Retrospective Cohort Study

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Safety, efficacy, and quality of life following Sphinkeeper™ implantation for fecal incontinence: a multicenter retrospective cohort study with mid-term follow-up

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Background: Sphinkeeper™ (SK) implantation has emerged as a minimally invasive option for patients with fecal incontinence (FI) who fail to respond to conservative therapies. While preliminary outcomes have been encouraging, robust mid-term data remain limited. This study aimed to evaluate the safety, efficacy, and quality-of-life outcomes of SK implantation in a large, multicenter European cohort.

Materials and methods: This retrospective cohort study included patients with FI who underwent SK implantation between 2017 and 2022 across seven tertiary referral centers in Europe. Eligible patients had failed pharmacological and pelvic floor rehabilitation therapies and completed at least 3 years of follow-up. Primary outcomes included changes in the Cleveland Clinic Incontinence Score (CCIS), Vaizey score, weekly incontinence and soiling episodes, and the ability to postpone defecation. Secondary outcomes assessed changes in the fecal incontinence quality of life (FIQoL) scale. All patients underwent standardized clinical, ultrasonographic, and manometric evaluations preoperatively and at 3 months postoperatively.

Results: A total of 111 patients (61.2% female; median age 59.4 years) were included. Median CCIS decreased from 12 (range: 6–18) at baseline to 7 (1–10) at 12 months, with sustained improvement at 3 years ($P < 0.0001$). Vaizey scores and weekly incontinence episodes significantly declined, while the ability to postpone defecation improved from 8 to 18 seconds ($P < 0.001$). All FIQoL domains showed significant enhancement by 12 months and remained stable through 36 months. No major complications were reported, and implant positioning was confirmed as adequate in 91.9% of cases.

Conclusion: SK implantation is a safe and effective treatment for refractory FI, offering durable improvements in continence, urgency control, and quality of life over a 3-year follow-up period. These findings support its role as a viable minimally invasive alternative in the contemporary management of FI.

Keywords: anal prosthesis, fecal incontinence, minimally invasive surgery, pelvic floor disorders, quality of life, Sphinkeeper implantation

Introduction

Fecal incontinence (FI) is a distressing and socially disabling condition, with an estimated prevalence of up to 19.5% in the general population[1,2]. It significantly impairs quality of life and remains frequently underdiagnosed and undertreated. First-line management typically consists of conservative measures, including dietary modification, pharmacologic therapy, and pelvic floor rehabilitation[3–5]. However, a considerable proportion of

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patients fail to achieve satisfactory control with these approaches and may require procedural interventions.

Among the therapeutic options for refractory FI, injectable bulking agents have been proposed to restore sphincter competence through mechanical augmentation of the anal canal[6]. Within this context, the Sphinkeeper™ (SK; THD SpA, Correggio, Italy) has emerged as a novel device aimed at improving continence by combining bulking and remodeling effects on the anal sphincter complex. SK is an evolution of the earlier Gatekeeper™ (GK) system and involves the implantation of ten self-expanding prostheses composed of polyacrylonitrile (Hyexpan) into the intersphincteric space[7–10]. Upon water absorption, these implants expand up to 700-fold, theoretically enhancing sphincter contractility and restoring functional continence[8,11].

Early studies have reported encouraging short-term results for both GK and SK in improving objective continence measures and patient-reported outcomes[8–12]. Nonetheless, evidence regarding mid- and long-term efficacy remains sparse, and questions persist regarding the durability of therapeutic benefit across different etiologies and severities of FI.

The aim of the present study was to evaluate the mid-term outcomes of SK implantation in a large, multicenter European cohort of patients with FI, focusing on its safety, clinical efficacy, and impact on quality of life. This investigation seeks to fill existing gaps in the literature by providing standardized data with extended follow-up from seven tertiary referral centers.

HIGHLIGHTS

- This study represents the largest multicenter European cohort investigating SK implantation for fecal incontinence.
- The procedure was performed at seven tertiary referral centers, with a minimum of three years of follow-up.
- Patients demonstrated significant and sustained improvements in continence, urgency control, and quality of life.
- SK implantation showed a strong safety profile, with no major complications observed during the perioperative period.
- The technique was effective even in patients with sphincter defects and may serve as a valuable option for elderly or frail individuals unsuitable for complex reconstructive surgery.

