NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of stimulated graciloplasty

Introduction

- This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

- This overview was prepared in June 2005.

Procedure names

- Stimulated graciloplasty.
- Anal stimulated graciloplasty
- Electrically stimulated gracilis neo-sphincter surgery.

Specialty society

- Association of Coloproctology of Great Britain and Ireland.

Description

Indications

- Intractable anal incontinence that is refractory to pharmacological therapy.

Current treatment and alternatives

The traditional treatment is a colostomy to divert the faecal stream; this is often unacceptable to patients. An alternative surgical approach to attempt to establish continence is an artificial bowel sphincter, and sacral nerve stimulation may be used as another approach to treatment.

What the procedure involves

Stimulated graciloplasty involves the creation of a new anal sphincter using transposed gracilis muscles (thigh adductor muscles) implanted with an electrode from an electric pulse generator. The continuous current of the pulse generator gradually converts the skeletal muscle fibres of the gracilis from fast-twitch to the slow-twitch fibres that are usually found in sphincters.

The gracilis muscle lies down the medial side of the thigh from the pelvis to the knee. In this situation it is a non-essential muscle. It is detached from the knee and brought up under the skin and 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 muscle fibres from fast-twitch to slow-twitch muscle fibres is completed. The procedure can be performed in stages, with the muscle wrapping preceding the electrode implant by a few weeks, or as one procedure

Efficacy

The definitions used to define clinical success vary widely across the primary studies included in this overview, making comparison between studies difficult.

A controlled study found that frequency of incontinence had significantly improved from baseline to 24 months in patients undergoing graciloplasty ($p < 0.0001$) with no improvement found in patients who were not offered surgery over the same period[1]. A systematic review of 37 studies in graciloplasty found the proportion of patients achieving continence to range from 42% to 85%, using different definitions and over a variety of time scales[2]. Other case series found successful outcomes in between 43% (9/21)[3] (for patients with a stoma) and 72% (144/200)[4] of patients with follow-up from 2 to 5 years.

A controlled trial found that quality of life improved more in patients treated with graciloplasty than in those not offered surgery and being medically managed, using the following outcome measures: the Cleveland clinic faecal incontinence scale ($p = 0.001$), the Hospital Anxiety and Depression Scale for anxiety ($p = 0.03$) and depression ($p = 0.05$), and a validated study-specific scale for psychological wellbeing ($p < 0.0001$) and lifestyle ($p < 0.0001$) characteristics[1]. In a case series of 129 patients graciloplasty was found to significantly improve quality of life on the SF–36 scale in physical and social functioning at 12 months follow-up[3]

Safety

The most common complication of the graciloplasty procedure is wound infection. This has been recorded in between 12% (24/200)[4] and 65% (31/48)[1] of patients in case series. In a systematic review including 403 patients assessed for safety outcomes the overall rate of infection was 28%[2]. Where reported separately, serious infection needing hospitalisation and or surgery was reported in 15% (18/121) of patients[5], and in another series it occurred in 14% (17/123) of patients[6].

Circuitry or technical problems with the pulse generator requiring hospitalisation occurred in 48% (23/48) of patients undergoing graciloplasty in a controlled trial through follow up of 42 months[1]. Elsewhere deep vein thrombosis was found in 2%

(3/123) graciloplasty cases, and in one of these cases the patient died following a pulmonary embolism 3 weeks after surgery[6]

A comparative study of a series of patients having graciloplasty found that 69% (33/48) had evacuation difficulties or pain requiring hospitalisation[1]; disturbed evacuation was reported in 16% (32/200) of patients in a prospective case series[4].

Literature review

Rapid review of literature

- The medical literature was searched to identify studies and reviews relevant to Stimulated graciloplasty. Searches were conducted via the following databases, covering the period from their commencement to 05/2005: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

- The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with end-stage faecal incontinence.
Intervention/test	Stimulated graciloplasty.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

- This overview is based on one systematic review, one HTA trial consisting of a single-site controlled study and a multi-site retrospective case series, and four case series.

