European Colorectal Congress

29 November – 2 December 2020, St.Gallen, Switzerland

Sunday, 29 November 2020

MASTERCLASS

Introduction & course objectives
Michel Adamina, Winterthur, CH

Myths and facts about oral antibiotics, bowel preparation, and timing of iv antibiotics to reduce surgical site infection
Frédéric Ris, Geneva, CH

Management of colorectal GIST – all you should know from diagnosis to handling recurrences
Paris Tekkis, London, UK

Do and don't in taTME surgery – a decade of experience explaned
Roel Hompes, Amsterdam, NL

What your pathologist can do for you: from standard margins recommendations to molecular pathology, liquid biopsies, and the microbiome
Phil Quirke, Leeds, UK

Prehabilitation, patient blood management, frailty index – welcome addition or resource wasting
Des Winter, Dublin, IE

Selective use of neoadjuvant and adjuvant radiotherapy for rectal cancer
Chris Cunningham, Oxford, UK

Handling large rectal adenoma and malignant polyps
Willem Bemelman, Amsterdam, NL

All techniques to avoid staple line intersections in colorectal surgery
Antonino Spinelli, Milano, IT

Management of pelvic sepsis after colorectal / coloanal anastomosis and oncological outcomes of the GRECCAR 5 trial
Quentin Denost, Bordeaux, FR

Best practices in colostomy construction and repair of parastomal hernia
Eva Angenete, Göteborg, SE

The EBSQ Coloproctology Examination
Michel Adamina, Winterthur, CH

Wrap-up
Michel Adamina, Winterthur, CH

Sunday, 29 November 2020

COURSE OF PROCTOLOGY

Introduction & course objectives
Bruno Roche, Geneva, CH

Complex pelvic fistula revisited: established wisdom and innovative approaches
Alexander Herold, Mannheim, DE

Obstretrical trauma: assessment, timing and options to repair
Patrick Hohlfeld, Lausanne, FR

The painful bottom – Proctalgia beyond the classical abscess, fissures, and hemorrhoids
Bruno Roche, Geneva, CH

Sexually transmitted diseases in proctology
Karel Skala, Geneva, CH

Anorectal trauma and foreign bodies
Richard Cohen, London, UK

Pilonidal sinus – strategies and outcomes
Frédéric Ris, Geneva, CH

Fecal incontinence: investigations and conservative treatment
Beatrice Salvioli, Milano, IT

Fecal incontinence: neuromodulation and interventional options
Joan Robert-Yap, Geneva, CH

The pelvic floor revealed: transperineal / transvaginal / transanal repairs explained
Bruno Roche, Geneva, CH

The pelvic floor revealed: investigations and pelvic floor therapy
Jacqueline de Jong, Bern, CH

Obstructed defecation and IBS: investigations, differential diagnosis, and treatment strategies
Daniel Pohl, Zurich, CH

Obstructed defecation: surgical options
André d'Hoore, Leuven, BE

Wrap-up
Alexander Herold, Mannheim, DE

Monday, 30 November 2020

SCIENTIFIC PROGRAMME

Opening and welcome
Jochen Lange, St. Gallen, CH

Is cancer an infectious disease: role of the microbiome
Philip Quirke, Leeds, UK

Ethical considerations in crisis – lessons from Covid-19
Omar Faiz, London, UK

SATELLITE SYMPOSIUM
Medtronic

Prophylactic mesh in colorectal surgery
René H. Fortelny, Wien, AT

Lars Pahlman lecture: Extending the limits of liver surgery
Markus Büchler, Heidelberg, DE

Multimodal approaches to colorectal liver metastases
Mohammed Abu Hilal Brescia, IT

SATELLITE SYMPOSIUM
Ethicon

Urogenital dysfunction in patients treated for rectal cancer – what do we know and what can we do?
Eva Angenete, Göteborg, SE

Hemorrhoids – new options and time-tested solutions
Alexander Herold, Mannheim, DE

Anal pain and emergency proctology: what every surgeon should know & do
Richard Cohen, London, UK

All you need to know about anorectal fistula
Bruno Roche, Genève, CH

Strategies and outcomes for obstructive cancers of the colon and rectum
Willem Bemelman, Amsterdam, NL

Tuesday, 1 December 2020

BREAKFAST SYMPOSIUM
Karl Storz

Lessons learned along the robotic learning curve: a video guide for colorectal surgeons
Jim Khan, Portsmouth, UK

EAES presidential lecture: Strategies for lifelong learning and implementation of new technologies
Andrea Pietrabissa, Pavia, IT