Methods

Study design and patient enrollment

This was an international, multicenter, retrospective cohort study conducted across seven tertiary referral centers in Europe: University of Campania "Luigi Vanvitelli" (Naples, Italy); Medical University of Vienna (Vienna, Austria); Hospital Universitari Mutua Terrassa, University of Barcelona (Terrassa, Spain); Academy of Applied Medical and Social Sciences – AMiSNS (Elbląg, Poland); Dnipro State Medical University (Dnipro, Ukraine); Royal London Hospital, Barts Health (London, UK); and St Mark's Hospital and Imperial College London (London, UK). Patients with FI who underwent SK implantation (THD SpA, Correggio, Italy) between 2017 and 2022 and had a minimum of three years of postoperative follow-up were eligible for inclusion.

This study involved retrospective analysis of anonymized data routinely collected during clinical care. Ethical approval was obtained from the Ethical Committee of the Italian Unitary Society of Coloproctology, Protocol No. SIUCP-01-2022, 6 June 2022. The study complied with the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants for both the surgical intervention and the use of anonymized clinical data for research. The study was registered at ClinicalTrials.gov (ID: NCT06958497) and followed the STROCSS (Strengthening the Reporting of Cohort Studies in Surgery) guidelines[13] (Supplemental Digital Content 1, available at: http://links.lww.com/JS9/E754).

Baseline clinical and instrumental assessment

All patients underwent standardized preoperative assessment, including clinical history, physical examination, and validated scoring systems: the Cleveland Clinic Incontinence Score (CCIS)[14], Vaizey score[15], and the fecal incontinence quality of life (FIQoL) scale[16].

Each patient also underwent physiatric evaluation to assess thoraco-abdominal-sphincter coordination, with specific attention to voluntary contraction of the external anal sphincter in the absence of agonist (gluteal/adductor) or antagonist (abdominal) muscle recruitment[5]. Those with abnormal coordination were offered pelvic floor rehabilitation aimed at selectively activating internal sphincter musculature and improving tone. Rehabilitation consisted of 8–10 weekly 30-minute sessions. Patients who failed to improve within 3 months or who were non-adherent were subsequently referred for surgery.

To quantify baseline symptom severity, patients maintained a 3-week diary documenting weekly episodes of soiling and incontinence to gas, liquid, and solid stool. In patients with urge FI, the time between defecation urge onset and actual defecation or incontinence was recorded.

Instrumental assessments included three-dimensional endoanal ultrasound (3D-EAUS) and anorectal manometry (ARM). 3D-EAUS was performed in the left lateral decubitus position using a B-K Medical 2052 probe (B-K Medical ApS, Herlev, Denmark; 6–16 MHz) with a 360° rotating head, producing a cubic reconstruction of the distal rectum and anal canal[17–19]. Sphincter lesions were defined as areas of complete discontinuity or segmental echogenicity changes (scarring), while sphincter atrophy was defined as circumferential echogenic alteration of the sphincter complex[20]. Implant positioning was deemed adequate when at least two-thirds of the prostheses were located in the upper and middle anal canal[12].

ARM was performed using a wireless, solid-state catheter (Anopress, THD SpA, Correggio, Italy), inserted beyond the anorectal junction in the left lateral position. Parameters assessed included resting pressure, maximum voluntary squeeze pressure, cough reflex, endurance, strain pressure, rectoanal inhibitory reflex, and rectal sensitivity[21–23].

Inclusion and exclusion criteria

Inclusion criteria were age ≥18 years; diagnosis of FI, defined as ≥1 incontinence episode per week for at least 6 months; failure of conservative therapies (pharmacologic, behavioral, and pelvic floor rehabilitation); and the presence of either intact anal

sphincters or focal sphincteric defects (internal, external, or both) involving ≤120° of the anal circumference on 3D-EAUS.

Exclusion criteria included inflammatory bowel disease with anorectal involvement, anorectal malignancy, perianal sepsis, and sphincter defects exceeding 120° on ultrasound. Patients previously treated with sacral neuromodulation were also excluded to avoid confounding effects.

Operative procedure

SK implantation was performed under spinal anesthesia with the patient in lithotomy position. Ten 2-mm perianal skin incisions were made 1–2 cm from the anal verge (0.5–1 cm from the intersphincteric sulcus), equidistantly spaced around the anal circumference (Fig. 1). Prostheses were delivered into the intersphincteric space below the puborectalis muscle using the dedicated THD SK Delivery System. Proper placement was confirmed by digital palpation and direct visualization through an Eisenhammer speculum. Patients were discharged the same day and advised to avoid trauma or sexual activity for 48 hours. A 5-day postoperative antibiotic course was prescribed.

