NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Stimulated Graciloplasty

Introduction
This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name
Stimulated graciloplasty

SERNIP procedure number
19

Specialty society
Association of Coloproctology of Great Britain and Ireland

Executive Summary
Stimulated graciloplasty is effective at producing satisfactory incontinence outcomes in at least 40% of cases and up to 85% of cases. The conventional procedure – colostomy – of course does not result in continence in any cases. Mortality rates for graciloplasty are 4%, which is double the mortality rate for the conventional procedure of colostomy. Likewise, morbidity rates are not insignificant, with most patients on average experiencing more than one morbidity. The most common morbidity is infection.

Indication(s)
Final stage anal incontinence.

Summary of procedure
Stimulated graciloplasty involves the creation of a new anus using transposed gracilis muscles (which are thigh adductor muscles) implanted with electrode from an electric pulse generator. The continuous current of the pulse generator gradually converts the skeletal muscle fibres of the gracilis into smooth muscles fibres, thus allowing sustained contraction of the new anus and producing continence to faeces.

The procedure can be performed in stages, or all at once. Generally it involves mobilising one or both gracilis muscles by detaching the muscles from the knee ligament. The muscle remains fastened to its pelvic attachments with the blood supply intact, but is brought up into the abdomen, where it is placed around the anus, which may be pre-existing but not functioning, or be created from other tissues such as colon pulled through after an operation such as abdominoperineal resection. The 'knee-end' of the gracilis is fastened to the contralateral pelvis. A pulse generator is implanted in the abdomen and electrodes are implanted in the gracilis. Training of the gracilis begins some weeks after the operation, with the periods that the pulse generator is switched on gradually increasing until the conversion of the gracilis fibres from skeletal to smooth muscle is largely completed.

The standard intervention for final stage faecal incontinence is colostomy.

The claimed benefit of stimulated graciloplasty is restoration of faecal continence.

Literature review
A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on stimulated graciloplasty in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. Foreign language papers were included if they contained safety and efficacy data and were considered to add substantively to the English language evidence base. In the case of duplicate publications, the latest, most complete study was included. All identified studies were included.

List of studies found
Total number of studies: 13

Systematic literature review	1*
Randomised controlled trials	0
Non-randomised comparative studies	1
Case series	11
Case reports	0

*The systematic literature review incorporated data from 1 comparative and 39 case series studies.

Papers were rejected for reporting no clinical outcomes, or being review articles without data, or involving techniques other than stimulated graciloplasty, or for reporting data which is included in later papers. Data for 5 papers are tabulated below. Papers were chosen for tabulation firstly if they were comparative. Then case series were rated as to breadth of study population (thus prospective multicentre studies were rated most highly), followed by papers which reported outcomes for patients with diverse aetiologies, and then those reporting on the application of a particular subtype of graciloplasty (eg. Total anorectal reconstruction patients only). Retrospective studies were given the lowest rating. Studies for which data were not tabulated are listed in the annex following the reference list.

Summary of key efficacy and safety findings
See following tables;

Abbreviations
SF-36 - Short Form 36
STAI - State trait anxiety index.

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Systematic literature review			
Chapman *et al.*[1] 2002, AUSTRALIA. 37 graciloplasty studies (403 patients for safety); 3 colostomy studies (289 patients for safety). *Follow-up:* Up to 13 years. *Selection criteria*: all papers published between 1991 and 2000 that provided safety or efficacy data for either dynamic graciloplasty or colostomy.	Graciloplasty: Reoperation rate: 0.14 – 1.07 per patient. Percent achieving continence: 42% - 85% (measured in various terms, including Cleveland and William's continence scales). Colostomy: Reoperation rate: 0.17 per patient at 11 years. Percent achieving continence: 0%	Graciloplasty: Mortality rate: 0.04 (95% CI 0.02 – 0.06) Morbidity rate: 1.12 (95% CI not calculated) note: rate = greater than 1 per patient. Most common complication: Infection (28%) Colostomy: Mortality rate: 0.02 (95% CI 0.01 – 0.04) Morbidity rate: 0.51 (95% CI 0.44 – 0.58) Most common complication: paracolostomy hernia (21%)	*Potential for bias*: None of the retrieved papers directly compared the comparator procedures, therefore the level of evidence that the review relies upon is poor. *Outcome measures and their validity*: Cleveland Clinic and William's continence scores of unknown validity. *Other comments:*This was a systematic literature review.