SATELLITE SYMPOSIUM
Intuitive

A journey in global surgery – why getting out of the comfort zone
Raffaele Rosso, Lugano, CH

Enhanced recovery pathwaysreloaded – a practical guide to success
Roberto Persiani, Roma, IT

Cancer at the extremes of age: are there any differences in handling youngsters and seniors
Des Winter, Dublin, IE

Management pearls for early rectal cancer
Roel Hompes, Amsterdam, NL

Ventral rectopexy: indications, tricks of the trade, and long-term results
Chris Cunningham, Oxford, UK

SATELLITE SYMPOSIUM
BBraun

Total neoadjuvant therapy for colon and rectum cancers
Ronan O'Connell, Dublin, IE

Randomized trial evaluating chemotherapy followed by pelvic reirradiation vs chemotherapy alone as preoperative treatment for locally recurrent rectal cancer (GRECCAR 15)
Quentin Denost, Bordeaux, FR

Timeline of surgery following neoadjuvant radiotherapy – balancing morbidity and efficacy
Torbjörn Holm, Stockholm, SE

Poster award
Michel Adamina, Winterthur, CH

Wednesday, 2 December

Place and outcome of total colectomy in the surgical armentarium
Neil Mortensen, Oxford, UK

Kono S anastomosis and over the valve stricturoplasties: hope for better outcomes
André D'Hoore, Leuven, BE

New drugs, old fears: state of the art management of IBD patients
Gerhard Rogler, Zurich, CH

SATELLITE SYMPOSIUM
Takeda

Do resection of the mesentery in Crohn's & appendectomy in ulcerative colitis alter the course of disease
Christianne Buskens, Amsterdam, NL

The septic abdomen: getting out of misery and closing the case
Marja Boermeester, Amsterdam, NL

Management strategies for patients with advanced colorectal cancers
Paris Tekkis, London, UK

Anastomotic leak in colorectal surgery: insights, perspectives, and practical strategies
Antonino Spinelli, Milano, IT

Closing words
Michel Adamina, Winterthur, CH

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Original article

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Initial experience with SphinKeeper™ intersphincteric implants for faecal incontinence in the UK: a two-centre retrospective clinical audit

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Abstract

Aim The SphinKeeper™ artificial bowel sphincter implant is a relatively new surgical technique for the treatment of refractory faecal incontinence. This study presents the first experience in two UK tertiary centres.

Method This is a retrospective audit of prospectively collected clinical data in relation to technique, safety, feasibility and short-term effectiveness from patients undergoing surgery from January 2016 to April 2019. Baseline data, intra-operative and postoperative complications, symptoms [using St Mark's incontinence score (SMIS)] and radiological outcomes were analysed.

Results Twenty-seven patients [18 women, median age 57 years (range 27–87)] underwent SphinKeeper. In 30% of the patients, the firing device jammed and not all prostheses were delivered. There were no intra-operative complications and all patients were discharged the same or the following day. SMIS significantly improved from baseline [median −6 points (range −12 to +3); $P < 0.00016$] with 14/27 (51.9%) patients achieving a 50% reduction in the SMIS score. On postoperative imaging, a median of seven prostheses (range 0–10) were identified with a median of five (range 0–10) optimally placed. There was no relationship between number of well-sited prostheses on postoperative imaging and categorical success based on 50% reduction in SMIS (χ^2 test, $P = 0.79$).

Conclusion SphinKeeper appears to be a safe procedure for faecal incontinence. Overall, about 50% patients achieved a meaningful improvement in symptoms. However, clinical benefit was unrelated to the rate of misplaced/migrated implants. This has implications for confidence in proof of mechanism and also the need for technical refinement.

Keywords SphinKeeper, faecal incontinence, anal incontinence, pelvic floor diseases

What does this paper add to the existing literature?

Our audit data show technical feasibility, safety and short-term effectiveness of the SphinKeeper, a relatively new procedure for patients suffering from faecal incontinence. Published evidence supporting the use of SphinKeeper is poor and, to our knowledge, this is the first described experience in the UK. Our experience questions proof of mechanism and highlights the need for technical refinement.

Introduction

Faecal incontinence is a highly prevalent condition affecting 8% of the adult population with high societal impact [1–3]. Treatments are usually delivered in a stepwise manner. Conservative management includes drug therapy, pelvic floor rehabilitation, biofeedback, inserts, plugs and percutaneous tibial nerve stimulation, but the efficacy of these treatments may be unsatisfactory [4–8]. Other procedures such as sphincteroplasty, dynamic graciloplasty and artificial anal sphincter placement can be considered to treat severe faecal incontinence but can cause substantial comorbidity and have variable outcomes [9–12]. Sacral nerve stimulation is an effective approach for a variety of faecal incontinence conditions,

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but is expensive and a lifelong journey [13–15]. For patients with primary sphincteric dysfunction, injection of bulking agents has been proposed and considered as a safe alternative, although there are no guidelines or robust outcome measures reported for this treatment and long-term outcomes remain questionable [16–19].

