Surgical Technique for Sphinkeeper® Implantation

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ABSTRACT

Fecal incontinence is a distressing condition characterized by the involuntary loss of solid and liquid stool and gas, It affects a significant proportion of the general population, with a reported prevalence ranging from 1% to 20%. Despite its considerable impact on quality of life, therapeutic options for fecal incontinence remain limited.

Current treatment modalities for fecal incontinence include conservative approaches such as dietary modifications, pelvic floor exercises, and pharmacotherapy. Surgical interventions, including sphincteroplasty or sacral nerve stimulation, may be considered in more severe cases.

Recently, THD Labs (THD S.p.A. Correggio (RE), Italy) introduced the Gatekeeper® as a novel device that supports the implantation of up to four solid prostheses into the intersphincteric groove. Early data were promising, with success rates above 50% and only a few perioperative complications.

Subsequently, Gatekeeper® was modified by increasing the length and number (up to 10) of prostheses, and renamed Sphinkeeper® (THD). With this device, nine to 10 small incisions measuring 2 mm are made at a distance of 2-3 cm from the anus. The intersphincteric space is accessed using the delivery system, and positioning is verified through endoanal ultrasound. This procedure is repeated for all 10 prostheses placed around the entire circumference. The Sphinkeeper® offers the potential to improve the management of fecal incontinence, and offers patients a less-invasive alternative to traditional surgical approaches.

INTRODUCTION

Fecal incontinence (FI) is a multifactorial disorder that affects up to 20% of the general population.[1-3]

Despite increased awareness of this stressful taboo topic, the treatment of FI remains challenging. If conservative therapy fails, more invasive operations such as sacral neuromodulation, sphincter repair, or bulking agents are indicated. However, surgical techniques remain limited, and novel therapeutic techniques are urgently required.

The Gatekeeper® (THD S.p.A. Correggio (RE), Italy) is a novel tool for the treatment of FI.[4] In contrast to bulking agents, self-expandable solid prostheses constructed of inert Hyexpan (polyacrylonitrile) are implanted into the intersphincteric groove. Within 48 hours following implantation, the prostheses expand to up to 700% of their initial volume due to delayed water absorption. The prostheses are considered to cause enhanced pressure on the anal canal, thereby improving FI. It has also been proposed that an implanted prosthesis increases muscle fiber length, leading to improved contractility.[5]

This technique was later modified using slightly longer, wider and more (up to 10) prostheses, and renamed Sphinkeeper® (THD).[6] Current literature on the Sphinkeeper® procedure is limited, and therefore its role in the management of FI is not clearly defined. Notably, a small number of short-term trials found encouraging effects with a considerable decrease in incontinence episodes and success rates of up to 50%.[6-12]

Patient selection and preoperative care

Fecal incontinence is a significant medical challenge, necessitating a multidisciplinary diagnostic and therapeutic strategy.

Conservative therapies, including dietary changes, pelvic floor rehabilitation, biofeedback techniques, and stool regulation, play an essential role in the management of FI and should be considered before choosing surgical procedures.

The indication for choosing the Sphinkeeper® surgery has not been clearly defined. In early studies on its predecessor (Gatekeeper®), predominantly patients with passive FI were selected for surgery.[13,14] Later, the indication for Sphinkeeper® therapy has been expanded to also include individuals with urge incontinence.[5,9,10] Furthermore, individuals with anal internal and external sphincter defects were chosen to undergo this procedure, with outcomes comparable to those with previous indications.[12]

Notably, patients with chronic inflammatory bowel disease, anal fistulas or malignant anal diseases are still considered to be contraindicated for implantation of the Sphinkeeper® prostheses.