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Non-randomised comparative studies			
Rongen *et al.*[2] 2001, NETHERLANDS. 13 patients 1-step graciloplasty. 13 patients 2-step graciloplasty. *Follow-up:* Mean 521 days. *Selection criteria*: end stage incontinent for solid & liquid stool. Consecutive patients from the waiting list underwent a 1-step procedure. In the same period (Sep 1996 – June 1997), 13 patients matched for gender, age & aetiology had a 2-stage procedure a few months earlier.	<u>1-step graciloplasty:</u> "Success" for 85% of patients. 1 patient did not have a functioning graciloplasty. <u>2-step graciloplasty:</u> "Success" for 69% of patients. 2 patients had evacuation problems (no abnormalities on examination, defaecography & manometry). Note: "success" defined as score 1 or 2 on William's scale. No significant difference in quality of life outcomes between groups. Within groups, Mental health significantly improved (p=0.027), as did change in health perception (p=0.001) and anxiety (p=0.001).	<u>1-step graciloplasty:</u> 1 necrosis of neosphincter followed by infection of pulse generator. 1 persistent superficial infection at site of pulse generator. 1 emergency resection for diverticulitis. <u>2-step graciloplasty:</u> 1 urinary retention. 1 pain at donor site from stimulation, solved with colostomy. 1 pain due to periosteal reaction, resolved by removal of suture.	*Potential for bias*: patients matched rather than randomised. *Outcome measures and their validity*: SF-36, STAI and Zung are well established measures. *Other comments:* The 1-step treatment involves transposition of the gracilis and implantation of electrodes in one operation; the 2-step treatment involves separate procedures for both of these steps.

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Case series			
Baeten *et al*.[3] 2001, NETHERLANDS. 200 patients *Follow-up*: unknown. *Selection criteria*: referred patients with severe incontinence without control of liquid or solid faeces.	76% had "successful" outcomes (1 or 2 on the William's scale of continence).	No safety data reported.	*Potential for bias*: Unknown range of follow-up periods for different patients. Unknown patient selection biases. *Outcome measures and their validity*: William's scale of unknown validity. *Other comments:* This was a single centre trial.
Matzel *et al*.[4] 2001, GERMANY, USA, NETHERLANDS, CANADA, DENMARK. 129 patients (8 had a previously stimulated gracilis muscle). *Follow*-up: 18 months *Selection criteria*: Prospective enrolment. End stage faecal incontinence.	No efficacy data reported.	211 complications in 93 patients; 89 of these in 61 patients were severe. The most common complication was major infection (19 events in 18 (15%) patients). Two deep vein thrombosis, one pulmonary embolus (resulting in death), one superficial thrombophlebitis.	*Potential for bias*: Less than 100% follow-up, and not all patients followed up for same period of time. *Outcome measures and their validity*: Complication rates. *Other comments:* This was a prospective multicentre trial. Success in non-stoma patients at 24 months does not total 100% of patients.

Authors, date, location, number of patients, length of follow-up, selection criteria	Key efficacy findings	Key safety findings	Appraisal/Comments
Wexner *et al*.[5] 2002, ITALY, NETHERLANDS, NORWAY, CANADA, USA, GERMANY, DENMARK, SWITZERLAND, SWEDEN, FRANCE. 129 patients (115 evaluable). *Follow-up*: 24 months. *Selection criteria*: end stage fecal incontinent; refractory incontinent to standard treatments; *in situ* rectal, anal, and sphincter anatomy; age 18-80. Excluded: inflammatory bowel disease; unmanageable diarrhoea; total anal agenesis; no gracilis; <1 year life expectancy; cardiac pacemaker.	Note: "Success" defined as 50% or greater reduction in incontinent episodes. Overall "success" achieved in 47/76 (62%) of non-stoma patients at 12 months, and 37/67 (55%) at 18 months, and 35/62 (56%) at 24 months. At 24 months 15% completely continent, 42% had 50-99% continence, 10% had 1-49% continence, 6% opted for stoma, and 21% exited the study. Overall "success" achieved in 9/24 (38%) of stoma patients at 12 months, and 13/21 (62%) at 18 months, and 9/21 (43%) at 24 months. At 24 months 33% completely continent, 17% had 50-99% continence, 22% had 0-49% continence, 6% opted for stoma, and 22% exited the study. SF-36: Physical and social functioning significantly improved at 12 months (66 vs 71, p=0.006 and 58 vs 66, p=0.02 respectively). Social functioning correlated with continence (p=0.0003).	No safety data reported.	*Potential for bias*: Large percentage of patients dropped out (around 20%). *Outcome measures and their validity*: Graciloplasty "success" somewhat subjective. SF-36 is a well-established psychological measure. *Other comments:* This was a prospective multicentre trial.