Follow-up and outcome measures

Patients who had undergone SK implantation at least three years prior to the time of data analysis were eligible for evaluation. Clinical follow-up was systematically conducted at 3, 6, 12, 24, and 36 months postoperatively. During each visit, a comprehensive assessment was performed, including symptom scores, diary-based quantification of incontinence episodes, and quality-of-life evaluation.

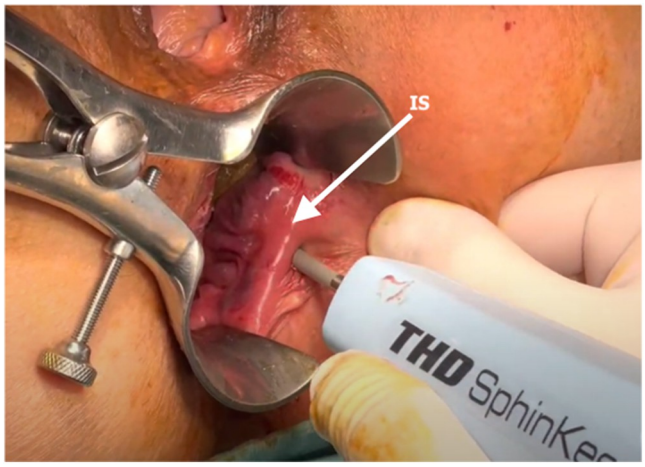

Figure 1. Intraoperative identification of the internal anal sphincter and prosthesis placement during Sphinkeeper™ implantation. The intraoperative image demonstrates the identification of the internal anal sphincter (IS, indicated by the white arrow) during Sphinkeeper™ implantation. Following progressive dilation with an Eisenhammer retractor, the IS appears as a taut fibrous band resembling a "violin string," serving as the key anatomical landmark for correct identification of the intersphincteric space. The IS is indicated by a white arrow. An index finger is inserted into the anal canal to palpate the sphincter from within, while the prosthesis is positioned just lateral to this structure using the dedicated THD delivery device. This visual and tactile approach ensures accurate and reproducible prosthesis placement through 2-mm perianal incisions.

The primary clinical outcomes included longitudinal changes in the number of fecal incontinence episodes per week, soiling frequency, and the patient's ability to postpone defecation following urge sensation. Additionally, validated scoring systems – the CCIS[14] and Vaizey score[15] – were employed to quantify the severity of FI at each time point. Improvements in these metrics were interpreted as indicators of therapeutic response.

Quality of life was assessed using the FIQoL scale[16], which includes 29 items distributed across four domains: Lifestyle, Coping/Behavior, Depression/Self-Perception, and Embarrassment. Patients completed the FIQoL questionnaire at baseline and during follow-up visits, allowing for longitudinal comparison. Higher scores in each domain indicated better functioning and reduced impact of symptoms.

In addition to subjective and clinical outcome measures, instrumental assessments were repeated three months postoperatively. All patients underwent ARM to evaluate functional pressure changes, and 3D-EAUS to assess prosthetic positioning and any structural changes. Implant positioning was considered satisfactory if at least two-thirds of the prostheses were located within the upper and middle thirds of the anal canal[12].

Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 17.0 (SPSS Inc., Chicago, IL, USA; released 2008). Descriptive statistics were used to summarize baseline characteristics, surgical variables, and follow-up outcomes. Categorical data were expressed as absolute frequencies and percentages, while continuous variables were reported as medians with interquartile ranges or as means ± standard deviation (SD), depending on data distribution. The normality of distributions was evaluated using the Shapiro–Wilk test.

For comparisons between preoperative and postoperative values, the Wilcoxon signed-rank test was applied for non-parametric variables, and the paired Student's t-test was used for normally distributed continuous variables. A two-sided P value <0.05 was considered statistically significant.

An *a priori* sample size estimation was performed to ensure adequate power for detecting clinically meaningful changes in the primary endpoint, defined as a reduction of at least 3 points in the CCIS. Assuming a standard deviation of 6, a two-tailed alpha of 0.05, and 80% power ($\beta = 0.20$), the minimum sample size required was 88 patients. With a final cohort of 111 individuals, the study maintained sufficient statistical power to detect significant differences in all primary and secondary outcomes with confidence.