Conventionally, the use of injectable materials relies on the bulking effect of the injected agent and subsequent fibrosis and collagen deposition. In the past, several materials such as autologous fat, glutaraldehyde crosslinked collagen (Contigen), pyrolytic carbon beads (Durasphere), silicone biomaterial (PTQ, Bioplastique) and dextranomer (NASHA Dx, Solesta) have been trialled [20–23]. Injectable agents have been reported to be more successful than sham treatment in a double-blind randomized controlled trial, with a success rate of 50%–70% [22].

Recently, other bulking agents have been developed, including those specifically targeting the intersphincteric plane. Early reports of a self-expanding device of polyacrylonitrile (Gatekeeper™) showed a sustained improvement of faecal incontinence in a follow-up period over 33 months [18]. This prosthetic implant has been further developed into the SphinKeeper™ prostheses (THD SphinKeeper, THD SpA, Correggio, RE, Italy). Both expand and change their size and physical properties within 48 h of contact with fluids, becoming shorter, thicker and softer over time. They remain identifiable by palpation and ultrasonography within a soft fibrous coat caused by the host reaction. SphinKeeper also differs from the Gatekeeper technique by the bigger size of the injectable agents and number of prostheses used. A preliminary report has claimed that SphinKeeper implants optimize closure of the anal canal at rest [24].

Published evidence supporting use of SphinKeeper is poor. To date, only three small prospective studies report preliminary results. All assessed small numbers of patients over short follow-up periods [17,24]. The aim of the current study audited outcomes (safety, feasibility and short-term effectiveness) of SphinKeeper in a larger UK dual centre cohort of patients.

Method

Data on the first cohorts of patients treated for faecal incontinence with SphinKeeper in two major tertiary referral centres in the UK were prospectively collected using a specifically designed registry and retrospectively analysed. The hospitals were the Royal London and Whipps Cross Hospitals (part of Bart's Health NHS Trust: hereafter BARTS) and St Mark's Hospital (SMH) (part of London North West University Healthcare NHS Trust). This service evaluation was registered with the local research and audit departments (London North West NHS Trust Research and Development Office, SUR.StM.20.030; Bart's Health NHS Trust, No. 7068A).

Standardized preoperative care

Eligible patients for SphinKeeper treatment were evaluated on the basis of medical history, physical examination and anorectal physiology tests. All patients had exhausted nurse-led conservative management, and the decision to perform the SphinKeeper procedure was discussed and agreed by the local pelvic floor multidisciplinary team. Data on previous treatments of faecal incontinence were recorded, and residual faecal incontinence symptoms, ability to defer defaecation, the need to wear pads, and/or the need for constipating drugs were summarized by the St Mark's incontinence score (SMIS score range 0–24) [25]. Patients were only considered to be suitable for the procedure if they had at least moderate symptoms of faecal incontinence (> 10 on the SMIS).

As part of routine management, anorectal physiology investigations including anorectal manometry and endoanal ultrasonography (EAUSS) were performed to assess anorectal function and morphology. Colonoscopy was performed only if indicated. At BARTS, manometry was performed using a high-resolution anorectal manometry system (Solar GIHRM v9.1, Enschede, The Netherlands; MMS), utilizing a solid-state catheter incorporating 12 microtransducers (UniTip: UniSensor AG, Attikon, Switzerland). Normal values were based on our previously published work [26]. At SMH, manometry was also performed using a high-resolution anorectal manometry system (Solar GIHRM v9.5; MMS), utilizing water-perfused catheters incorporating 10 microtransducers spaced at 8 mm intervals. Normal values were based on previously published work [27,28]. Anal hypotonia was defined as resting tone below normal limits; anal hypocontractility was diagnosed if maximum voluntary incremental squeeze pressure was below normal limits [29].

