvement | 10 | 1 | 11 | 2 | 8 | 0.134 |
| No. with ≥ 20% deterioration | 2 | 3 | 5 | 6 | 3 | 1.000 |
| NHP pain scale | | | | | | |
| No. of patients | 27 | 7 | 34 | 27 | 30 | |
| No. with ≥ 20% improvement | 2 | 0 | 2 | 3 | 4 | 0.475 |
| No. with ≥ 20% deterioration | 9 | 2 | 11 | 4 | 3 | 0.027 |
| NHP isolation scale | | | | | | |
| No. of patients | 28 | 7 | 35 | 29 | 30 | |
| No. with ≥ 20% improvement | 11 | 1 | 12 | 5 | 4 | 0.042 |
| No. with ≥ 20% deterioration | 3 | 2 | 5 | 3 | 3 | 1.000 |
| HADS anxiety score | | | | | | |
| No. of patients | 28 | 7 | 35 | 29 | 32 | |
| No. with ≥ 20% improvement | 9 | 1 | 12 | 3 | 1 | 0.006 |
| No. with ≥ 20% deterioration | 5 | 2 | 7 | 4 | 3 | 0.368 |
| HADS depression score | | | | | | |
| No. of patients | 28 | 7 | 35 | 29 | 32 | |
| No. with ≥ 20% improvement | 5 | 0 | 5 | 1 | 3 | 0.290 |
| No. with ≥ 20% deterioration | 1 | 1 | 2 | 3 | 3 | 0.706 |
| RLH psychosocial impact score | | | | | | |
| No. of patients | 23 | 7 | 30 | 29 | 31 | |
| No. with ≥ 20% improvement | 14 | 3 | 17 | 5 | 6 | < 0.001 |
| No. with ≥ 20% deterioration | 0 | 1 | 1 | 4 | 5 | 0.155 |
| RLH lifestyle impact score | | | | | | |
| No. of patients | 26 | 7 | 33 | 29 | 31 | |
| No. with ≥ 20% improvement | 17 | 4 | 21 | 4 | 6 | < 0.001 |
| No. with ≥ 20% deterioration | 3 | 0 | 3 | 1 | 6 | 1.000 |

*Clinical success was defined as no stoma and a functioning neosphincter with intact electronic circuitry. †Applies only to patients who did not have a stoma at either baseline or 2-year follow-up. ‡Total DGP group *versus* combined comparison groups (Fisher's exact test). DGP, dynamic graciloplasty; NHP, Nottingham Health Profile; HADS, Hospital Anxiety and Depression Scale; RLH, The Royal London Hospital.

large improvements at 2 years after surgery (Table 5). Mean within-DGP group improvements of 26 and 31 per cent respectively were seen at 2 years for these RLH impact scores, significantly greater than values in either comparison group ($P < 0.001$) (Table 6).

Improvements in the DGP group were maintained at 3 years of follow-up (Table 6), and at 4 years (data not shown), although numbers in the cohort were small by 4 years. The generic QoL measures (EQ-5D and NHP) did not indicate significant improvements in general health status for the DGP group as a whole at 2 years after surgery, although there were wide variations between individuals: nearly one-third (ten of 28) of patients whose DGP had been clinically successful experienced a large improvement as measured by the EQ-5D index of health status (Table 5). At 3 years after surgery there was a modest but significant improvement for the whole DGP group as measured by this generic index ($P = 0.032$).

The comparison groups showed little change in QoL over the 2-year follow-up period. There were indications of small improvements in a number of measures for the 'refused surgery' group at 1 year; however, these improvements were not sustained at 2 years (Table 6).

Psychological distress

Scores for the Hospital Anxiety and Depression Scale (HADS) suggested that the majority of patients in all groups were not clinically anxious or depressed at baseline. There were non-significant improvements in postoperative

scores for the DGP group and no changes for the comparison groups at the same follow-up points. There was an indication of further improvement in scores for the DGP group at 3 years of follow-up (Table 6).

Outcomes for patients with congenital anomalies

DGP was unsuccessful in four of six patients whose disorders were caused by congenital anomalies. None of the findings was altered by reanalysis that excluded patients with congenital disorders.

