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Magnetic sphincter augmentation in patients with fecal incontinence after failure of an implanted artificial bowel sphincter

Fecal incontinence (FI) is a distressing condition with a major impact on quality of life. The incidence of FI varies considerably in the literature, depending on country, population examined, and diagnostic criteria applied. Up to 20% of women in the United States are reported to suffer from FI [1]. Risk factors include age, obstetric and other trauma, diabetes, neurological disorders, and congenital malformations.

After failure of non-surgical treatment, the surgeon can choose between several surgical options. Patients not suitable for sacral nerve stimulation (SNS) but capable of keeping control of a device that artificially maintains control of their fecal continence were eligible in the past for implantation of an artificial bowel sphincter (ABS; Acticon Neosphincter, American Medical Systems, Minnetonka, MN, USA). The ABS consists of three parts connected by tubes. An inflatable cuff is formed around the rectum, and water from the second part, the reservoir, is transferred into the cuff by means of a control pump. The device requires a compliant patient with the mental capacity to control it. Long-term success rates between 49 and 83% have been reported, but also explantation rates between 11 and 65% [2–9].

We had performed ABS implantation in 28 patients between 2008 and 2015, until ABS was no longer available. In the meantime, in five patients, the ABS was without function after technical failure. The ABS had been implanted 3 years ago (34–37 months) in four patients and 14 months ago in one patient. All patients were female. While FI was under good control with the ABS in all patients, after loss of ABS function, FI was once again complete in all patients.

In recent years, implantation of a magnetic anal sphincter device has become an option in the treatment of FI. Several studies have reported promising functional results and low complication rates [10–12]. We had performed magnetic sphincter augmentation (MSA; Torax Medical, Shoreview, MN, USA; **Fig. 1**) between January 2012 and November 2016 in 40 patients, 35 of whom were

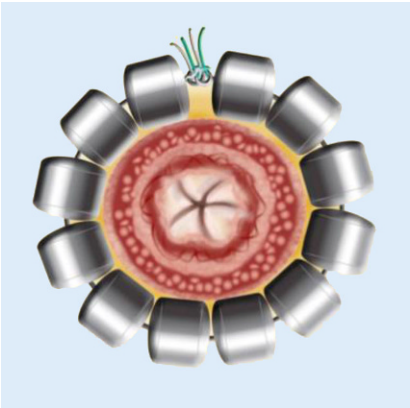

Fig. 1 ▲ Fenix® Magnetic Sphincter Augmentation Device (graphic generously provided by Torax Medical®, Shoreview, MN, USA)

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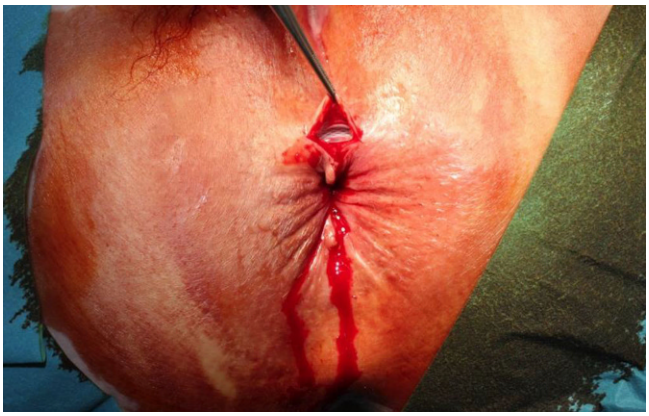

Fig. 2 ◄ Opening the surrounding connective tissue sheath

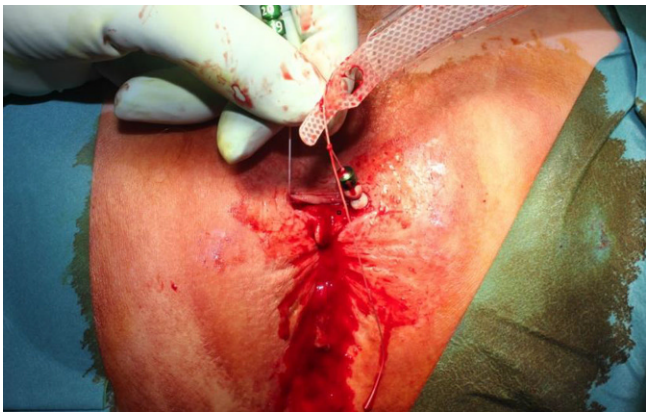

Fig. 3 ◄ Removing artificial bowel sphincter (ABS) and subsequent insertion of the Fenix® sizing tool (Torax Medical®, Shoreview, MN, USA)