Standardized operative procedure

All patients were prepared with a phosphate enema, and broad spectrum antibiotic prophylaxis was given intravenously on induction. Patients were operated on under general anaesthesia in the lithotomy position. Povidone iodine solution or cetrimide and chlorhexidine gluconate solution were used to disinfect the skin. Ten equally spaced 2-mm perianal skin incisions were made

2 cm from the anal verge on the anoderm side, avoiding the 12 o'clock position to prevent any possibility of injury to the vagina or urethra. The SphinKeeper delivery system was loaded before each insertion, by pushing an activating button for 5 s resulting in the extrusion of a guiding cannula. Under digital guidance (BARTS) or ultrasonography guidance (SMH), the introducer was then inserted into the intersphincteric space through a short subcutaneous tunnel and pushed up to reach the upper part of the anal canal, corresponding to the puborectalis muscle level. After firing, the delivery system allowed the cannula to retract and the prostheses were deployed. The skin wounds were closed with absorbable sutures. Postoperatively, all patients were instructed to minimize mobilization for a minimum of 48 h to reduce the risk of early prosthesis dislocation. Lidocaine gel and systemic painkillers were prescribed as needed for postoperative pain. A 5-day course of oral antibiotics was used postoperatively.

Postoperative results/follow-up

Data on intra-operative/postoperative complications were collected prospectively. These included data from all operation notes, discharge letters and other details of hospital visits in the preoperative and postoperative period. The SMIS was collected at the first postoperative visit in the outpatient clinic, 3 months after SphinKeeper placement. Postoperative imaging was used to confirm the positioning of the introduced prostheses, utilizing EAUSS, CT or MRI depending on individual centre preference.

Review of postoperative imaging

All anonymized EAUSS, CT and MR images were reviewed retrospectively by a sonographer or gastrointestinal radiologist with a specialist interest in pelvic floor imaging. The total number of prostheses and their position relative to the sphincter complex in the anal canal were reviewed. The location of the prostheses was categorized as either in an ideal position (the proximal intersphincteric space) or in a sub-optimal position (migrated distally or outside of the intersphincteric plane) [30].

Statistical analysis

Results have largely been presented descriptively (symptom scores, incidence of adverse events and radiological findings). For efficacy data, 'success' was defined as reduction of $\geq 50\%$ in SMIS after treatment [14,31–34] with before and after comparison of incontinence scores analysed using a paired t test. Other limited comparisons were made statistically to give an indication of effect of centre. The relationship between number of prostheses and categorical outcome (based on 50% reduction in SMIS) was presented as a contingency table and analysed using chi-squared analysis. Statistical significance was defined as $P < 0.05$. Proprietary software (SPSSl IBM, v.2018, Armonk, NY, USA) was used for all analyses.

Results

Patients

Between January 2016 and April 2019, 27 patients underwent the SphinKeeper procedure: 19 at BARTS and eight at SMH. The cohort consisted of nine men and 18 women (median age 57 years, range 27–87; median body mass index 29, range 23–34). Forty-four per cent (12/27) of patients had undergone previous pelvic floor surgery, and 56% (10/18) of female patients had a history of obstetric anal sphincter injury.

Of the 27 patients, 75% had had symptoms of faecal incontinence for more than 2 years, and all patients had exhausted other conservative treatments. Five patients had undergone an initial trial of sacral nerve stimulation that had failed. Seventy-eight per cent (21/27) of patients suffered from mixed symptoms of faecal incontinence (i.e. urge and passive in nature), while 22% (6/27) suffered from passive faecal incontinence in isolation. Median preoperative SMIS was 15/24 (11–24).

Preoperative EAUSS showed degeneration or disruption of the internal anal sphincter in 12 (44%) of the 27 patients and disruption of the external anal sphincter in 10 (37%) of 27 patients. Resting pressures were attenuated (hypotonia) in 17 (63%) patients; squeeze pressures and endurance squeeze were attenuated (hypocontractility) in six (22%) patients. The median length of the anal canal was 3.4 cm (2.3–4.6 cm). The baseline patient characteristics of the study cohorts in each hospital are listed in Table 1.

Operative experience and postoperative complications

At BARTS, 19 consecutive patients were treated with the placement of SphinKeeper prostheses under digital guidance. In 10 procedures, the device was noted to misfire for technical reasons intra-operatively. At SMH, where prostheses were placed under ultrasound guidance during surgery, difficulties with device misfire also occurred, although the number of occasions this happened was not recorded.

Table 1 Demographics and baseline characteristics obtained retrospectively from a retrospective database in two major tertiary centres in the UK.

