



Research Article

The Use of Sphinkeeper® In Faecal Incontinence

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Abstract

Introduction: Faecal Incontinence is a condition that can affect up to 20% of population during their lifetime with female predominance. Sacral Nerve Stimulation (SNS) has been recently shown to have significant benefits in mainly urge incontinence but this has left a large group of patients with passive incontinence without effective management options. The SphinKeeper® (SK) allows treatment of more sizeable defects in the internal or external anal sphincter. Preliminary series have shown some benefit of the procedure in treatment of faecal incontinence.

Methods: A single-centre retrospective observational study of SphinKeeper® prostheses was conducted at St Helens and Knowsley NHS trust and we believe this to be one of the largest series of SphinKeeper® in the UK. SphinKeeper® restores sphincter function by using placement of self-expanding prostheses into the inter-sphincteric space. The operation involves implantation of 10 self-expanding sterile prostheses between the internal and the external sphincter, thus creating a third ring around the circumference of the anal canal.

Results: Most patients were ASA 2 (n=10). 43% (6/14) patients had previous colorectal surgery - THD and mucopexy (n=3), anorectal fistula surgery (n=1), anterior resection of rectum (n=1) and pelvic floor repair (n=1). EUS was carried out in 6 patients and in all 6 cases identified internal or external anal sphincter defect (IAS n=1, EAS n=3, IAS and EAS n=2). No patient sustained intraoperative complications. 2 patients reattended within 48 hours post op due to severe post-operative pain and were discharged with analgesia. Subjective results were evaluated using Vaizey and Wexner scores and showed significant improvement 4/14 patients, partial improvement in 7/14 patients and no improvement in 3/14 patients.

Discussion: Our study evaluated the short-term outcomes of the procedure in 14 patients who had SphinKeeper® surgery between May 2017 and August 2020. Patients who took part in our

study had previous treatment for faecal incontinence by a variety of methods (both medical and surgical) and suffered from different types of FI (passive, urge, mixed, associated urinary incontinence). It was promising to see there was a clinically significant improvement in continence indicated by a decrease in Vaizey and Wexner scores (p=0.00377 and p=0.00334 respectively (Wilcoxon test)) with 11 patients improving in scores. It is reasonable to consider SphinKeeper™ as a safe and minimally invasive surgical intervention to achieve some degree of positive improvement for patients suffering from faecal incontinence.

Keywords: Sacral Nerve Stimulation; SphinKeeper®; Faecal Incontinence; Endoanal Ultrasound

Introduction

Faecal incontinence is a condition that can impact up to 20% of individuals throughout their lives, with a higher prevalence among females. It significantly diminishes quality of life and often leads to enduring psychological trauma for those affected. While Sacral Nerve Stimulation (SNS) has recently demonstrated significant benefits for urge incontinence, a considerable portion of patients with passive incontinence have been left without effective management options. In 2015, the initial form of

peri-anal bulk forming treatments was introduced as The Gatekeeper™ (GK; THD SpA, Correggio, Italy) procedure. This procedure involved the implantation of four or six self-expandable prostheses into the intersphincteric space of the anal canal. However, the success rates of this system varied, prompting the development of an improved version known as the Sphinkeeper™ (SK) procedure (THD SpA, Correggio, Italy). The Sphinkeeper™ procedure is indicated for individuals experiencing passive, urge, or mixed incontinence that occurs more than once a week and does not respond to conservative measures. It is also recommended for faecal incontinence associated with urinary incontinence, previous radiotherapy to the pelvic area, or previous surgical procedures such as sphincteroplasty, sacral nerve stimulation, or anal surgery. The SK procedure allows for the treatment of larger defects in the internal or external anal sphincter, and early studies have shown some benefit of the system in addressing faecal incontinence.

