Efficacy of Sphinkeeper™ implant in treating faecal incontinence

F. Litta[1], A. Parello[1], V. De Simone[1], P. Campennì[1], R. Orefice[1], A. A. Marra[1], M. Goglia[1], R. Moroni[2] and C. Ratto[1,3] (iD)

[1]Proctology Unit and [2]Direzione Scientifica, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, and [3]Università Cattolica del Sacro Cuore, Rome, Italycarloratto@tiscali.it

Correspondence to: Prof. C. Ratto, Proctology Unit, Fondazione Policlinico Universitario, Agostino Gemelli IRCCS, Largo A. Gemelli 8, 00168 Rome, Italy (e-mail: carloratto@tiscali.it)

Introduction

Faecal incontinence is a common condition, affecting up to 19·5 per cent of the general population, which has a negative effect on quality of life (QoL)[1]. Management of faecal incontinence can be challenging owing to its multifactorial aetiology. When conservative treatment fails (dietary modifications, pharmacological treatment and pelvic floor rehabilitation programmes), surgical intervention can be considered, but is limited by a lack of long-term improved continence[2,3]. Sacral nerve stimulation (SNS) has been popularized recently as it has been found to be of significant benefit in selected patients, but the risk of complications and time spent learning the operation are not insignificant[4]. The Gatekeeper™ (GK; THD SpA, Correggio, Italy) procedure, introduced to treat faecal incontinence in 2011[5], involves implanting four or six self-expandable prostheses into the intersphincteric space of the anal canal when the sphincter is intact or there is only a small defect in the internal anal sphincter. The initial GK procedure was later modified to the Sphinkeeper™ (SK) procedure (THD SpA, Correggio, Italy) (*Fig. 1*), whereby ten modified prostheses (longer and larger than GK) are inserted into the intersphincteric space[6]. The SK allows treatment of more sizeable defects in the internal or external anal sphincter, and preliminary feasibility data for the SK procedure have been encouraging[6].

The primary aim of this prospective study was to assess the efficacy of the SK in patients with faecal incontinence. Secondary endpoints were QoL evaluation, safety of implantation, and frequency of prosthesis displacement.

Methods

A single-centre prospective observational study of SK prostheses (*Fig. 1*) was conducted at University Hospital A. Gemelli, Rome, Italy. The study protocol was approved by the local ethics committee (protocol number 30984).

Inclusion and exclusion criteria

Included patients were aged between 18 and 85 years; had experienced faecal incontinence for at least 6 months; had failed conservative treatment; had faecal incontinence episodes more than once a week; had a sphincter defect affecting no more than 120° of the internal or external sphincter, or both; and were able to consent to participate and attend all scheduled follow-up visits. Exclusion criteria were: current diagnosis of cancer; rectal bleeding of unknown origin; chronic diarrhoea unresponsive to medical treatment; inflammatory bowel disease; acute anorectal sepsis; concomitant rectal prolapse; obstructive defaecation syndrome; neurological disease; coagulation disorder; previous rectal resection; and sphincter(s) defects of the internal or external anal sphincter, or both, of more than 120° of anal canal circumference.

Study design

SK implantation was performed as described previously[6]. Follow-up visits were scheduled at 3, 6 and 12 months, and annually thereafter. At each visit, implant position was evaluated by endoanal ultrasonography. A prosthesis was considered adequately placed when at least two-thirds of it were found within the target area (*Fig. 2*). Prosthesis placement was considered adequate when the