Results

Study population

Between 2017 and 2022, a total of 211 patients presented with FI. Of these, 125 (59.2%) were referred for conservative management due to abnormalities identified during physiatric assessment. Among them, 88 patients (70.4%) achieved symptom relief and opted to continue non-surgical treatment, while the remaining 37 (29.6%) proceeded to surgical evaluation. An additional 86 patients, deemed not suitable for rehabilitation, were evaluated directly for surgery. After excluding 12 patients (9.7%) lost to follow-up, 111 individuals were included in the

Table 1

Baseline clinical characteristics of the study population

Clinical feature	Value
Age (years)	59.4 (range, 39–89)
Sex (M/F)	43/68
Comorbidities	
Type 2 diabetes mellitus	20 (18%)
Pudendal neuropathy	9 (8.1%)
Neurological disorders	11 (9.9%)
Previous anorectal surgery	31 (27.9%)
Previous pelvic radiotherapy	4 (3.6%)
Cleveland Clinic Incontinence Score (CCIS)	12 (range, 6–18)
Vaizey score	14 (range, 8–20)
Endoanal ultrasonography findings	
Isolated internal sphincter lesions	9 (20.9%)
Isolated external sphincter lesions	18 (41.9%)
Combined internal and external sphincter lesions	16 (37.2%)
Sphincteric inhomogeneity	17 (25%)
Sphincter atrophy	10 (14.7%)

Values are expressed as absolute numbers with percentages in parentheses, or as medians with ranges, as appropriate. CCIS = Cleveland Clinic Incontinence Score.

final analysis, all of whom completed the 36-month postoperative assessment schedule.

The study cohort consisted of 68 women (61.2%) and 43 men (38.7%), with a median age of 59.4 years (range: 39–89). All patients demonstrated passive FI related to pelvic floor muscle weakness. Key baseline demographic and clinical characteristics are summarized in Table 1. Notably, 20 patients (18.0%) had long-standing type 2 diabetes mellitus, 9 (8.1%) had a history of pudendal neuropathy, and 11 (9.9%) presented with neurologic conditions. Previous pelvic radiotherapy was reported in 4 cases (3.6%), and obstetric anal sphincter injury in 12 cases (10.8%). Prior anorectal surgery had been performed in 31 patients (27.9%), including hemorrhoidectomy (n = 13, 41.9%), fistula surgery (n = 12, 38.7%), and internal sphincterotomy (n = 6, 19.4%).

Baseline 3D-EAUS revealed no sphincter defects in 68 patients (61.2%), although 17 (25.0%) of these exhibited inhomogeneity in sphincter architecture and 10 (14.7%) showed features of sphincter atrophy. A total of 43 patients (38.7%) had detectable sphincter lesions: 18 (41.9%) with isolated external sphincter injury, 9 (20.9%) with internal sphincter injury, and 16 (37.2%) with combined defects. Baseline manometric parameters are presented in Table 2.

Surgical outcomes

The median operative time for SK implantation was 19 minutes (range: 13–25). No intraoperative or early postoperative complications occurred. In 12 patients (10.8%), partial extrusion of one or two prostheses was observed intraoperatively and was promptly corrected using forceps without compromising the procedure.

Primary outcomes

Longitudinal evaluation demonstrated statistically and clinically significant improvements in all primary endpoints (Fig. 2). Median CCIS decreased from 12 (range: 6–18) at baseline to 10 (4–12) at 1 month, 8 (2–10) at 6 months, and 7 (1–10) at 12 months ($P < 0.0001$; Wilcoxon matched pairs test), with stability maintained through the 24- and 36-month assessments. The Vaizey score showed a parallel trend, declining from 14 (8–20) at baseline to 13 (6–18), 10 (2–12), and 10 (1–12) at 1, 6, and 12 months, respectively ($P < 0.0001$), with no further significant change through 3 years.

The median time patients could postpone defecation improved from 8 seconds (range: 3–15) at baseline to 12 seconds (9–18) at 1 month, 15 seconds (10–20) at 6 months, and 18 seconds (12–25) at 12 months ($P < 0.001$), with this improvement sustained at 2 and 3 years. Additionally, the median weekly frequency of soiling and incontinence to gas, liquid, and solid stool decreased significantly by 6 months ($P < 0.001$), with stable improvements maintained through 36 months (Fig. 3).

Subgroup analysis showed that outcomes were independent of baseline sphincter integrity. Patients with and without 3D-EAUS-confirmed sphincter defects exhibited similar improvements in CCIS: from 11 (6–17) to 7 (1–10) vs. 12 (6–18) to 8 (1–10) at 3 years ($P = 0.10$), respectively (Fig. 4), confirming broad efficacy across anatomical subtypes.

Table 2

Baseline anorectal manometric characteristics of the study population

Parameter	Value (median, range)
Anal resting pressure (mmHg)	52 (40–65)
Maximum voluntary contraction (mmHg)	80 (60–100)
Duration of voluntary contraction (sec)	10 (8–12)
Rectal sensitivity thresholds (mL)	
First threshold	25 (20–30)
Second threshold	50 (40–60)
Third threshold	90 (70–120)

Values are reported as medians with corresponding ranges in parentheses. Measurements were obtained via high-resolution anorectal manometry.