Existing reviews on this procedure

- The systematic review of dynamic graciloplasty in the treatment of faecal incontinence by Chapman *et al* (2002), summarised in Table 2, was developed as part of the ASERNIP-S review programme. The review group allocated the following safety and efficacy classification:

- "The safety of the procedure cannot be determined at the present time due to an incomplete and or poor quality evidence base. It is recommended that further research is conducted to establish safety.

- Efficacy is established. Dynamic graciloplasty is equal to or better than the best practice based on the currently available evidence. The procedure may be introduced into practice."

Table 2 Summary of key efficacy and safety findings on stimulated graciloplasty

Abbreviations used: Short Form 36 questionnaire– SF 36, electrically stimulated gracilis neosphincter surgery – ESGNS, Royal London Hospital - RLH			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**

Abbreviations used: Short Form 36 questionnaire– SF 36, electrically stimulated gracilis neosphincter surgery – ESGNS, Royal London Hospital - RLH

Study details	Key efficacy findings	Key safety findings	Comments
Tillin T (2005) [1] Case series/controlled trial UK Controlled trial n = 126 (ESGNS = 48, not offered surgery = 40, not accepting surgery = 38) Retrospective series n = 108 Patients living with a stoma or with end-stage faecal incontinence not amenable to conventional medical or surgical treatment. Bowel disorders due to anorectal agenesis, previous cancer surgery, obstetrics or other forms of trauma, neurogenic cause, or idiopathic Comparison groups were those either not offered surgery (those referred to centres that did not offer ESGNS or not eligible to NSCAG surgery), or those not accepting surgery Age = 45 years, male = 25%, stoma on recruitment = 44% For controlled trial ESGNS and not offered surgery groups Data collected by patent questionnaires and interviews Outcome measures included, the EuroQol, Nottingham health profile, hospital anxiety and depression scale, Cleevland clinic faecal incontinence scale, and a condition-specific questionnaire developed for this study Follow up to 42 months in case series	**Procedure characteristics** The mean total operative time for all stages was 12 hours, the interval from first treatment to completion of primary treatment ranged from 2.5 to 16 months **Clinical outcomes** At 2 years follow up 75% (95% CI 63 to 87%) patients were without stoma and with working devices, at 3 years it was 73% (61 to 85%), at 4 years 57% (41 to 73%). Frequency of incontinence ENGNS group: baseline / 24 mth Not offered surgery group: baseline / 24 mth Never / < once a week: 5% / 62% / 23% / 20% Several times a week: 14% / 19% / 9% / 9% Daily / stoma: 81% / 19% / 69% / 71% p < 0.0001 for within ENGNS group change from baseline Other outcome measures – data shown are mean percentage change from baseline (and 95% CI), positive results = improvement with between group differences in change from baseline at 24 months outcome: ESGNS 12 mth / ESGNS 24 mth / Not offered surgery 12 mth / Not offered surgery 24 mth / p = Cleveland clinic: +5 (+2 +7) / +24 (+11 +37) / -1 (-3 +1) / -8 (-19 +3) / 0.001 EuroQol: +4 (-5 +13) / +7 (-3 +18) / -1 (-8 +5) / +7 (-3 +16) / 0.92 NHP pain scale: -8 (-18 +7) / -0.3 (-0.6 0) / -6 (-13 +2) / 0 (-0.2 +0.2) / 0.21 NHP social isolation: +12 (+3 +13) / +10.2 (+0.4 +21) / 0 (0 +23) / +2 (-4 +9) / 0.07 HADS anxiety: +8 (-1 +16) / +9 (+0.1+17) / -2 (-6 +2) / -3 (-9 +3) / 0.03 HADS depress.: +7 (-1 +16) / +6 (-3 +15) / -5 (-8 -1) / -4 (-8 +1) / 0.05 RLH psych: +28 (+19 +38) / +26 (+16 +36) / +0.2 (-6 +7) / +0.1 (-8 +8) / <.0001 RLH lifestyle: +36 (+26 +46) / +31 (+19 +43) / -4 (-10 +2) / -3 (-11 +5) / <.0001 Excluding subgroups of patients whose incontinence was congenital or cancer origin did not alter major outcomes	**Complications** For RLH patients in comparative study Requiring hospitalisation: Rate Evacuation difficulties or pain: 69% (33/48) Infection: 65% (31/48) Circulatory problems: 48% (23/48) Frequency of incontinence at 48 months postoperatively RLH / Others Never / < 1week: 55% * / 50% (8/16) ≥ 1 week: 11%* / 19% (3/16) Daily/ stoma: 34%* / 31% (5/16) * absolute figures not available Frequency of evacuatory difficulty at 48 months RLH / Others Never: 33% (7/21) / 50% (9/18) Several times a week: 5% (1/21) / 17% (3/18) Daily: 24% (5/21) / 28% (5/18) Colonic conduit: 10% (2/21) / 6% (1/18) Stoma: 29% (6/21) / 11% (2/18)	Authors note that surgical outcomes remain unstable for many years postoperatively. Similar but not identical surgical technique used across the four participating centres. Baseline characteristics in the comparative study were not similar owing to the nature of recruitment. Slow case accrual required a longer study period and inclusion of additional sites. Good piloting of outcome assessment tools prior to study. Case selection of patients who were likely to have better outcomes Less invasive surgical option such as sacral nerve stimulation were developed during the study period. Many more outcomes are reported for the comparative study and multicentre case series that cannot be summarised here.