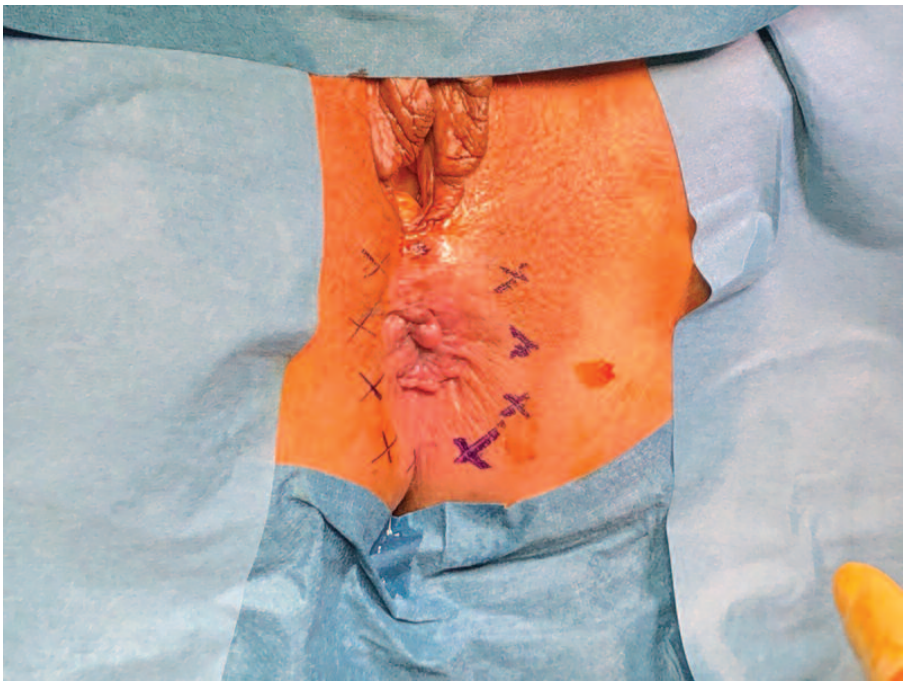

Figure 1. Ten markings are made around the anal canal using a skin pen.

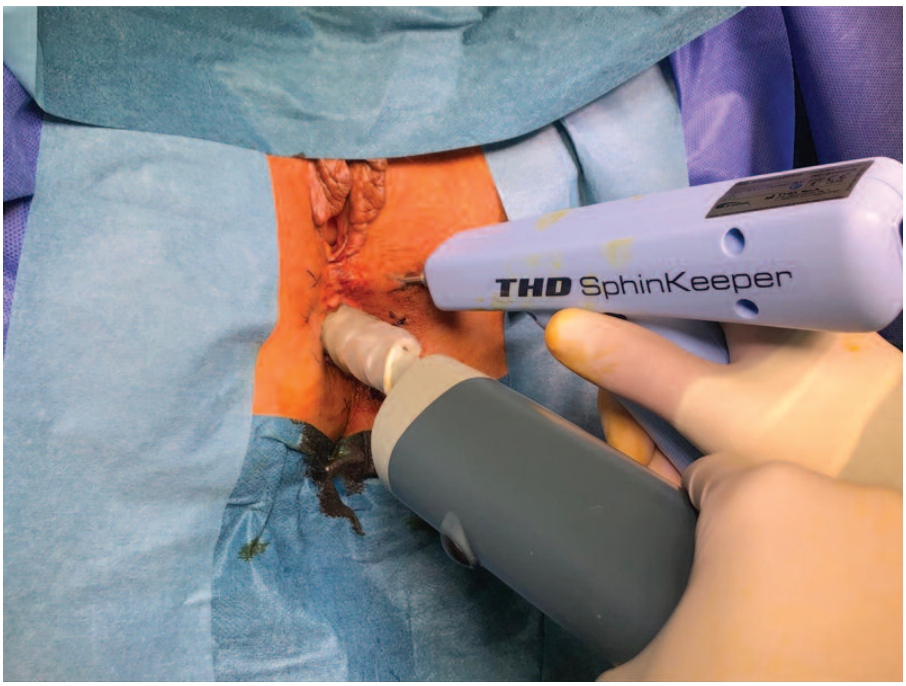

Figure 2. The intersphincteric space is entered using the delivery system, and the position is checked simultaneously by endoanal ultrasound.

Surgical Aspects

This section provides an overview of Sphinkeeper® implantation at the Division of Visceral Surgery, Department of General Surgery, at the Medical University of Vienna.

Patients receive a preoperative enema (Klistier® Fressenius, 130 ml) approximately 2 hours before surgery. The operation is mainly performed under general anesthesia and the patient is placed in the lithotomy position. The procedure can also be conducted under local or spinal anesthesia. A single-shot antibiotic prophylaxis (Cefuroxime 1.5 gm and Metronidazole 1.5 gm) is administered preoperatively. A urine catheter can be implanted in elderly patients to support a 24-hour bed rest following surgery.

After aseptic prepping with povidone-iodine solution and trapping, 9-10 marks are made at a distance of 2-3 cm from the anus at a distance of 1 cm from each other to determine the number of planned implants (Fig. 1).