	BARTS group $N = 19$	SMH group $N = 8$
Male/female	7/12	2/6
Age, years, median (IQR)	57 (51–67)	64 (54–73)
BMI, kg/m^2, median (IQR)	29 (26–32)	27(24–33)
Previous pelvic floor surgery, % (n)	52 (10/19)	25 (2/8)
Obstetric injury, % (n)	50 (6/12)	66 (4/6)
ASA I/II/III/IV	2/15/2/0	3/4/1/0
EAUSS: IAS defect or degeneration, % (n)	47 (9/19)	38 (3/8)
EAUSS: EAS defect or degeneration, % (n)	52 (10/19)	0 (0/8)
Length anal canal, median (cm)	3.2 (2.1–4.1)	3.1 (2.0–5)
Anal hypotonia, % (n)	52 (10/19)	87.5 (7/8)
Anal hypocontractility, % (n)	26 (5/19)	12.5 (1/8)

ASA physical status classification system by the American Society of Anaesthesiologists; BARTS, Royal London and Whipps Cross Hospitals; BMI, body mass index; EAS, external anal sphincter; EAUSS, endo-anal ultrasonography; IAS, internal anal sphincter; IQR, interquartile range; SMH, St Mark's Hospital.

The median intra-operative time for the SphinKeeper procedure in the whole cohort was 35 min (30–55 min). There were no intra-operative complications other than device misfire. All patients at BARTS were discharged on the same day, with a few patients at SMH staying overnight for social reasons. There were no readmissions within 30 days of surgery; however, two patients returned to the emergency department because of perianal pain and bloody discharge, which was managed conservatively with oral antibiotics and analgesia in both cases.

Follow-up

All patients were followed up at least once in the outpatient department within 3 months of surgery (Table 2). No significant postoperative complications were reported by any of the patients at that time point. Patients continued to receive outpatient review as clinically necessary. Median follow-up of the whole cohort was at 12 months (3–26). SMIS at follow-up significantly improved from baseline [median −6 points (range −12 to +3); paired t test, $P < 0.00016$] with 14/27 (51.9%) patients achieving a ≥ 50% reduction in SMIS. Eight (29.7%) patients had no improvement or a worsening (increase) in score after implant.

Postoperative imaging

Postoperative imaging was carried out in 26/27 patients (one patient declined radiological follow-up). Imaging was performed in most cases within 6 months, at the time of the follow-up. Three patients had imaging at 12 months as they were unable to attend their initial appointment. Of the patients who had postoperative imaging, 20 underwent EAUSS and five underwent MRI. In one patient who presented with abdominal pain to the emergency department 7 months after surgery, a CT of the pelvis was carried out and this was used as postoperative radiological follow-up for the SphinKeeper procedure.

Despite the SphinKeeper procedure aiming to insert 10 prostheses (i.e. 10 firings of the device), a median of seven prostheses (range 0–10) were visualized per patient in the postoperative imaging scans (Table 2; Figs 1 and 2). Of those visualized, a median of five (range 0–10) were ideally placed. There was no obvious relationship between number of optimally placed prostheses and outcome based on reduction in SMIS score (Table 3 and Fig. 3). Thus in the 48% patients ($n = 14$) with significant improvement in SMIS, the median number of prostheses visualized was 10 (6–10), and, of these, a median of five (1–10) were placed in an ideal position. In the 12 patients without a 50% reduction in SMIS, the median of prostheses visualized was also seven (0–10) with a median of five prostheses (1–8) optimally placed; χ^2 test, $P = 0.79$.

Median postoperative SMIS did not vary by centre [BARTS 10/24 (3–22) *vs* SMH 10/24 (5–17), $P = 0.912$] but the median number of visualized prostheses was slightly higher at SMH [BARTS 7 (0–10) *vs* SMH 9 (7–10), $P = 0.056$]. Five patients implanted at BARTS had substantially fewer prostheses seen in the postoperative imaging than would be expected (median

Table 2 St Mark's incontinence scores and results of postoperative imaging at SMH and BARTS.

	SMIS			Radiological prosthesis location			
Hospital	Preoperative	Postoperative	Change	Modality	Total prostheses visualized	Ideal placement	Sub-optimal placement
SMH	21	10	−11*	EAUSS	10	8	2
SMH	15	11	−4	MRI	7	6	1
SMH	15	10	−5	MRI	7	5	2
SMH	18	7	−11*	EAUSS	10	7	3
SMH	21	17	−4	CT	10	8	2
SMH	11	5	−6*	MRI	10	3	7
SMH	15	15	0	MRI	8	8	2
SMH	17	7	−10*	MRI	8	6	2
BARTS	14	17	3	EAUSS	6	5	1
BARTS	18	15	−3	EAUSS	3	0	3
BARTS	11	11	0	EAUSS	6	3	3
BARTS	18	6	−12*	EAUSS	7	4	3
BARTS	14	5	−9*	EAUSS	7	1	6
BARTS	20	10	−10*	EAUSS	10	9	1
BARTS	12	5	−7*	EAUSS	6	5	1
BARTS	15	18	3	EAUSS	7	2	5
BARTS	18	18	0	EAUSS	3	1	2
BARTS	14	5	−9*	EAUSS	6	1	5
BARTS	12	4	−8*	EAUSS	6	6	0
BARTS	16	17	1	EAUSS	0	0	0
BARTS	22	10	−12*	EAUSS	10	5	5
BARTS	12	3	−9*	EAUSS	9	3	6
BARTS	14	7	−7*	EAUSS	10	10	0
BARTS	24	22	−2	EAUSS	9	7	2
BARTS	11	12	1	EAUSS	7	5	2
BARTS	11	13	2	NA	NA	NA	NA
BARTS	18	8	−10*	EAUSS	10	8	2
Summary Median (range)	15 (11–24)	10 (3–22)	−6 (−12 to + 3)	–	7 (0–10)	5 (0–10)	2 (0–7)