Abbreviations used: Short Form 36 questionnaire– SF 36, electrically stimulated gracilis neosphincter surgery – ESGNS, Royal London Hospital - RLH

Study details	Key efficacy findings	Key safety findings	Comments
Chapman A E (2002) [2] Systematic review 37 graciloplasty studies (403 patients for safety); 3 colostomy studies (289 patients for safety) Selection criteria: all papers published between 1991 and 2000 that provided safety or efficacy data for either dynamic graciloplasty or colostomy Follow-up: up to 13 years	**Operative success** 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%	**Adverse events** 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%)	Comprehensive literature search strategy and cross reference of bibliography of selected studies. No details given of duplicate data extraction. No formal quality assessment of included studies, over and above assessment of hierarchy of evidence. 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.

Abbreviations used: Short Form 36 questionnaire– SF 36, electrically stimulated gracilis neosphincter surgery – ESGNS, Royal London Hospital - RLH

Study details	Key efficacy findings	Key safety findings	Comments
Rongen M-J G M (2003) [4] Case series The Netherlands n = 200 Selection criteria: end stage incontinent for solid & liquid stool; consecutive patients from the waiting list, following thorough history and assessment by anal manometry, defecography, and electromyography Age = 48 years, male = 24% Follow-up: mean 261 weeks	**Clinical outcomes** success was defined as score 1 or 2 on William's scale For all indications the procedure was successful in 72% (144/200) of cases The success rate for subgroups based on cause of incontinence was 52% for congenital cause, 82% trauma, 72% idiopathic, 80% neurologic No significant difference in efficacy was found for any particular wrap configuration 16% (32/200) of patients were not continent despite a functioning graciloplasty, and persisting diarrhoea was present in 9% (17/200) of cases **Device durability** The mean survival of the stimulator battery was 405 weeks before replacement was required. This has been achieved with no complication in any case	**Adverse events** There was no mortality within the series Complication rate Disturbed evacuation 16% (32/200) Infection 12% (24/200) Pain with stimulation 8% (16/200) Pulse generator displacement* 6% (12/200) Rectal perforation 5% (10/200) Failure to contract 5% (9/200) Lead problems 3% (6/200) Perineal pain 3% (6/200) Urinary retention 3% (5/200) Wound abcess 3% (5/200) * after the 65th patient the device was placed underneath the rectus fascia and no further displacement was recorded	Consecutive case series with prospective evaluation. Authors comment that the procedure has a significant learning curve.
Matzel K E (2001) [5] Case series International multicentre n = 129 patients (8 had a previously stimulated gracilis muscle). Selection criteria: prospective enrolment; end stage faecal incontinence Follow-up: 18 months	No efficacy data reported	**Adverse events** 211 complications in 93 patients; 89 of these in 61 patients were severe 109 secondary operations performed The most common serious complication was major infection in 15% (18/121) of patients. This resulted in hospitalisation and/or surgery in all cases Minor infection was reported in 24% (29/121) of patients Other complications include 2% (2/121) of cases with deep vein thrombosis, 1% (1/121) pulmonary	Not all patients followed up for same period of time. This was a prospective trial. Some results are reported per patient and some per event. Authors attempt to correlate adverse events with successful clinical outcome.