Subsequently, 9-10 2-mm skin incisions are performed. The intersphincteric space is then entered using the delivery system, and the position is checked by endoanal ultrasound (Fig. 2). A non-sterile assistant stands next to the surgeon and guides the ultrasound. The delivery system must be introduced via the subcutaneous tissue at a different angle to reach the intersphincteric groove (Fig. 3). After the system is fired, the prosthesis is placed and the same procedure is repeated for all of the remaining prostheses around the entire circumference. The skin wounds are closed with absorbable sutures.

Technical Highlights

- ◆Sonographic knowledge of the anal region is essential. Intraoperative guidance via endoanal sonography should be applied for correct prosthesis implantation (Fig. 4). Otherwise, there is a risk of incorrect positioning of the implants, which can lead to impaired functional outcome.
- ◆As this is a foreign body implantation, utmost sterility is required, and constant prepping of the surgical field is recommended.
- ◆It is critical to avoid perforating the rectum when inserting the delivery device. It is advisable to provide anal counterpressure with a finger once the subcutaneous tissue has been passed to guarantee safe guidance of the delivery system into the intersphincteric groove.
- ◆During firing of the prosthesis, it is important to remain steady without retracting the delivery device too early. The prosthesis should be released completely into the desired position (Fig. 5).
- ◆All of the prostheses should be placed circumferentially at the same height in the intersphincteric gap. Therefore, it can be helpful to palpate the already-placed prostheses with the finger and the tip of the delivery system.

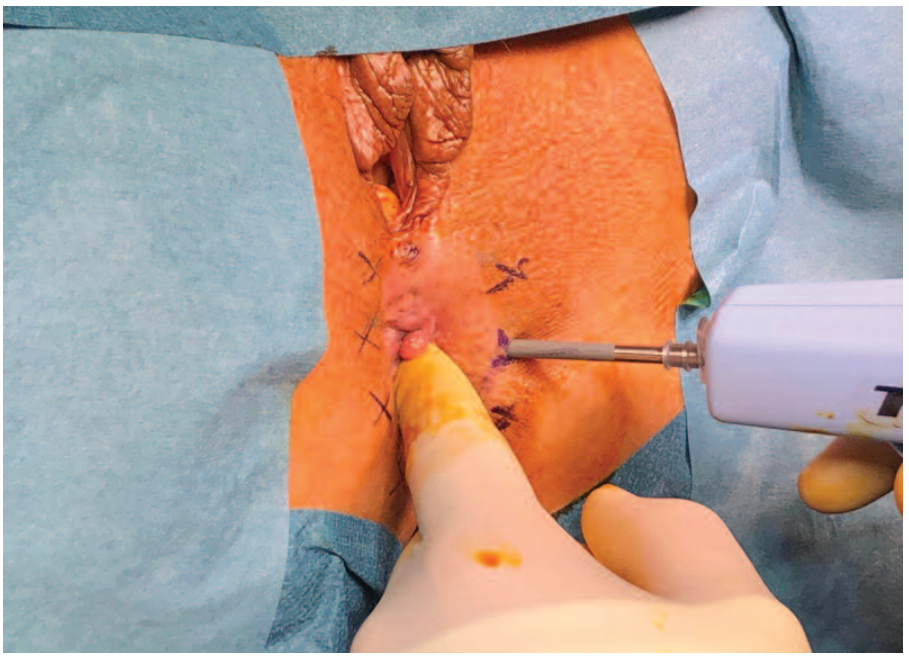

Figure 3. The delivery device is initially inserted into the subcutaneous tissue at an angle pointing towards the rectum. The surgeon's finger is put in the anal canal to provide pressure against the system.

Postoperative Care [12]

Antibiotic treatment is not administered routinely after surgery. Patients should avoid strenuous physical activity and remain in bed for at least 24 hours after surgery. Patients in our department are given weight-adapted low-molecular-weight heparin subcutaneously for the duration of their hospital stay. Oral pain medication may be necessary for the first 2 weeks after surgery. Mild laxatives may also be required in the first few days postoperatively.