BARTS, Royal London and Whipps Cross Hospitals; EAUSS, endo-anal ultrasonography; NA, patient lost in the follow-up; SMH, St Mark's Hospital; SMIS, St Mark's incontinence score.
*≥ 50% reduction in SMIS (defines success; n = 14).

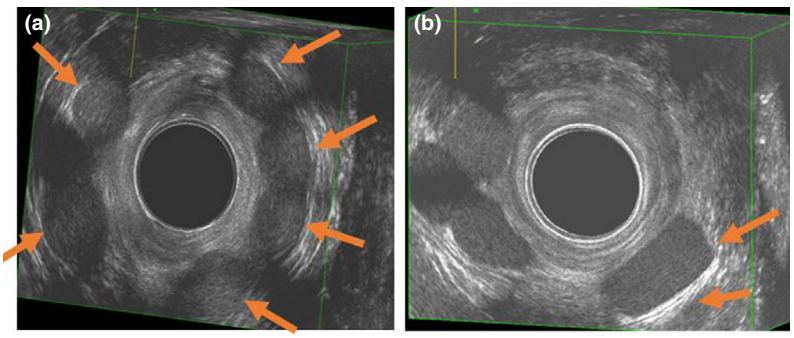

Figure 1 EAUSS. (a) Postoperative EAUSS in a patient with ideal placement of the prostheses in the intersphincteric plane in the mid-anal canal. (b) Horizontal orientation of the intersphincteric prostheses in the distal anal canal.