Abbreviations used: Short Form 36 questionnaire– SF 36, electrically stimulated gracilis neosphincter surgery – ESGNS, Royal London Hospital - RLH

Study details	Key efficacy findings	Key safety findings	Comments
		embolus (resulting in death), 1% (1/121) superficial thrombophlebitis	
Wexner S D (2002) [3] Case series International multicentre n = 129 patients (115 evaluated) Selection criteria: end stage faecal 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 Follow-up: 24 months	**Clinical outcomes** 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 In non-stoma patients at 24 months 15% (9/62) were completely continent, 42% (26/62) had 50–99% continence, 10% (6/62) had 0–49% continence, 6% (4/72) opted for stoma, and 21% (13/62) 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 Among stoma patients at 24 months 33% (9/27) were completely continent, 17% (5/27) had 50–99% continence, 22% (6/27) had 0–49% continence 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) Univariate logistic regression found that duration of faecal incontinence was predictive of a successful continence outcome following graciloplasty (p = 0.04)	No safety data reported	Large percentage of patients dropped out (around 20%). Graciloplasty “success” somewhat subjective. SF-36 is a well-established psychological measure. This was a prospective multicentre trial. Patients may be from the same series as in Matzel (2001)

Abbreviations used: Short Form 36 questionnaire– SF 36, electrically stimulated gracilis neosphincter surgery – ESGNS, Royal London Hospital - RLH

Study details	Key efficacy findings	Key safety findings	Comments
Baeten C G M I (2000) [6] Case series International multicentre n = 123, 110 for efficacy evaluation Patients with severe faecal incontinence that did not respond to or was not amenable to standard treatment Age = 50, male = 20%, previous sphincter surgery for incontinence 62%, existing stoma = 23% Clinical success defined as a decrease in incontinent episodes > 50% from baseline. For patients with pre-existing stomas a continence rate of > 50% was considered a success Follow up = 23 months	**Clinical outcomes** Non-stoma: Outcome / 12 mnths / 18 mnths Stoma: 12 mnths / 18 mnths Success: 63% (45/72) / 57% (35/61) / 33% (8/24) / 60% (12/20) Minor improvement: 11% (8/72) / 13% (8/61) / 25% (6/24) / 10% (2/20) failure: 23% (17/72) / 30% (18/61) / 42% (10/24) / 30% (2/20) There was no significant difference in the outcomes of the subgroups of patients with congenital or acquired faecal incontinence **Physiology** At 12 months enema retention time had improved in 78% (52/67) of cases **Quality of life** There were no significant changes from baseline in scores on the Zung depression scale, the STAI anxiety scale or the VAS-1 Scale at 12 months Using the SF-36 scale there was a significant improvement in three of the eight domains: physical role, vitality, and social functioning **Operative technique** There were no malfunctions of the pulse generator or any breakage of electrodes; 9% (11/123) of patients experienced lead dislodgement and this required re-operation in 7% (9/132)	**Complications** Complication / rate Deep vein thrombosis 2% (3/123) Superficial phlebitis 1% (1/123) Major infection 14% (17/123) Minor infection 23% (28/123) Wound healing problems 11% (14/123) Muscle wrap problems 7% (9/123) Pain 28% (34/123) Device use or problems 13% (16/123) Other 8% (10/123) Stoma problems 11% (13/123) constipation 23% (28/123) One of the patients who developed deep vein thrombosis died of pulmonary embolism 3 weeks after graciloplasty	123 cases across 20 sites suggests that some centres provided very few cases and results may be influenced by any learning curve. Results analysed on intention-to-treat basis. Authors state that no specific faecal incontinence assessment tool was available at time of the study. Study probably underpowered to evaluate different efficacy in subgroups. Patients may be from the same series as in Matzel (2001).

Validity and generalisability of the studies

- 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.