Methods

We conducted a retrospective observational study on SphinKeeper® prostheses at St Helens and Knowsley NHS Trust, which we believe to be one of the largest series of SphinKeeper® cases in the UK. The study included patients ranging in age from 34 to 79 years. The procedure was performed by two trained surgeons following a standardized protocol provided by the manufacturer of the product. During the operation, ten self-expanding sterile prostheses were implanted between the internal and external sphincter, creating a third ring-like structure around the circumference of the anal canal. While the implant procedure can be carried out under local anaesthesia, in our series, all patients underwent general anaesthesia. As a preventive measure, intravenous Metronidazole was administered at the beginning of the operation. With the patient in a lithotomy position, small incisions were made approximately 2 cm from the anal verge, through which the prostheses were inserted using a specific delivery system. The cannula of the device was then inserted into the inter-sphincter space, and the prostheses were released. Ultrasound guidance was used to position the prostheses at 1, 5, 4, 9, 10, 6, 8, 7, 2 and 3 O'clock positions, allowing the surgeon to monitor the progress of the operation and ensure correct placement of the implant. Statistical analysis was performed using the Wilcoxon Mann-Whitney U test for non-parametric data, and the analysis was conducted using SPSS 24 software.

Results

Between May 2017 and August 2020, a total of 14 patients were recruited for the series and underwent SphinKeeper implantation. The primary indication for surgery was passive incontinence in 10 patients, followed by urge incontinence and mixed incontinence in 2 patients each. Four patients also had associated urinary incontinence. The female predominance was evident, with 12 female patients and 2 male patients, and the median age of the patients was 59 years (range 34-79). Most patients were classified as ASA 2 (n=10), indicating mild systemic disease, and six out of the 14 patients had previous colorectal procedures.

All patients are currently being followed up, and the median duration of follow-up is 29.7 months. Among the six patients who underwent preoperative Endoanal Ultrasound (EUS), all six cases showed defects in either the internal or external anal sphincter, with one case involving the Internal Anal Sphincter (IAS), three cases involving the External Anal Sphincter (EAS), and two cases involving both the IAS and EAS. Preoperative anal manometry was performed in all patients, but one report was unavailable for review due to technical issues. Table 1 displays the pre and post-procedure manometry results. Two patients opted not to undergo follow-up manometry studies.

	Maximum resting pressure (mmHg)		Maximum squeeze pressure (mmHg)	
	pre	post	pre	post
1	62	53	71	72
2	26	declined	48	declined
3	78	49	85	55
4	44	55.4	63	92.4
5	51	54	61	90
6	35	declined	85	declined
7	43	35.8	110	88.5
8	32	17	43	35.5
9	51	27	121	131
10	85	78.4	100	105.7
11	NA	19.5	NA	100
12	41	27	101	173
13	27	47	90	115
14	81	101	91	114

Table 1: Pre and post procedure manometry.

In one patient, the initial attempt to deliver a single implant was unsuccessful, but it was subsequently reattempted and successfully implanted during the same procedure. There were no intraoperative complications observed among the patients. However, two patients experienced severe post-operative pain and returned within 48 hours for further evaluation. They were discharged with appropriate analgesic medications. Out of the 14 procedures, 12 were performed as day cases, while two patients required an overnight stay due to social reasons and late surgery timing.

Subjective results reported significant improvement in 4 out of 14 patients, partial improvement in 7 out of 14 patients, and no improvement in 3 out of 14 patients. Table 2 provides an overview of the pre and post-operative differences in both Vaisey and Wexner scores, which assess specific aspects related to faecal incontinence.

Pre-op Vaizey	Pre-op Wexner	Post-op Vaizey	Post-op Wexner	Vaizey improvement	Wexner improvement
21	17	18	14	3	3
20	16	20	16	0	0
19	15	13	13	6	2
20	18	16	14	4	4
24	20	18	16	6	4
21	19	3	3	18	16
12	10	6	8	6	2
15	17	14	16	1	1
20	18	10	12	10	6
17	13	0	0	17	13
10	6	10	6	0	0
14	16	10	11	4	5
10	9	8	7	2	2
24	20	24	20	0	0
				p = 0.00377	p = 0.00334

Table 2: Pre and post op Vaizey and Wexner score with difference.

2 patients had post operative endoanal USS. One patient had migration of 1 implant and the other had migration of 2 implants.