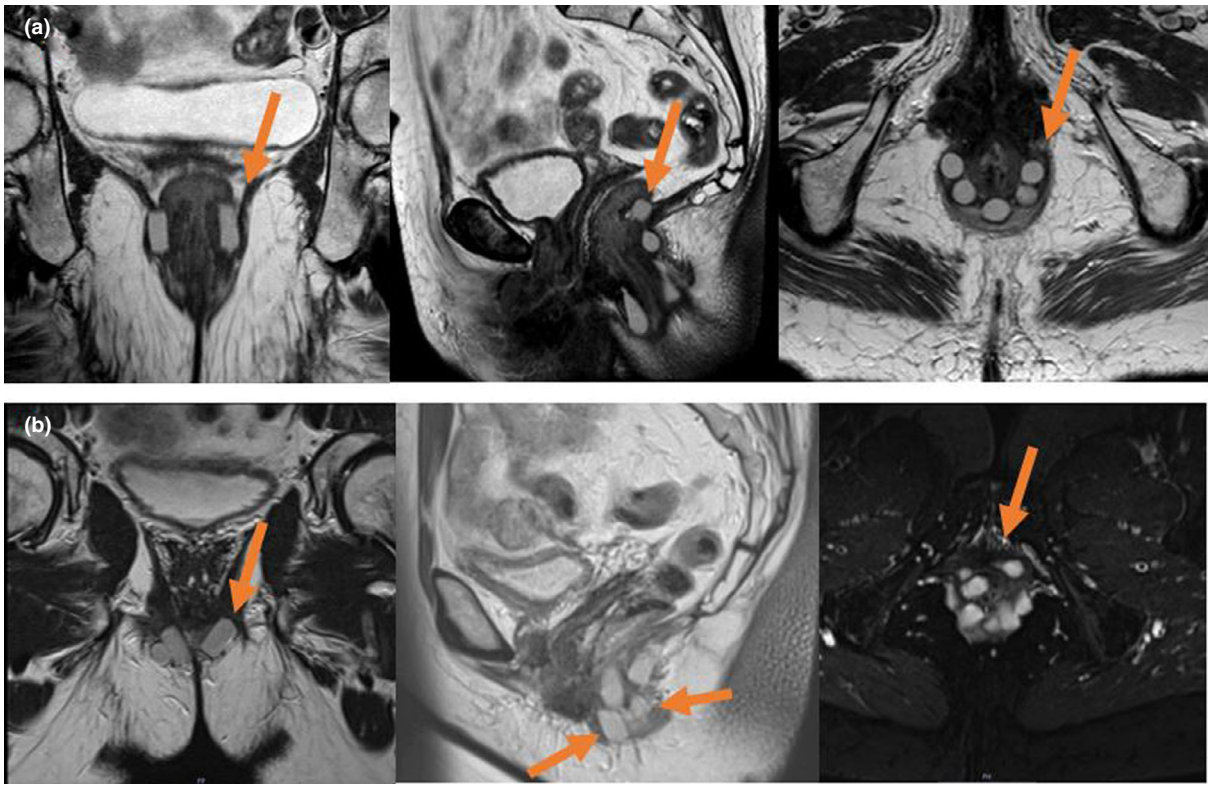

Figure 2 MRI. (a) Intersphincteric placement of the identified prostheses; however, gaps are demonstrated. Also, one prosthesis has partially traversed the levator plane posteriorly. This patient was implanted under intra-operative guidance with EAUSS. (b) Appropriate intersphincteric placement of a proportion of prostheses; however, some of the prostheses are more distally sited.

Table 3 Contingency table showing no relationship between numbers of optimally placed prostheses and outcome based on ≥ 50% reduction in SMIS score (χ^2 test, $P = 0.79$).

	≥ 50% SMIS	< 50% SMIS	Marginal rows totals
≥ 50% ideal placement	10	8	18
< 50% ideal placement	4	4	8
Marginal columns total	14	12	26

SMIS, St Mark's incontinence score.

3, range 0–6), whereas at SMH the number of prostheses identified by the postoperative imaging was always greater than seven (median 9, range 7–10).

Discussion and conclusions

This retrospective clinical audit evaluated the first experience of SphinKeeper prosthetic implants for treatment of faecal incontinence in two specialist UK centres. SphinKeeper proved to be safe, easily performed as a day case and well tolerated in all patients without any serious complications. The procedure was relatively simple to perform from a technical perspective apart from surgeons in both hospitals experiencing frequent difficulties with the firing of the SphinKeeper delivery system. With the caveats of a retrospective study (lack of prospective standardization of intervention, follow-up and radiological methods), our presentation of 'real-life' data does, however, merit some discussion.

Just over half (51.9%) of patients showed a clinically meaningful improvement in SMIS as defined by a halving of symptom score at short-term follow-up. Although failure could be attributed to many factors other than technical issues with placement, such as selection of patients with non-sphincteric causes of incontinence, there was clearly a technical issue with deployment of prostheses as evidenced by radiologically absent or misplaced prostheses in a high proportion of patients. Our results in this regard are at odds with the original description of the SphinKeeper technique reported by Ratto *et al.* [17], in a prospective study of