Values are expressed as absolute numbers with percentages in parentheses, or as medians with ranges, as appropriate. CCIS = Cleveland Clinic Incontinence Score.

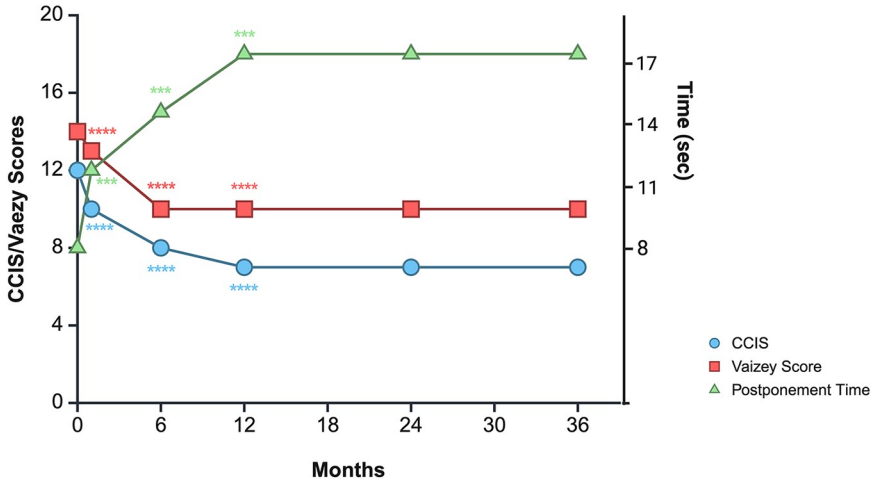

Figure 2. Trends in functional outcomes and continence control following Sphinkeeper™ implantation. Median values for Cleveland Clinic Incontinence Score (CCIS), Vaizey score, and time to postpone defecation at baseline and during follow-up at 1, 6, 12, 24, and 36 months after Sphinkeeper™ implantation. Significant reductions were observed in both CCIS and Vaizey scores, with sustained improvement over time ($P < 0.0001$). Postponement time improved from 8 seconds at baseline to 18 seconds at 12 months ($P < 0.001$), and remained stable at 2 and 3 years. Asterisks indicate statistical significance vs. baseline: $P <$ 0.001 (***), < 0.0001 (****); statistical analysis was performed using the Wilcoxon matched-pairs test.

Secondary outcomes

Marked and sustained improvements were observed across all four FIQoL domains. At 12 months, mean scores significantly declined from baseline: lifestyle from 3.8 ± 1.9 to 2.3 ± 0.4, coping/behavior from 3.0 ± 1.5 to 1.6 ± 0.8, embarrassment from 3.0 ± 2.2 to 1.5 ± 2.6, and depression/self-perception from 3.7 ± 1.9 to 2.4 ± 0.4. These gains remained stable at 24 and 36 months, with lifestyle at 2.3 ± 0.4, coping at 1.2 ± 0.8, embarrassment at 1.0 ± 0.3, and depression at 2.4 ± 1.3 (all $P < 0.001$; paired t-test) (Fig. 5).

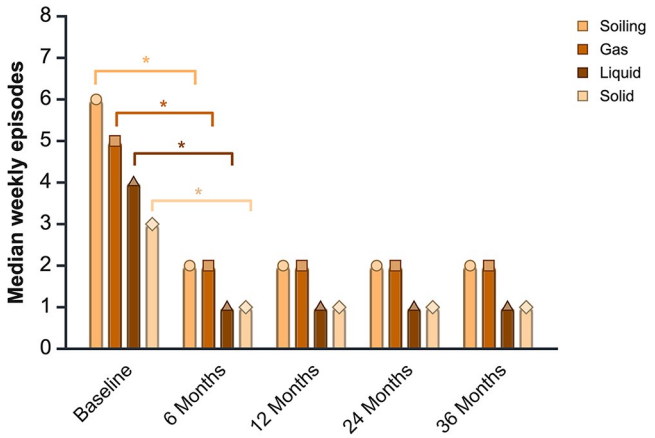

Figure 3. Reduction in weekly episodes of soiling and fecal incontinence post-Sphinkeeper™ implantation. The graph displays the median number of weekly episodes of soiling and incontinence to gas, liquid, and solid stool at baseline and during follow-up at 6, 12, 24, and 36 months post-implantation. A significant reduction was observed in all parameters by 6 months ($P <$ 0.001), with improvements maintained throughout the 3-year follow-up period. Asterisks denote statistically significant differences versus baseline (Wilcoxon matched-pairs test).