Fig. 1 Device for Sphinkeeper™ implantation
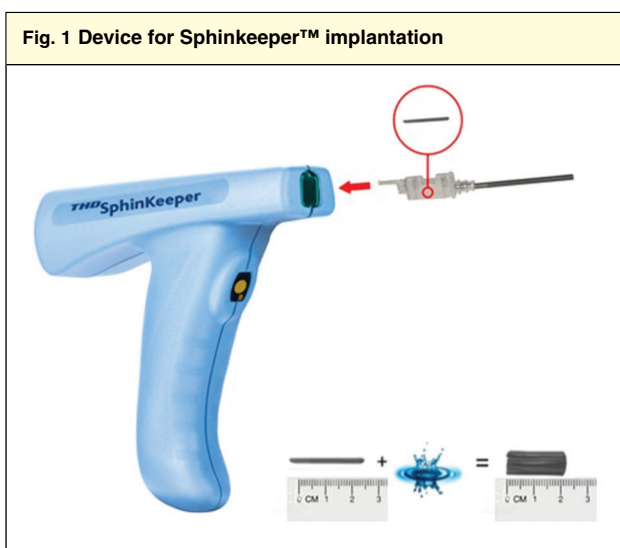
The device includes both the delivery system and dispensers in which a single prosthesis is placed; the prostheses are made of polyacrylonitrile (Hyexpan™; THD SpA, Correggio, Italy). When in a dehydrated state, they are thin and solid cylinders; 48 h after contact with body fluids, they change size, becoming shorter.

majority of prostheses (at least 6 of 10) were found in the target area.

Assessment of faecal incontinence

Symptoms of faecal incontinence were evaluated by means of a daily diary of faecal incontinence episodes over 2 weeks, ability to defer defaecation (in minutes), need to wear pads and/or take constipating drugs, and validated Cleveland Clinic Fecal Incontinence Score (CCFIS)[7] and Vaizey score[8]. QoL and health status were assessed using the

Table 1 Baseline patient characteristics

	No. of patients*
Age (years)†	66·6(10·6)
Sex ratio (F : M)	36 : 6
Duration of FI (years)†	6·8(6·1)
Episodes of FI (per week)†	
Soiling	8·2(6·4)
Gas	13·9(12·4)
Liquid stools	2·9(3·4)
Solid stools	2·0(2·1)
CCFIS score†	12·0(3·7)
Vaizey score†	14·6(4·4)
3D-EAUS features	
Sphincter lesion(s)	14
IAS	2
EAS	9
IAS + EAS	3
Sphincter atrophy without lesion	33
Urinary incontinence	23
Previous pelvic radiotherapy	2
Previous anorectal surgery	
Sacral nerve stimulation	4
Haemorrhoidectomy	1
Rectocele repair	1
Correction of anorectal malformation	1
Co-morbidities	
Endocrine disease	6
Gynaecological disease	4
Diabetes	3
Neurological disease	2

*With percentages in parentheses unless indicated otherwise; †values are mean(s.d.). FI, faecal incontinence; CCFIS, Cleveland Cleveland Clinic Fecal Incontinence Score; 3D-EAUS, three-dimensional endoanal ultrasonography; IAS, internal anal sphincter; EAS, external anal sphincter.

Fig. 2 Target area for prosthesis placement
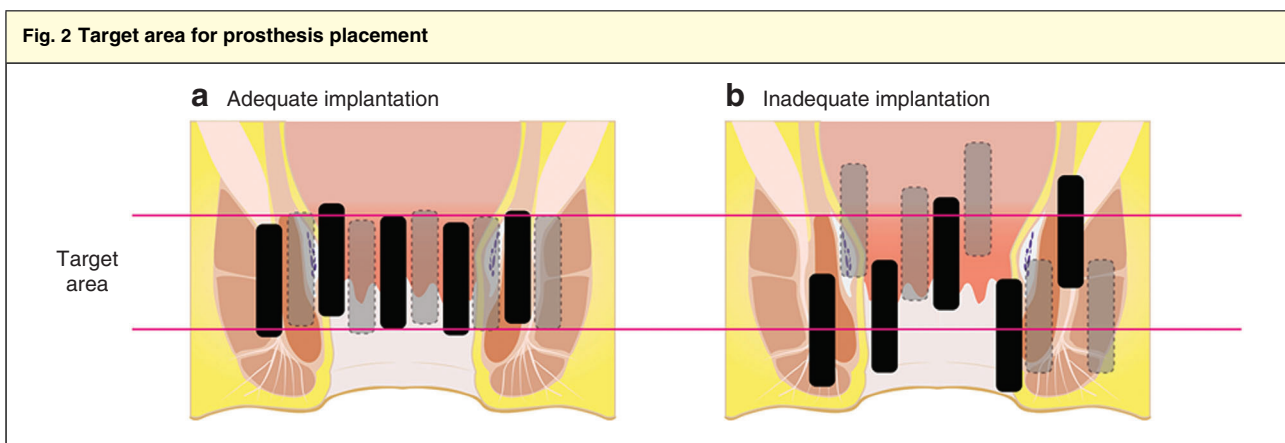
The target area is at the level of the upper and middle thirds of the anal canal. **a** Adequate and **b** inadequate implantation.