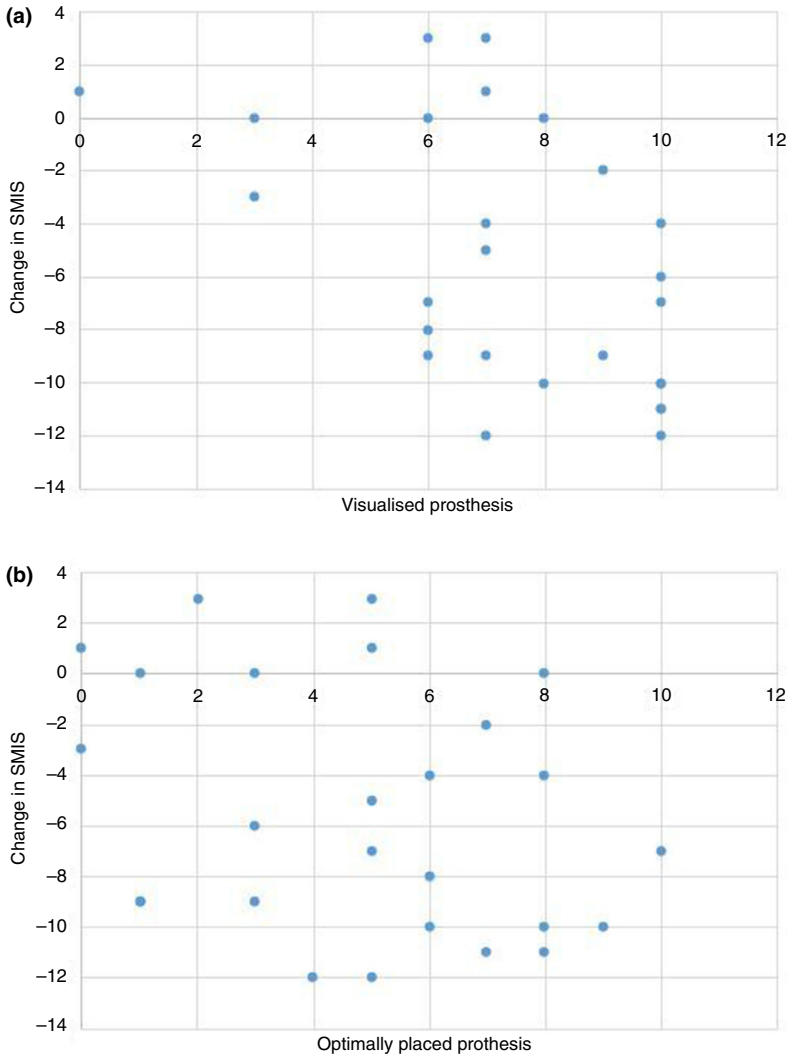

Figure 3 (a) Correlation between change in SMIS score and the total number of prostheses visualized. (b) Correlation between change in SMIS score and the total of ideally placed prostheses.

10 patients. At 3 months' follow-up, all patients were reported to have 10 prostheses successfully implanted, with all perfectly positioned without any missing or misplaced prostheses. Furthermore, the authors did not report any device misfires or technical difficulty with the delivery system. A subsequent report from La Torre *et al.* [24], in a cohort of 13 patients, indicated that only one patient had an anterior displacement of a single prosthesis, prosthesis extrusion occurred in two other patients, and no device misfires were reported [24]. Both of these studies used EAUSS guidance intraoperatively. However, our experience, even in those patients in whom EAUSS guidance was used, was that no patient had a radiological outcome that resembled the images produced by ultrasonographic reconstruction in these previous studies [17,24].

Our results are more akin to those of Litta *et al.* [30]. Using follow-up EAUSS assessment of prosthetics, they found that the implantation was adequate in only 23 of the 42 patients (based on 6/10 prostheses placed in the target area). The SMIS in their study decreased from a median of 15/24 to 10/24 ($P < 0.001$), i.e. nearly identical to our study. Using a categorical cut-off in a subgroup of 14 women with sphincter defects, they reported results similar to our own experience, i.e. eight of 14 patients (57%) showed a > 50% reduction in the total number of faecal incontinence episodes per week.

It is unknown whether the eventual disposition of prostheses reflects operative misplacement or subsequent migration since none of our patients was scanned early after the procedure. The former is quite possible,

although poor eventual positioning occurred even with use of EAUSS and occurred in both centres (i.e. by both experienced consultant specialist surgeons). Overall the clinical outcome appeared to be similar for patients treated in the two centres; however, the number of prostheses identified postoperatively in the SMH group, where the use of intra-operative EAUSS was routinely used, was greater. The use of intra-operative ultrasound guidance allows undiagnosed missed firings of the prosthetic to be detected during the procedure, although this may not be sufficient to identify every missed firing and it is possible that the prostheses have migrated postoperatively. For this reason, we would strongly recommend that every cartridge is inspected after each firing to ensure that the implant has been satisfactorily deployed and it is not retained within the cartridge.

While it remains possible that the variability evidenced between different studies (above) in part reflects the learning curve, it is slightly disturbing that radiological outcome appeared to have no association with clinical improvement. This suggests that the manufacturer's basic premise that clinical effect is mediated as a factor of expansion of prosthetics in the intersphincteric space (and thence anal closure) is, at best, unlikely to be the whole story.

In conclusion, SphinKeeper appears to be a safe procedure for faecal incontinence. Overall, about 50% patients achieved a meaningful improvement in symptoms. However, clinical benefit was unrelated to rate of misplaced/migrated implants. This has implications with regard to confidence in proof of mechanism and also the need for technical refinement.

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Conflicts of interest

None.

Author contributions

Cosimo Alex Leo and Marjolein Leeuwenburgh have contributed to design of the study, acquisition of data, analysis and interpretation of data, and drafting/revising the manuscript critically for important intellectual content; Mark Scott, Alison Corr, Alessandra Orlando and Jamie Murphy have contributed to the design and interpretation of data and revising the manuscript; Charles Knowles, Carolynne Vaizey and Pasquale Giordano have contributed to the conception and design, acquisition of data, analysis and interpretation of data, drafting/revising the manuscript critically for important intellectual content; all authors provided a final approval of the version to be published.

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