Discussion

Faecal Incontinence (FI) is a prevalent health issue that significantly impacts quality of life and burdens healthcare services [2]. Studies have revealed that around 5.9% of adults, or roughly 1 in 8 adults, experience FI. Managing this complex condition involves a multidisciplinary approach, tailoring treatment to each patient's needs [3,4]. Currently, conservative measures are the primary treatment for FI, with surgery considered if other options fail. However, long-term continence is often not sustained, and drawbacks such as long-term commitment and cost highlight the need for further research and new interventions. Sphinkeeper™ (SK) is an innovative procedure derived from the previous Gatekeeper™ technique. It involves inserting 10 self-expanding prostheses between the internal and external anal sphincter, creating a reinforcing "third ring" to enhance the shape of the anal canal and physiological mechanisms of continence. SK offers several advantages over other interventions, including minimal invasiveness, applicability to multiple types of incontinence, low risk of serious complications, unlikely dislocation, cost-effectiveness, and simplicity of execution [5-7]. However, there is limited research on the procedure's efficacy, complication rates, and expected outcomes. Our study focused on evaluating short-term outcomes in 14 patients who underwent SK surgery between May 2017 and August 2020. The study participants exhibited various comorbidities (endocrine disease, neurological disease, gynecological disease, and inflammatory bowel disease) and received diverse methods of FI management (medical and surgical) due to different types of FI (passive, urge, mixed, associated urinary incontinence). This diversity allowed us to observe how a sample with varied circumstances responded to SK. Notably, the female-to-male patient ratio was 12:2. Regarding preoperative investigations, 6 out of 14 patients underwent endoanal ultrasound, and 3 out of 14 had an MR proctogram as part of their assessment for faecal incontinence symptoms. While these studies helped assess internal or external sphincter defects, there is no specific recommendation from the current body of evidence or manufacturers regarding preoperative investigations. Encouragingly, our study demonstrated clinically significant improvement in continence, as indicated by decreased Vaizey and Wexner scores ($p=0.00377$ and $p=0.00334$, respectively, Wilcoxon test). Eleven patients experienced score improvement, while 3 patients showed no change. This higher proportion of improvement compared to Leo, et al., results is noteworthy, despite our study having a relatively smaller sample size. During follow-up consultations, no patients reported deterioration, with most reporting partial or significant improvement in symptoms [8]. This overall enhancement in Vaizey and Wexner scores, along with the absence of reported deterioration, suggests that SK can bring about positive changes for faecal incontinence symptoms. Moreover, our results contribute to the growing evidence that the procedure carries low risk and burden. No patients experienced intraoperative or postoperative complications, except for one instance of failed implant delivery, which was successfully reattempted during the same procedure. Therefore, our findings align with previous research in indicating no serious complications during or after the procedure [6,8-10]. A subgroup analysis involving preoperative and postoperative anal manometry was conducted on 11 out of the 14 patients, yielding varying results. Postoperatively, 7 patients experienced a decrease in maximum resting pressure, while 4 patients exhibited an increase. Similarly, 3 patients had a decrease in maximum squeeze pressure, while 8 patients showed an increase. No clear relationship was established between pressure changes and patient satisfaction or Vaizey and Wexner scores. The inconsistency of these pressure values obtained from anal manometry contradicts the expected overall pressure increase resulting from the SK intervention. Thus, further research should investigate this matter. Additionally, postoperative endoanal ultrasound scans were performed on 2 patients, revealing implant migration in both cases. Implant migration seems consistent with findings in other studies and should be noted [8,10]. The cause of such migration requires more data to ascertain whether it is procedure-related or influenced by other factors [8]. Although the impact of implant migration on failure remains unclear, other potential causes include technical aspects such as incorrect implant positioning. However, the risk of such errors should be minimal due to the intraoperative use of endoanal ultrasound. Treating faecal incontinence is challenging due to its various etiologies and symptomatology. It is widely recognized that even a combination of physiotherapy and surgical treatments may not achieve perfect continence. Considering the low incidence of adverse events, Sphinkeeper should be viewed as a safe adjunct to other treatments.

Conclusion

In summary, the Sphinkeeper™ procedure has demonstrated an improvement in continence, supported by reductions in Vaizey and Wexner scores and positive reports from patients regarding symptom relief. The study's limitations include inconsistent pre- and post-operative investigations, preventing assessment of EAU findings and implant positions' relationship to outcomes. Nevertheless, given that Sphinkeeper™ is a novel procedure, similar case numbers have been reported in other published series, and thus, our study retains significance. Multicenter trials are necessary to further evaluate the efficacy of the Sphinkeeper procedure. Importantly, our results indicate no significant negative side effects or serious complications during the perioperative

period or short-term follow-up. Consequently, Sphinkeeper™ can be considered a safe and minimally invasive surgical intervention for achieving positive improvements in patients with faecal incontinence.

Conflict of Interest

The authors have no conflict of interest to declare.

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