Table 2 Number of soiling and incontinence episodes per week, and faecal incontinence severity scores at baseline and during follow-up

	Baseline (*n* = 42)	3 months (*n* = 42)	6 months (*n* = 42)	12 months (*n* = 28)	Last follow-up (*n* = 42)	*P**
Soiling (episodes per week)	8·2(6·4)	5·2(4·7)	3·0(3·6)	3·1(3·8)	3·2(3·8)	<0·001
Incontinence to gas (episodes per week)	13·9(12·4)	9·6(7·8)	7·1(6·7)	7·0(6·7)	7·5(7·1)	0·001
Incontinence to liquid stools (episodes per week)	2·9(3·4)	2·1(3·0)	1·1(1·8)	1·1(1·6)	1·4(1·9)	0·005
Incontinence to solid stools (episodes per week)	2·0(2·1)	1·3(1·5)	0·9(1·5)	0·6(1·4)	0·8(1·5)	0·003
CCFIS score	12·0(3·7)	10·1(3·8)	7·8(4·1)	7·7(4·2)	7·6(4·1)	<0·001
Vaizey score	14·6(4·4)	13·0(4·7)	10·2(5·0)	10·0(4·5)	10·2(4·7)	0·001

Values are mean(s.d.). CCFIS, Cleveland Clinic Fecal Incontinence Score. *Comparison between baseline and data collected at last follow-up session (Wilcoxon test).

Fig. 3 Frequency of postdefaecation episodes of soiling at baseline and during follow-up
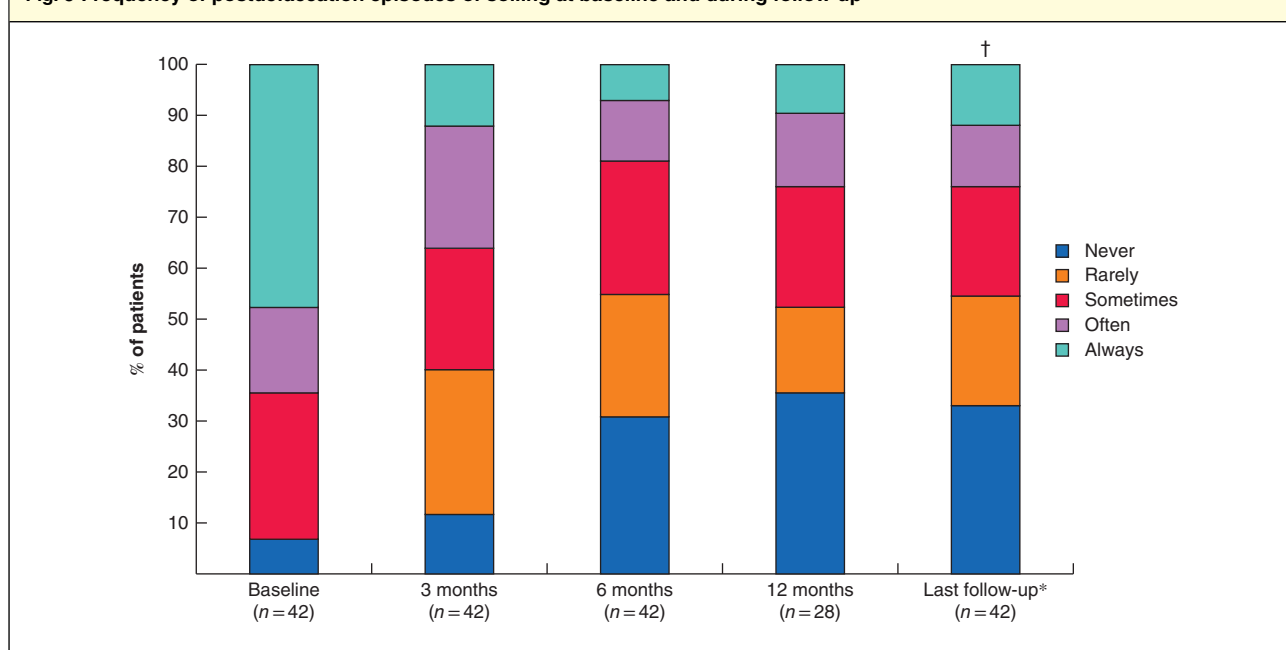
*Data collected at last follow-up session. Frequency: never – none; rarely – less than once per month; sometimes – less than once per week to once or more per month; often – less than once per day to at least once per week; always – at least once per day. †$P < 0.001$ *versus* baseline (marginal homogeneity test).