Specialist Advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr A Horgan, Mr G Duthie, Mr D Bartolo, Mr J Varma, Prof. N Williams

- All the Specialist Advisors stated that the procedure was established practice.
- The intended benefits of the procedure are improved continence and better quality of life.
- Advisors identified the main reported adverse events as being related to the pacemaker implants, particularly the risk of infection (short and long term). They also identified chronic leg pain related to neuro-stimulation as a risk, and hardware problems with potential loss of stimulation.
- Because of the small number 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 within an MDT.
- This procedure may be suitable for patients with intractable incontinence in whom the alternative is permanent colostomy
- Advisors suggested that this procedure has been superseded by sacral nerve stimulation.

Issues for consideration by IPAC

- Very few specialists in the NHS undertake this procedure
- Potentially an end stage procedure, where recent developments have been focused on the alternative treatment of sacral nerve stimulation.

References

(1) Tillin T, Chambers M, Feldman R. Outcomes of electrically stimulated gracilis neosphincter surgery. Health Technol Assess 2005; 9(28):1-118.

(2) 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. British Journal of Surgery Vol 89(2)()(pp 138-153), 2002 2002;(2):138-153.

(3) 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 Vol 45(6)()(pp 809-818), 2002 2002;(6):809-818.

(4) Rongen M-J, Uludag O, El Naggar K, Geerdes BP, Konsten J, Baeten CGMI. Long-term follow-up of dynamic graciloplasty for fecal incontinence. Diseases of the Colon & Rectum Vol 46(6)()(pp 716-721), 2003 Date of Publication: 01 JUN 2003 2003;(6):716-721.

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

(6) Baeten GMI, Bailey HR, Bakka A, Belliveau P, Berg E, Buie WD et al. Safety and efficacy of dynamic graciloplasty for fecal incontinence: Report of a prospective, multicenter trial. Diseases of the Colon & Rectum Vol 43(6)()(pp 743-751), 2000 2000;(6):743-751.

Appendix A: Additional papers on stimulated graciloplasty not included in the summary tables

Article title	Number of patients (n)/ follow-up (FU)	Comments	Direction of conclusions
Adang EMM, Engel GL, Konsten J, Baeten CGMI. Quality of life after dynamic graciloplasty for faecal incontinence: First results. Theoretical Surgery Vol 8(3) (pp 122-124), 1993 1993;(3):122-124.	n=15 FU=6 months	Case series Outcomes reported separately for successful and failed cases	The procedure was successful in 9 patients and failed in 6
Baeten CGMI, Geerdes BP, Adang EMM, Heineman E, Konsten J, Engel GL et al. Anal dynamic graciloplasty in the treatment of intractable fecal incontinence. New England Journal of Medicine Vol 332(24) (pp 1600-1605), 1995 1995;(24):1600-1605.	n=52 FU=2.1 years	Case series Larger series included in table 2	73% (38/52) were continent after 2.1 years. At 1 year the median frequency of defecation had reduced significantly
Baeten CGMI, Uludag O, Rongen M-J. Dynamic graciloplasty for fecal incontinence. Microsurgery Vol 21(6) (pp 230-234), 2001 2001;(6):230-234.	n=200 FU=?	Cases series No useful clinical outcomes reported	76% considered to have successful outcomes
Christiansen J, Rasmussen OO, Lindorff-Larsen K. Dynamic graciloplasty for severe anal incontinence. British Journal of Surgery Vol 85(1) (pp 88-91), 1998 1998;(1):88-91.	n=13 FU= up to 27 months	Case series Larger series included in table 2	6 patients obtained satisfactory continence, and 5 showed improvement, the procedure failed in 2 cases. Rectal evacuation problems were reported in 3 cases
Geerdes BP, Heineman E, Konsten J, Soeters PB, Baeten CGMI. Dynamic graciloplasty: Complications and management. Diseases of the Colon & Rectum Vol 39(8) (pp 912-917), 1996 1996;(8):912-917.	n=67 FU=2.2 years	Case series Larger series included in table 2	Successful in 78% of cases. 53 complications were reported in 36 patients
Konsten J, Baeten CG, Spaans F, Havenith MG, Soeters PB, Williams NS. Follow-up of anal dynamic graciloplasty for fecal continence. World Journal of Surgery Vol 17(3) (pp 404-409), 1993 1993;(3):404-409.	n=26 FU=1 year	Case series Larger series included in table 2	Graciloplasty increased anal pressure, and enema retention time, compared to baseline evaluation
Ortiz H, Armendariz P, DeMiguel M, Solana A, Alos R, Roig JV. Prospective study of artificial anal sphincter and dynamic graciloplasty for severe anal incotinence. International Journal of Colorectal Disease Vol 18(4) (pp 349-354), 2003 2003;(4):349-354.	n=8 (4 gracil) FU=44 months	Non randomised controlled trial Very few cases in each arm	8 cases of wound healing (4 in graciloplasty group) Four patients undergoing graciloplasty had the stimulator removed
Penninckx F. Belgian experience with dynamic gracitoplasty for faecal incontinence. British Journal of Surgery Vol 91(7)()(pp 872-878), 2004 2004;(7):872-878.	n=66 FU=4 years	Case series Larger series included in table 2	75 complications requiring 61 reoperations were recorded in 44 patients