Postoperative manometric and ultrasonographic findings

At the 3-month postoperative assessment, anorectal manometric measurements showed a significant increase only in maximum voluntary squeeze pressure, rising from 80 mmHg (range: 60–100) at baseline to 90 mmHg (range: 80–110) ($P < 0.01$), suggesting enhanced voluntary contractility. Other manometric parameters remained unchanged (Table 3).

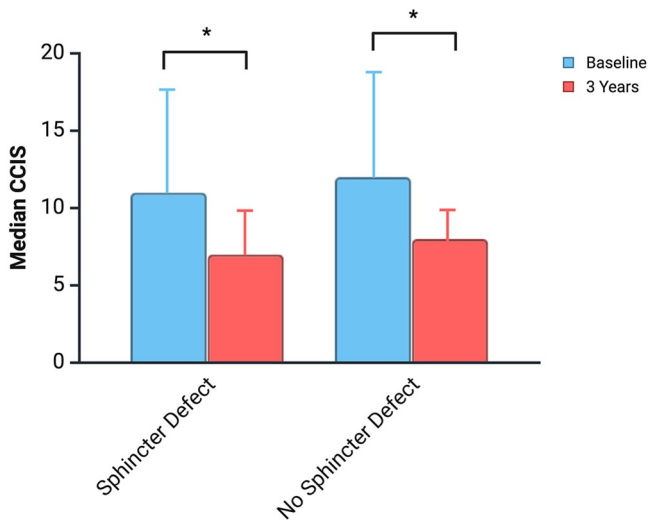

Figure 4. Subgroup analysis of CCIS improvements according to baseline sphincter integrity. Subgroup analysis based on 3D endoanal ultrasound (3D-EAUS) findings demonstrated that long-term clinical outcomes were independent of baseline sphincter integrity. Patients with confirmed sphincter defects showed a reduction in Cleveland Clinic Incontinence Score (CCIS) from a median of 11 (range: 6–17) at baseline to 7 (1–10) at 3 years, while those without sphincter defects improved from 12 (6–18) to 8 (1–10). Although within-group improvements were statistically significant ($P < 0.05$), no significant difference was observed between the two groups at 3 years ($P = 0.10$). Error bars indicate the full observed range. Asterisks denote within-group significance vs. baseline (Wilcoxon matched-pairs test).