Faecal Incontinence Quality of Life Scale (FIQL)[9] and Short Form 36 (SF-36®; Rand Corporation, Santa Monica, CA, USA) questionnaires[10]. Anorectal manometry and endoanal ultrasonography were used for both the assessment of anorectal function and morphology, and evaluation of the location of the SK prosthesis after implantation.

Results

Between March 2016 and October 2018, 45 consecutive patients (36 women; mean(s.d.) age 66·6(10·6), range 38–85 years) underwent SK implantation. Baseline clinical characteristics are summarized in *Table 1*. Three patients

were lost to follow-up after the first postoperative visit, leaving 42 for evaluation. Mean follow-up was 15·9(8·6) (range 6–33) months. Single implant delivery failed in two patients, and was reattempted successfully during the same procedure. No patient sustained intraoperative or postoperative complications.

Continence

Compared with baseline values, faecal incontinence of all types decreased (*Table 2*). Five patients became fully continent. The number of patients who never or rarely experienced postdefaecation soiling episodes increased

significantly from three at baseline to 23 at date of last follow-up ($P < 0.001$) (*Fig. 3*). The ability to defer defaecation improved significantly, with 14 patients able to defer for more than 5 min at baseline, compared with 29 at last follow-up ($P = 0.001$). The mean(s.d.) CCFIS changed from $12.0(3.7)$ at baseline to $7.6(4.1)$ at last follow-up ($P < 0.001$); similarly, the Vaizey score decreased from $14.6(4.4)$ to $10.2(4.7)$ ($P < 0.001$).

Quality of life, anorectal manometry and endoanal ultrasonography findings

All domains of the FIQL improved after the SK procedure (*Fig. S1*, supporting information), but only physical functioning improved on the SF-36® questionnaire (*Table S1*, supporting information). Maximum squeeze pressure increased, from mean(s.d.) $80.7(68.5)$ mmHg at baseline to $90.1(48.7)$ mmHg at last follow-up ($P = 0.006$), with no difference in maximum resting pressure and rectal sensory thresholds. Full anorectal manometry results are available in *Table S2* (supporting information).

At the last follow-up, endoanal ultrasound assessment of prosthesis position found that SK implantation was adequate in 23 of the 42 patients, with at least six of ten prostheses placed in the target area. Patients with adequate SK placement had improved outcomes and CCFIS compared with those with inadequate placement (*Tables S3* and *S4*, supporting information).

Patients with anal sphincter lesions

Fourteen patients (all women; mean age $67.4(9.3)$ years) with faecal incontinence and anal sphincter defects underwent SK implantation. The range of sphincter defect extension was 30–120° for the internal anal sphincter and 30–120° for the external anal sphincter. After SK placement, eight of 14 patients showed an over 50 per cent reduction in the total number of faecal incontinence episodes per week (*Table S5*, supporting information).

Discussion

This study of 42 patients undergoing a SK procedure for faecal incontinence found improved incontinence in the majority of patients during the early postoperative phase and long-term follow-up, regardless of the type of faecal incontinence treated. The SK procedure used more prostheses than the previously described GK procedure[5]. The prostheses are optimally positioned circumferentially at high–middle anal canal level, similar to a 'third sphincter' between the internal and external sphincters. This aims to reinforce and/or reshape the area where the continence mechanisms are elicited physiologically through the rectoanal inhibitory reflex. The observed improvement in soiling and gas continence is particularly relevant because these are challenging to control with other treatment modalities. It is accepted that any procedure to treat faecal incontinence is unlikely to result in perfect continence[11]. In such situations, SK could be considered a helpful 'adjuvant therapy' following other treatment strategies.

