A systematic review of dynamic graciloplasty for the treatment of faecal incontinence

Authors' objectives
To evaluate the efficacy and safety of dynamic graciloplasty for the treatment of faecal incontinence.

Searching
MEDLINE, Current Contents, EMBASE and the Cochrane Library were searched from 1991 to October 2000 without any language restrictions; the search terms were reported. The authors stated that after the initial search, papers were restricted to those in English if papers in other languages were not considered superior.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials, controlled clinical trials and case series were eligible for inclusion.

Specific interventions included in the review
Studies that assessed dynamic graciloplasty alone or in comparison with colostomy were eligible for inclusion. Studies of gluteal muscle plasty were excluded.

Participants included in the review
Both studies of humans and of animals were eligible for inclusion. Studies of humans had to include individuals with faecal incontinence.

Outcomes assessed in the review
Studies that reported on faecal incontinence, complications, psychosocial effects, revision rates (including time to battery replacement), mortality rates, cost-effectiveness, or failure of the operation were eligible for inclusion. Complications included systemic infection, respiratory complications, pulmonary embolism, leg pain, leg swelling, stimulator or lead problems, or wrap problems (tendon displacement, erosion, constipation). The included studies used different definitions for ‘satisfactory’ continence but most definitions included continence for solids at least.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The quality of the included studies was assessed in terms of the appropriateness of the study exclusion criteria, the quality of the reporting, and possible confounding variables. The authors did not state how many reviewers performed the quality assessment.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. Data were extracted on the study demographics, sample size and design, intervention, population, inclusion criteria and results.

Methods of synthesis
How were the studies combined?
The studies were grouped according to the outcome and combined in a narrative discussion.

How were differences between studies investigated?
Results of the review

In total, 40 studies were included. The total number of participants included was unclear, as there were a large number of studies that might have contributed patient data to more than one study. The study designs included in the review were one review of other studies, one historically controlled comparative study, and 38 case series.

Mortality rates.

The mortality rates for dynamic graciloplasty (14 studies, n=403) ranged from 0 to 31%. Some studies included patients with rectal cancer, treated with either abdominoperineal resection or dynamic graciloplasty, in which some of the deaths were attributable to cancer rather than the graciloplasty operation. When these patients were removed from the analysis, the mortality rates ranged from 0 to 13% with an overall rate of 2% (95% confidence interval, CI: 1, 3). The mortality rate for colostomy (1 study, n=289) was 2% (95% CI: 1, 4).

Morbidity.

The risk for morbidity with dynamic graciloplasty (12 studies, n=347) ranged from 0.14 to 2.08 per patient, with an overall risk of 1.12 across the studies. The morbidity risk for colostomy (1 study, n=203) was 0.51 per patient.

Complications.

The most commonly reported complications for dynamic graciloplasty were infections (28%), problems with simulator and fault leads (15%) and leg pain (13%). Battery exhaustion, constipation, anal and body pain, and injury to either or both the gracilis muscle and the colon stump were also reported in over 5% of the patients. The most commonly related complications for colostomy were paracolostomy hernias (21%) and skin complications (12%).

Continence.

Thirteen studies (n=332) assessed some measure of continence, but only one assessed the change in pre- and post-operation scores. This study (n=52) found that the frequency of defecation decreased from a mean of 5 times per day to 2 times per day, and time to delay defecation increased from a mean of 0.15 minutes to 19 minutes at the 12-month follow-up. Across the 13 studies, the proportion of patients achieving satisfactory continence ranged from 42 to 85%.

Anal manometry.

Thirteen studies (n=403) reported anal manometry data. Mean pre-operative basal and sphincter pressures ranged from 28 to 38 mmHg. The mean post-operative stimulated anal sphincter pressures ranged from 56 to 87 mmHg.

Reoperation rate and stimulator removal.

Eleven studies (n=319) reported adequate data for the reoperation rates to be calculated. The reported risk of reoperation was between 0.14 and 1.07 per patient. Of these studies, only one reported a risk of less than 0.30 and several reported risks of over 0.85 per patient. All of the studies also reported the necessity of explanting stimulators from at least some of their patients; the highest risk reported was 0.42 per patient. The risk of reoperation for colostomy was 0.13 in the one study (n=203) that reported this outcome.

Cost information

Yes. One cost-effectiveness analysis reported that the total incremental cost of dynamic graciloplasty was US$13,221, compared with US$53,065 for colostomy.

Authors' conclusions

While dynamic graciloplasty is associated with a higher rate of complications than colostomy, it is clearly a superior
intervention for restoring continence in some patients.

**CRD commentary**
The review question was loosely defined in terms of the interventions, participants, outcome measures and study designs. A number of databases were searched for relevant studies, but no efforts were made to identify unpublished studies. In addition, the authors stated that after the initial search, studies were restricted to English language papers only if other language papers were not considered superior. They did not, however, report whether any foreign language studies that were originally identified were subsequently included in the review. The review methodology was unclear, and it is not known whether any efforts were made to minimise reviewer bias and errors in the review process. The authors highlighted that there were a large number of studies that could have contributed patient data to more than one study, and it was not possible to determine the size of the evidence base from which the results were derived. Overall, because of the paucity of primary studies included in the review, and a number of potential biases to which the review may have been subject, the authors' conclusions may not be reliable.

**Implications of the review for practice and research**
**Practice:** The authors recommended that dynamic graciloplasty is only performed in centres where the operation is routinely performed, as this operation appeared to have a higher morbidity rate than colostomy and is technically demanding. It was also further advised that patients must be informed as to the probability that the procedure may have to be converted to colostomy if serious morbidity results.

**Research:** The authors stated that a comparative, but non-randomised study should be undertaken to evaluate the safety of dynamic graciloplasty in comparison with colostomy, and that as quality of life outcomes remain undetermined, these measures should be included in any trial.

**Bibliographic details**

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.