Sielezneff I, Malouf AJ, Bartolo DCC, Pryde A, Douglas S. Dynamic graciloplasty in the treatment of patients with faecal incontinence. British Journal of Surgery Vol 86(1)()(pp 61-65), 1999 1999;(1):61-65.	n=16 FU=20 months	Case series Larger series included in table 2	Eight of 16 cases has postoperative morbidity Continence scores were improved by the procedure from baseline
Thornton MJ, Kennedy ML, Lubowski DZ, King DW. Long-term follow-up of dynamic graciloplasty for faecal incontinence. Colorectal Disease Vol 6(6)()(pp 470-476), 2004 2004;(6):470-476.	n=38 FU=60 months	Case series Larger series included in table 2	At up to 5 years 72% had pain swelling or paraesthesia in the donor leg 16% converted to a colostomy for persisting incontinence and 11% for obstructed defecation

Appendix B: Literature search for stimulated graciloplasty

- The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.
- For all other databases a simple search strategy using the key words in the title was employed.

Action	Comments	Version searched (if applicable)	Date searched
Search for similar NICE topics	Sacral nerve stimulation		28/04/2005
Consult notification and specialist advisors questionnaires for additional papers	Additional papers in folder		28/04/2005
Conduct general internet search for background	Nothing relevant found		28/04/2005
Search for Cochrane systematic review	Electrical stimulation for faecal incontinence in adults 2000		28/04/2005
ASERNIP website	Systematic review available 2001		28/04/2005
FDA website	Nothing relevant		28/04/2005
Search conferences websites	Upcoming conference with live surgery workshop Long Term Efficancy and Quality of Life After Dynamic Graciloplasty for Fecal Incontinence , 2001		29/04/2005
Search Databases:			
The Cochrane Library	11 results found	Issue 2 2005	5/05/2005
CRD Databases	5 results found		5/05/2005
Embase	119 results found	1980 to 2005 Week 18	4/05/2005
Medline	130 results found	1966 to April Week 3 2005	3/05/2005
Premedline	3 results found	3rd May 2005	4/05/2005
CINAHL	4 results found	1982 to April Week 4 2005	3/05/2005
BLIC (limit to current year only)	Nothing found in last 12 months		5/05/2005
National Research Register	7 results found	Issue 2 2005	5/05/2005
Controlled Trials Registry	Nothing found		5/05/2005

Procedure Number: 019	Procedure Name: stimulated graciloplasty
Database: Medline	**Date searched: 3/05/05**

1. electric stimulation/
2. electrodes, implanted/
3. electric stimulation therapy/
4. or/1-3
5. muscle, smooth/tr
6. 4 and 5
7. graciloplast$.tw.
8. esgns.tw.
9. (gracilis adj5 neosphincter$).tw.
10. dgp.tw.
11. or/7-10
12. 6 or 11
13. fecal incontinence/
14. ((fecal or faecal or anus or anal) adj2 incontinence).tw.
15. anus/su
16. (anal adj5 sphincter$).tw.
17. or/13-16
18. 12 and 17
19. limit 18 to humans