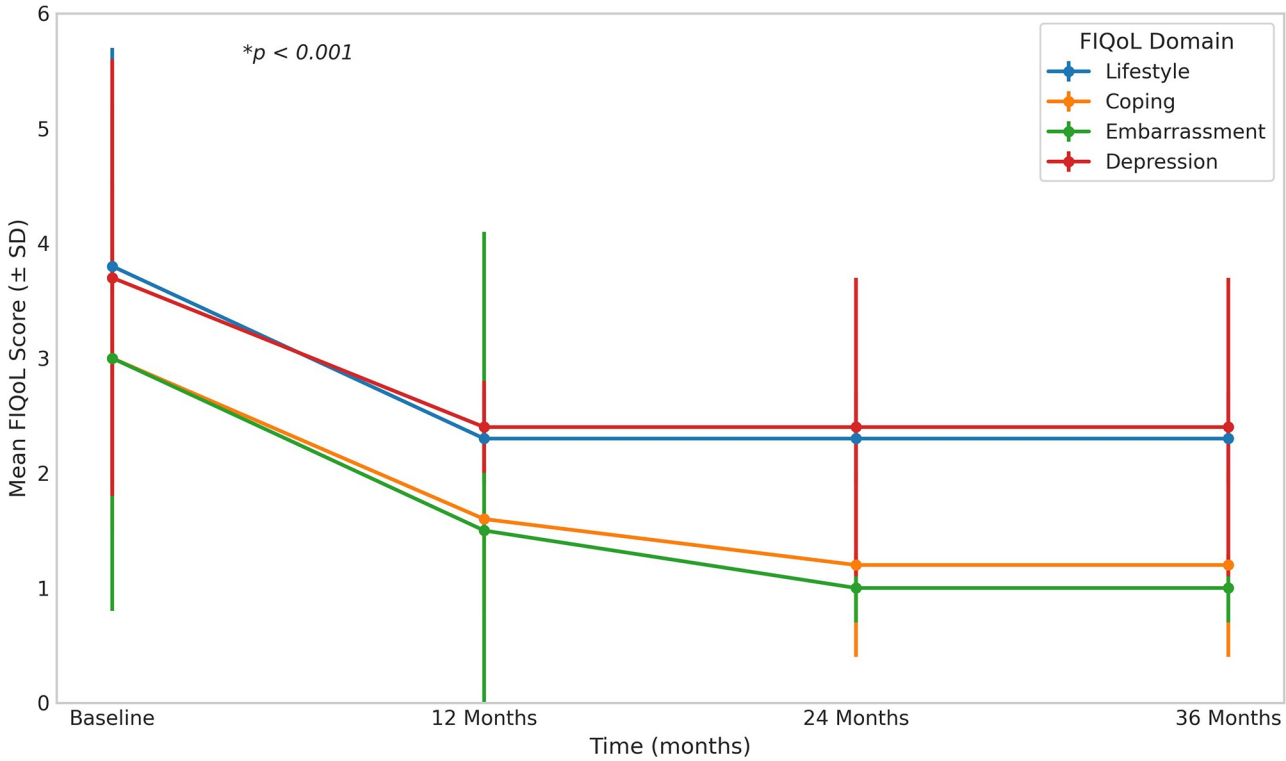

Figure 5. Longitudinal improvement in fecal incontinence quality of life (FIQoL) domains following Sphinkeeper™ implantation. Mean scores across all four domains of the fecal incontinence quality of life (FIQoL) scale – lifestyle, coping/behavior, embarrassment, and depression/self-perception – demonstrated significant improvement from baseline to 12 months following Sphinkeeper™ implantation. These gains were sustained through 24 and 36 months. Error bars represent standard deviations. $P < 0.001$ for all domains at 12 months versus baseline (paired t-test).

Follow-up 3D-EAUS confirmed appropriate prosthetic positioning in 102 patients (91.9%). In 9 patients (8.1%), implant distribution was suboptimal but did not require surgical revision.

Discussion

This multicenter retrospective cohort study represents the largest European series to date evaluating the clinical performance and safety profile of SK implantation in the management of FI. The findings provide compelling evidence that SK is associated with durable improvements in continence, urgency control, and quality of life over a three-year follow-up period. The absence of significant intraoperative or postoperative complications underscores the procedure's safety and reproducibility across different healthcare systems and patient populations.

Although mild forms of FI may respond to conservative interventions such as dietary modification and behavioral therapy, a significant proportion of patients exhibit persistent symptoms that necessitate escalation to procedural therapies[3–7]. Pelvic floor rehabilitation remains the cornerstone of non-operative management. However, its efficacy diminishes in the presence of overflow incontinence, impaired rectal sensation, or structural sphincter defects[3–5]. In such cases, SK implantation offers a promising alternative.

Our cohort demonstrated statistically and clinically meaningful improvements in validated continence scores, including the CCIS and Vaizey score, as well as in the ability to postpone

Table 3

Comparison of preoperative and postoperative anorectal manometric parameters

Manometric parameter	Preoperative	Postoperative	*P* value*
Anal resting pressure (mmHg)	52 (40–65)	58 (45–70)	NS
Maximum voluntary contraction (mmHg)	80 (60–100)	90 (70–110)	0.003
Duration of voluntary contraction (sec)	10 (8–12)	12 (10–14)	NS
Rectal sensitivity thresholds (mL)			
First threshold	25 (20–30)	35 (24–40)	NS
Second threshold	50 (40–60)	60 (50–70)	NS
Third threshold	90 (70–120)	100 (90–110)	NS

Values are expressed as medians with ranges in parentheses. Statistical comparisons were performed using the Wilcoxon matched-pairs test. NS = not significant.
Values are expressed as absolute numbers with percentages in parentheses, or as medians with ranges, as appropriate. CCIS = Cleveland Clinic Incontinence Score.

defecation. These outcomes were mirrored by significant gains across all domains of the FIQoL scale. These results are consistent with prior smaller-scale studies that have reported the short-term efficacy of SK in treating FI of various etiologies[24–28].

Notably, the therapeutic benefit of SK was independent of baseline sphincter integrity. Patients with either anatomically intact or structurally damaged sphincters experienced comparable improvements in continence outcomes, suggesting a mechanism of action that is not contingent upon sphincter preservation. This supports the hypothesis that the SK prostheses act through a combined bulking and remodeling effect, augmenting anal canal resistance and enhancing recruitment of residual sphincteric musculature[11]. In alignment with this hypothesis, our postoperative manometric findings – similar to those reported by other investigators[9] – showed a selective increase in maximum squeeze pressure, indicating enhanced voluntary contraction without adversely impacting resting tone or rectal compliance.