Discussion

This study reports the first third-party evaluation of DGP for faecal incontinence. The results indicate less favourable outcomes than previously reported in clinician-conducted studies²³⁻²⁶. At 3 years after surgery, the cumulative success rate was 74 per cent. Bowel-related QoL and continence, when assessed between 1 and 3 years after DGP, improved significantly and in excess of 20 per cent compared with the preoperative status for nearly two-thirds of patients, although half of those with a satisfactory continence outcome had ongoing evacuatory difficulties, and worsening pain was experienced by one-third.

Recent multicentre studies²³⁻²⁵ have suggested that continence is improved for 50-70 per cent of patients who undergo DGP. A long-term follow-up study²⁶ reported a success rate of 72 per cent in 200 patients at a median follow-up of 5 years (success being defined as continence

Table 6 Percentage changes in main outcome measures at follow-up in the three groups

| | Mean change versus baseline (%)* | | | | | | | | P‡ |
|---------------------------------------|----------------------------------|--------------------------|--------------------------|-----------------------------|--------------------------|--------------------------|------------------------|--------|----|
| | DGP group | | | 'Not offered surgery' group | | 'Refused surgery' group | | | |
| | 12 months (n = 37-40) | 24 months (n = 30-35) | 36 months (n = 23-24) | 12 months (n = 34-36) | 24 months (n = 28-32) | 12 months (n = 31-35) | 24 months (n = 29) | | |
| Cleveland Clinic Incontinence Scale** | 5 (2, 7) (n = 23) | 24 (11, 37) (n = 17) | 25 (16, 35) (n = 13) | -1 (-3, 1) (n = 13) | -8 (-19, 3) (n = 13) | 0 (-1, 2) (n = 17) | 5 (-5, 15) (n = 15) | 0.001 | |
| EQ-5D weighted index of health status | 4 (-5, 13) | 7 (-3, 18) | 11 (2, 20) | -1 (-8, 5) | 7 (-3, 16) | 4 (-10, 3) | -5 (-15, 6) | 0.21 | |
| NHP pain scale | -8 (-18, 7) | 0 (0, 0) | 0 (-13, 0)† | -6 (-13, 2) | 0 (0, 0) | 1 (-7, 6) | 0 (0, 0) | 0.16§ | |
| NHP social isolation scale | 12 (3, 20) | 10 (0, 21) | 6 (0, 22)† | 0 (0, 23) | 2 (-4, 9) | 11 (2, 19) | 3 (-5, 11) | 0.34§ | |
| HADS anxiety score | 8 (-1, 16) | 9 (0, 17) | 11 (2, 19) | -2 (-6, 2) | -3 (-9, 3) | 8 (3, 13) | 2 (-4, 8) | 0.06 | |
| HADS depression score | 7 (-1, 16) | 6 (-3, 15) | 18 (10, 26) | -5 (-1, -8) | -4 (-8, 1) | 5 (1, 9) | 1 (-8, 7) | 0.12 | |
| RLH psychosocial impact score | 28 (19, 38) | 26 (16, 36) | 34 (24, 44) | 0 (-6, 7) | 0 (-8, 8) | 4 (-2, 11) | 2 (-7, 11) | <0.001 | |
| RLH lifestyle impact score | 36 (26, 46) | 31 (19, 43) | 40 (28, 52) | -4 (-10, 2) | -3 (-11, 5) | 9 (2, 16) | 6 (-1, 14) | <0.001 | |

*A positive change represents an improvement in the score; values in parentheses are 95 per cent confidence intervals. **Applies only to those without stomas at both baseline and follow-up. †Median values are shown for the Nottingham Health Profile (NHP) scales at 36 months owing to non-normality of the distributions. DGP, dynamic graciloplasty; HADS, Hospital Anxiety and Depression Scale; RLH, The Royal London Hospital. ‡Between-group differences in change in score at 24 months (one-way ANOVA); §Kruskal-Wallis ANOVA.

to solid and liquid stool), with chronically disturbed evacuation in 16 per cent.

Previously published studies have all been conducted by clinicians involved in the care of patients undergoing DGP. Patients' responses to their healthcare professionals may be biased towards giving a more favourable picture of outcomes than would be revealed to an independent investigator; there may also be clinician bias in defining outcomes, in recording responses and in methods of analysis. These sources of bias may partly explain the more favourable findings reported in other studies. The proportion of patients with a previous stoma was high in the present study, possibly reflecting a more complex case mix.