Excessive physical activity should be avoided for 6 weeks to reduce the risk of prosthetic dislocation.[12]

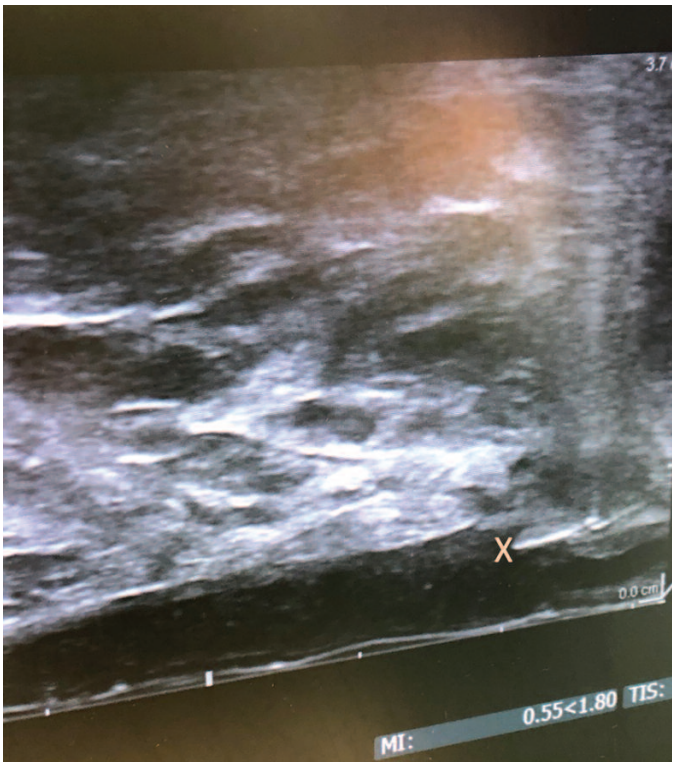

Figure 4. Intraoperative 2D endoanal ultrasound is used during every prosthesis implantation. The tip of the firing system is marked with an X.

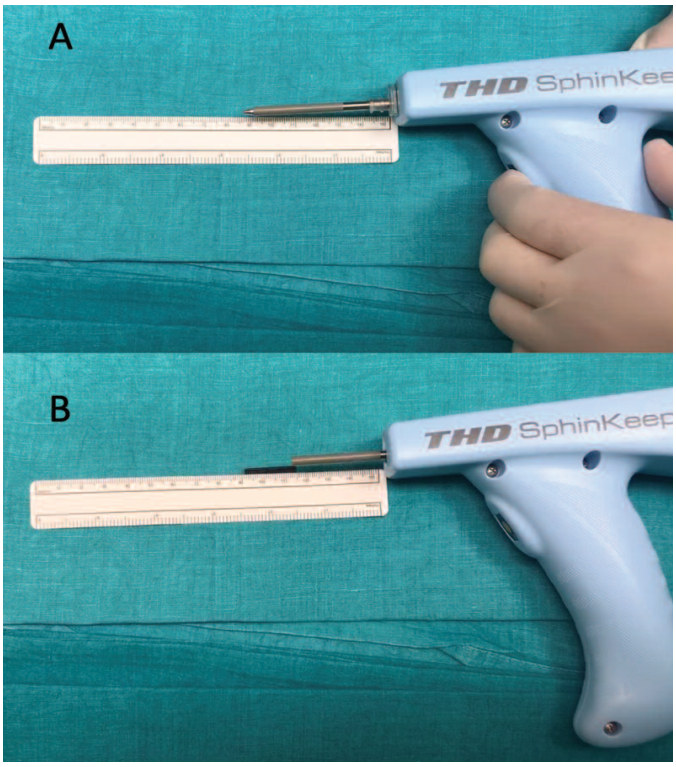

Figure 5. A) Sphinkeeper® delivery system before firing the prosthesis. B) Sphinkeeper® delivery system after firing the prosthesis, by retracting the cannula. The black prosthesis has been fired.

Patients should have regular endosonographic controls to detect and record any dislocation or migration of implants.

CONCLUSION

The Sphinkeeper® (THD) is a new tool for controlling fecal incontinence with success rates of up to 50% [7,10-12]. The patient selection process is considered to be crucial to achieve good results, although little is known about the ideal patient for choosing this approach.

Optimal placement of the Sphinkeeper® prostheses is essential and should be guided by sonography.[11] Since dislocation and migration of the implants can occur, a close follow-up is recommended. STI

AUTHORS' DISCLOSURES

SR is a consultant for AFS Medical (Teesdorf, Austria), which distributes the THD Sphinkeeper® in Austria. The remaining authors declare that there are no conflicts of interest.

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