From a mechanistic perspective, it is plausible that SK contributes not only passive bulking but also neuromuscular reconditioning. By re-establishing anatomical support and modulating afferent sensory pathways within the anorectal axis, the device may help restore continence reflex arcs and improve sensory-motor integration. This is particularly evident in the observed improvement in urgency control, an outcome often refractory to both conservative and surgical approaches. These effects warrant further investigation in translational studies incorporating electromyographic mapping and neurophysiologic modeling.

Another speculative, but relevant, mechanism involves local fibrotic integration of the prostheses, analogous to responses seen with injectable agents. Longitudinal imaging or histopathologic studies may help elucidate whether SK contributes to long-term structural remodeling of the sphincter complex, which could in turn enhance procedural durability.

The clinical utility of SK appears robust across etiologic subtypes, including both idiopathic FI and sphincter trauma (e.g., obstetric injury, surgical damage)[29–31]. Furthermore, the procedure's short operative time, minimal invasiveness, and favorable safety profile render it particularly suitable for elderly or frail patients, who often have limited surgical options. These characteristics also suggest a role for SK in day-surgery or ambulatory settings, potentially reducing hospital resource utilization and expanding access to care, especially in underserved or high-risk populations.

This study has certain limitations. The retrospective design carries inherent risk of selection bias, and although follow-up was complete for all included patients, variations in perioperative rehabilitation protocols across centers could have introduced heterogeneity in treatment response. However, data collection was prospective, and participating centers followed harmonized protocols for patient selection, operative technique, and postoperative care. All procedures were performed in high-volume, tertiary institutions with specific expertise in FI management, which strengthens both internal validity and external applicability.

Conclusion

SK implantation is a safe, reproducible, and minimally invasive intervention for patients with fecal incontinence who fail to respond to conservative or rehabilitative therapies. In this largest-to-date European series, the procedure was associated with sustained mid-term improvements in continence, urgency control, and quality of life, irrespective of baseline sphincter integrity. These findings support its integration into the treatment algorithm for FI, particularly for elderly, frail, or high-risk surgical candidates. Future prospective studies are warranted to elucidate the biological mechanisms underlying its efficacy and to define standardized protocols for optimal patient selection and procedural indications.

Ethical approval

Ethical approval was obtained from the Ethical Committee of the Italian Unitary Society of Coloproctology (SIUCP; Protocol No. SIUCP-01-2022, 6 June 2022, Reggio Emilia, Italy). The study complied with the principles outlined in the Declaration of Helsinki.

Consent

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

Sources of funding

None.

Author contributions

L.B.: conceptualization, data curation, writing – original draft, writing – review & editing; A.B.: data curation, investigation, writing – original draft, writing – review & editing; L.M.: conceptualization, data curation, formal analysis, supervision, writing – original draft, writing – review & editing; S.R.: data curation, formal analysis, writing – original draft; P.G.: formal analysis, validation, writing – review & editing; A.M.D.: data curation, formal analysis, writing – original draft; C.J.V.: formal analysis, resources, validation, writing – review & editing; C.G.: conceptualization, funding acquisition, resources, supervision, validation, visualization; F.S.L.: data curation, formal analysis, investigation, methodology; F.P.: methodology, software, validation, visualization; R.D.: conceptualization, formal analysis, funding acquisition, investigation, methodology, resources, software, writing – original draft; R.M.: investigation, methodology, resources, software, writing – original draft; P.T.: formal analysis, resources, validation, writing – review & editing; A.R.: data curation, formal analysis, software, visualization, writing – review & editing; C.A.: investigation, supervision, validation, visualization, writing – review & editing; L.D.: conceptualization, investigation, supervision, visualization, writing – review & editing.

Conflicts of interest disclosure

None.

Research registration unique identifying number (UIN)

The study was registered at ClinicalTrials.gov (ID: NCT06958497) (https://clinicaltrials.gov/study/NCT06958497?term=NCT06958497&rank=1).

Guarantor

Luigi Brusciano and Luigi Marano.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Data availability statement

The data that support the findings of this study are available from the corresponding author, Prof. Luigi Marano, upon reasonable request. Due to the multicenter retrospective nature of the study and institutional data protection regulations, individual patient-level data cannot be made publicly available. Aggregated, deidentified data relevant to the analysis, including summary tables and statistical code, may be shared with qualified researchers for academic and non-commercial purposes upon request and subject to ethical approval.

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