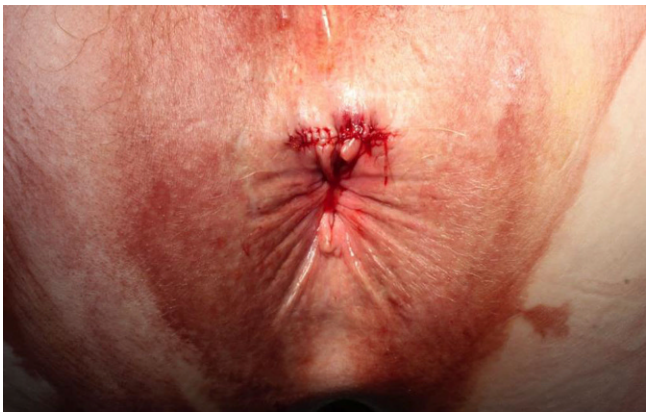

Fig. 4 ◄ Situation after wound closure

female. Age range was 31–92 years (median 71.5 years). Cleveland Clinic Incontinence Score (CCIS) decreased to 7.8 ± 4.4 after 6 months (55.4%) and did not increase during further follow-up. Fecal Incontinence Quality of Life Score (FiQL) increased between 1.8- and 2.5-fold 6 months after surgery as compared to preoperative values. The improvement was stable during further follow-up. A part of these patients' data has been published elsewhere [10]. Encouraged by these positive results, we decided to offer MSA to the patients with failure of ABS.

The success of MSA depends, among other conditions, on the elasticity of the rectum and surrounding tissue that will be compressed by the device. We were concerned that after the previous operation the tissue elasticity might be altered and it might be difficult to choose the right size of device. Moreover, we were not sure if we would be able to place the magnetic device in the correct position after removal of the ABS.

The surgeries could be performed without complications (**Fig. 2**, **3**, **4** **and 5**). The ABS could be removed easily after opening of the surrounding connective tissue sheath that had developed around the cuff. MSA was performed as described previously [10]. The sizer was introduced using the tool provided by the manufacturer. The size of the device was determined as suggested by

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Abstract

Magnetic sphincter augmentation (MSA) has become an option in the treatment of fecal incontinence (FI). We decided to perform MSA in five patients after technical failure of a previously implanted artificial bowel sphincter (ABS). In short-term follow-up, MSA resolved FI in all five patients.

Keywords

Pelvic floor · Quality of life · Colorectal surgery · Device Removal · Anal Canal

Implantation eines analen Magnetsphinkters bei Patienten mit Stuhlinkontinenz nach Funktionsverlust eines „artificial bowel sphincter"

Zusammenfassung

Die Implantation eines analen Magnetsphinkters („magnetic sphincter augmentation", MSA) ist eine Option in der Behandlung der Stuhlinkontinenz. Die Autoren implantierten einen Magnetsphinkter bei 5 Patienten, bei denen ein zuvor implantierter ABS („artificial bowel sphincter") insuffizient geworden war. Die kurzfristige Nachuntersuchung ergab, dass die Stuhlinkontinenz bei allen 5 Patienten wieder behoben wurde.

Schlüsselwörter

Beckenboden · Lebensqualität · Kolorektale Chirurgie · Implantatentfernung · Analkanal

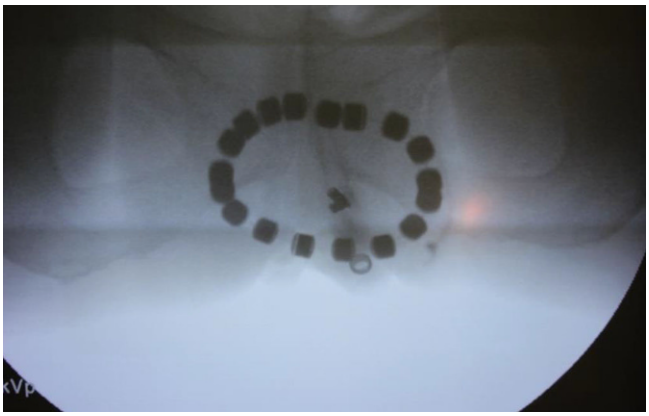

Fig. 5 ◀ Postoperative fluoroscopy to ensure correct flexibility

the manufacturer. The device was implanted into the connective tissue sheath induced by the ABS cuff.

In short-term follow-up (3 months), FI has resolved in all five patients. No perioperative complications have occurred, and wound healing was undisturbed. All five patients are very satisfied with the result of the operation. Patients will be monitored closely to ensure long-term success.

We are convinced that MSA is a valuable option in patients with failed ABS. One could even discuss the option of MSA in selected patients with ABS who are not satisfied with the functional result or who experience difficulty in handling the device.

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Compliance with ethical guidelines

Conflict of interest. F. Pakravan has a consulting agreement with Torax Medical. C. Helmes and I. Alldinger declare that they have no competing interests.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants from whom identifying information is included in this article.

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