The alternative technique to DGP is the implantation of an artificial bowel sphincter (ABS). No good quality outcome studies of the ABS technique have been published. The surgical team involved in the present study had always believed, from observations in animal studies, that placement of a Silastic cuff around bowel would lead to a high incidence of sepsis and erosion, and consequently had preferred to use autologous muscle. Although initial reports of the ABS technique were encouraging and indicated low morbidity rates in the short term^{27,28}, subsequent studies demonstrated such high medium-term failure rates that a recent systematic review of 14 studies stated that implantation of an ABS was of uncertain benefit and may possibly harm many patients²⁹.

The authors would have preferred to evaluate DGP as part of a randomized controlled trial. However, the overwhelming problem in mounting a randomized trial would have been in persuading patients, most of whom had been referred for a stoma-preventing procedure, to accept randomization to a stoma. Indeed, 18 of 48 patients in the DGP group had already undergone stoma formation before referral. In addition, the absence of a state of equipoise between the surgical options of DGP and ABS meant that it would have been ethically unacceptable to randomize patients to receive either DGP or ABS as alternatives to stoma formation.

There was a low overall response rate in both comparison groups. This is unsurprising given the embarrassing nature of the disorders and the fact that, for ethical reasons, patients in the 'not offered surgery' group could not be contacted directly by the researchers at the time of invitation to participation. The low rates of participation may have resulted in some selection bias, although participants and non-participants did not differ in age, sex or cause of disorder.

It could be suggested that patients who underwent DGP did so at a time when their symptoms were particularly distressing, and that this, combined with the fact that

postoperative improvements for patients in the DGP group brought their QoL and continence scores to a level similar to those in the comparison groups at 2 years of follow-up, might indicate regression to the mean as a possible explanation for the improvements in QoL observed in the DGP group. However, it seems more likely that patients in the comparison groups were consistently less affected by their bowel disorder than those in the DGP group, as would be expected in people who either chose not to undergo DGP or who were not actively seeking further intervention. If anything, the absence of change in the comparison groups over the follow-up interval indicates that QoL in people with a stoma or incontinence does not change grossly over time without intervention. It was also apparent that improvements in QoL experienced by the DGP group continued after 2 years of follow-up, and these improvements were seen on generic as well as bowel-specific scales.

However, the lack of differentiation in improvements in QoL between patients who had unsuccessful surgery and those whose surgery was successful was, on the face of it, surprising, although patients whose final outcome was a permanent stoma may have found this preferable to severe incontinence. There was a wide variation in QoL outcome for the DGP group and a sizable minority experienced very marked improvement, although the authors were not able to identify any predictors of favourable outcome. Interview evidence (to be reported) suggested that many patients in whom DGP failed had welcomed the opportunity to try a procedure that they regarded as their only possible alternative to life with a stoma or distressing bowel incontinence, and that exercising this choice was an important factor in the acceptance of unsuccessful outcomes.

Observational studies such as this are open to criticisms of selection and observer bias; although it was not possible to influence the surgeons' selection of subjects for DGP, observer bias was minimized by means of independently funded assessment.

In addition, the evaluation involved the collection of data from two additional groups of patients who did not undergo DGP. Although the process of identifying people for the comparison groups was laborious and the groups were imperfect comparators, their inclusion allowed the evaluation of changes in outcomes with more confidence than would have been possible with case series or historical controls alone.

Although methodological limitations are significant and the conclusions must be interpreted with caution, the authors believe that, without the option of a randomized controlled trial, this study has come as

close as is possible to providing robust evidence concerning outcomes of the procedure. However, the authors cannot discount regression to the mean as an explanation for the improvements seen in the DGP group, although this seems unlikely to account wholly for the improvements.

This study has indicated that the place for DGP is at the end of the treatment spectrum for severe and refractory faecal incontinence. It is a complex operation associated with high morbidity and failure rates in the long term. However, as an option for patients who have considered other conventional treatments and are facing the formation of a permanent stoma or continuing to live with a debilitating, socially disabling disorder, the procedure deserves consideration. It may be the only alternative for patients who are intolerant of a stoma. Importantly, patients should be given a realistic picture of the outcomes of DGP, which, even when successful, will include the need for lifelong specialist follow-up and will frequently involve a lengthy treatment period, failure, pain, and disordered continence and evacuation.

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