The finding of no intraoperative or perioperative procedure morbidity in the present study is in keeping with previously published data on GK and SK procedures[5,6,12–14]. Given that the procedure can be performed under local anaesthesia, it can be considered in elderly patients and those with co-morbidities. The finding of improved continence across different faecal incontinence aetiologies may be related to the bulking effect of the SK, with larger volumes of material implanted than with previous techniques, adding bulk between the internal and external sphincter which can increase muscle fibre length and therefore improve contractility. This may explain why an increase in squeeze but not resting pressures was seen on anorectal manometry. It may also explain why continence improved in patients with a 30–120° sphincter defect, and, for defects larger than 120°, why the SK can be used in combination with sphincter repair or SNS.

This study has some limitations, including a relatively small and heterogeneous sample size and the inclusion of patients with potentially more severe disease. The study also describes a single-centre experience and the results may not translate to other units. Future larger multicentre trials are required to confirm the efficacy and indications for the SK.

References

1 Sharma A, Yuan L, Marshall RJ, Merrie AE, Bissett IP. Systematic review of the prevalence of faecal incontinence. *Br J Surg* 2016; **103**: 1589–1597.

2 Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. *Dis Colon Rectum* 2008; **5**: 494–502.

3   Glasgow SC, Lowry AC. Long-term outcomes of anal sphincter repair for fecal incontinence: a systematic review. *Dis Colon Rectum* 2012; **55**: 482–490.

4   Bielefeldt K. Adverse events of sacral neuromodulation for fecal incontinence reported to the federal drug administration. *World J Gastrointest Pharmacol Ther* 2016; **7**: 294–305.

5   Ratto C, Parello A, Donisi L, Litta F, De Simone V, Spazzafumo L *et al.* Novel bulking agent for faecal incontinence. *Br J Surg* 2011; **98**: 1644–1652.

6   Ratto C, Donisi L, Litta F, Campennì P, Parello A. Implantation of SphinKeeper™: a new artificial anal sphincter. *Tech Coloproctol* 2016; **20**: 59–66.

7   Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum* 1993; **36**: 77–97.

8   Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut* 1999; **44**: 77–80.

9   Rockwood TH, Church JM, Fleshman JW, Kane RL, Mavrantonis C, Thorson AG *et al.* Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum* 2000; **43**: 9–16.

10 Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). Conceptual framework and item selection. *Med Care* 1992; **30**: 473–483.

11 Altomare DF, Giuratrabocchetta S, Knowles CH, Muñoz Duyos A, Robert-Yap J, Matzel KE; European SNS Outcome Study Group. Long-term outcomes of sacral nerve stimulation for faecal incontinence. *Br J Surg* 2015; **102**: 407–415.

12 Ratto C, Buntzen S, Aigner F, Altomare DF, Heydari A, Donisi L *et al.* Multicentre observational study of the Gatekeeper™ for faecal incontinence. *Br J Surg* 2016; **103**: 290–299.

13 Trenti L, Biondo S, Noguerales F, Nomdedeu J, Coret A, Scherer R *et al.* Outcomes of Gatekeeper™ prosthesis implantation for the treatment of fecal incontinence: a multicenter observational study. *Tech Coloproctol* 2017; **21**: 963–970.

14 de la Portilla F, Reyes-Díaz ML, Maestre MV, Jiménez-Rodríguez RM, García-Cabrera AM, Vázquez-Monchul JM *et al.* Ultrasonographic evidence of Gatekeeper™ prosthesis migration in patients treated for faecal incontinence: a case series. *Int J Colorectal Dis* 2017; **32**: 437–440.

Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.

Editor's comments

Faecal incontinence can be devastating, making life miserable. Many surgical options exist, but the problem is that none is particularly effective, especially with minimal risk. The authors herein report data on a new concept built upon previous technological solutions to bulk the anal sphincter complex. While previous attempts at this type of intervention were only minimally successful, the technology has evolved to contain an increased number of rods which further bulk the internal sphincter. The rate of complications reported is low, so even if only a modest success is found in larger numbers of patients, it may be an intervention worth trying.

A. Lightner
Associate Editor, BJS