Specialist advisor's opinion / advisors' opinions

Specialist advice was sought from the Association of Colopractology of Great Britain and Ireland.

Specialist Advisors stated that the procedure was established practice for a small number of specialists practicing in four centres in the UK, namely Edinburgh, Newcastle, Hull and London. They considered its impact on the NHS to be minor.

With regard to safety and efficacy issues, they identified the main risks to be with the pacemaker implants, particularly of infection, and also of chronic leg pain.

Because of the small numbers of patients treated, the Specialist Advisors suggested that the operation be performed in only a few specialist centres, and emphasised the need for the appropriate expertise. They did not think there was a specific code available and thought that the procedure merited a new specific code.

Issues for consideration by IPAC

Many of the patients reported in the graciloplasty literature are included in multiple studies, either as participants in multicentre trials as well as separately published single trials, or in studies that progressively report at various follow-up periods. It is very difficult to untangle the various overlapping reports and makes some double counting of outcomes highly likely. Studies prior to 2000 are summarised in the systematic literature review by Chapman *et al*. (2002) and have not been included in this overview.

A completed study on the quality of life of patients after graciloplasty was completed by Professor Feldman of the Selly Oak Hospital in Birmingham in April of 2002. This study appears not to be have been published yet and so data was not included in this review. Possibly of most interest, the study set out to determine the real long-term costs to both the NHS and society of anorectal reconstruction surgery compared to permanent stoma formation.

References

1. Chapman AE, Geerdes B, Hewett P, Young J, Eyers T, Kiroff G et al. Systematic review of dynamic graciloplasty in the treatment of faecal incontinence [Review]. *British Journal of Surgery* 2002; **89**(2):138-153.

   [There is also a more comprehensive version of this report on the ASERNIP-S website at http://www.surgeons.org/open/asernip-s/publications_dynamic.htm].

2. Rongen MJGM, Adang EMM, Gerritsen vdH, Baeten CGMI. One step vs two-step procedure in dynamic graciloplasty. *Colorectal Disease* 2001; **Vol 3**(1):51-57.

3. Baeten CG, Uludag OO, Rongen MJ. Dynamic graciloplasty for fecal incontinence. *Microsurgery* 2001; **21**(6):230-234.

4. Matzel KE, Madoff RD, LaFontaine LJ, Baeten GMI, Buie WD, Christiansen J et al. Complications of dynamic graciloplasty - Incidence, management, and impact on outcome. *Diseases of the Colon & Rectum* 2001; **44**(10):1427-1435.

5. Wexner SD, Baeten C, Bailey R, Bakka A, Belin B, Belliveau P et al. Long-term efficacy of dynamic graciloplasty for fecal incontinence. *Diseases of the Colon & Rectum* 2002; **45**(6):809-818.

ANNEX: Studies that met the inclusion criteria but which were not tabulated.

Bresler L, Reibel N, Brunaud L, Sielezneff I, Rouanet P, Rullier E et al. Dynamic graciloplasty in the treatment of fecal incontinence: A French retrospective multicentric study. *Annales de Chirurgie* 2002; **Vol 127**(7):520-526.

Isbister WH, Hubler M. Dynamic graciloplasty: A small and salutary experience. *Annals of Saudi Medicine* 2000; **20**(5-6):390-393.

Rosen HR, Urbarz C, Novi G, Schiessel R. Anal sphincter restoration following rectal excision by graciloplasty. *Viszeralchirurgie* 2000; **Vol 35**(6):396-399.

Rosen HR, Urbarz C, Novi G, Schiessel R. Graciloplasty following rectal excision - The total anorectal reconstruction (TAR). *Chirurgische Gastroenterologie* 2001; **Vol 17**(3):245-248.

Rosen HR, Urbarz C, Novi G, Spacing D, Schiessel R. Long-term results of modified graciloplasty for sphincter replacement after rectal excision. *Colorectal Disease* 2002; **Vol 4**(4):266-269.

Ruckauer KD. Dynamic graciloplasty in children with fecal incontinence: A preliminary report. *Journal of Pediatric Surgery* 2001; **36**(7):1036-1039.

Rullier E, Zerbib F, Laurent C, Caudry M, Saric J. Morbidity and functional outcome after double dynamic graciloplasty for anorectal reconstruction. *British Journal of Surgery* 2000; **87**(7):909-913.

Violi V, Boselli AS, De Bernardinis M, Costi R, Trivelli M, Roncoroni L. A patient-rated, surgeon-corrected scale for functional assessment after total anorectal reconstruction - An adaptation of the Working Party on Anal Sphincter Replacement scoring system. *International Journal of Colorectal Disease* 2002; **17**(5):327-337.