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LETTER TO THE EDITOR

Erosion Rate of the Magnetic Sphincter Augmentation Device Is Much Higher for Anal Incontinence than for Antireflux

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To the editor:

We have read with interest the article by Alicuben et al. that reported on the worldwide experience with erosion of the LINX magnetic sphincter augmentation device (Torax Medical, Inc.).[1] The LINX device was developed as a less disruptive and more reproducible surgical option for patients with early-stage gastro-esophageal reflux disease.[2] The authors concluded that erosion of the device into the esophagus is an important but rare complication to recognize, occurring in 29 reported cases among 9453 implanted devices (0.30%). The median time to presentation of erosion was 26 months, with most cases occurring between 1 and 4 years after placement.

The FENIX Continence Restoration System (Torax Medical, Inc.) is a magnetic anal sphincter augmentation device derived from the LINX system that has been introduced for the treatment of fecal incontinence in adults who fail to improve with other available treatment options.[3] The FENIX is a ring of magnetic beads that is surgically implanted around the anal canal and designed to reinforce weakened anal sphincter muscles.[3] It received European Commission approval in 2011 and Food and Drug Administration (USA) approval as a humanitarian-use device in December 2015. The effectiveness of this device for this purpose has not been demonstrated yet.

We also read with great interest the few articles that have been published on the FENIX experience of some experts.[3–8] We wonder why erosions seem to occur more frequently with the FENIX device than with the LINX device. As the magnetic anal sphincter augmentation device is a recent therapeutic option, the published paper on the experience of centers mainly report on short-term outcomes, so that the erosion's rate might be well higher that the ones published. Of 35 patients involved in a prospective multicenter pilot study with a median follow-up duration of 5 years (range, 0–5.6 years), 8 underwent a subsequent operation, including 7 device explantations mainly for sepsis (3 patients) or erosion (3 patients).[8] This makes a rate of 17.1%, far higher than the 0.3% published for the LINX device.[1] Bridoux et al. published an even higher explantation rate of 42.8% (3/7 patients) for the FENIX device.[5] In our small single-center case series of 6 implanted patients, we observed an explantation rate of 50% (day 10, month 10, and month 48), which led us to stop inclusions in a multicenter, randomized, interventional, open-label trial identified as MOS STIC (MOS, Magnets Or Stimulation; STIC, "Soutien aux Technologies Innovantes et Coûteuses"), a specially granted program currently underway under the auspices of the French Ministry of Health that aimed to compare the FENIX device and sacral nerve stimulation in selected patients with fecal incontinence. Some other experts involved in this trial also stopped including patients due to the same reasons, representing one of the reasons why the trial finally included 70 patients instead of the 156 initially statistically calculated to show non-inferiority of the FENIX device over the sacral nerve stimulation in managing severe fecal incontinence.[9]

Asti et al., in an attempt to identify factors associated with the LINX device removal, demonstrated that supine esophageal acid exposure before the implantation was the only factor associated with the LINX system removal.[2] Concerning the FENIX device, why explantations are so frequent is still not clear. It might be well due not only to the learning curve [5, personal communication] but also to the fact that the perianal region is a more septic area than the periesophageal region. A similar observation led to the de-reimbursement of the artificial sphincter AMS for the treatment of fecal incontinence.[10] Another explanation might be that the anal sphincter is more tonic than the lower esophageal muscle. Publication of the results of the MOS STIC and SaFaRI trials will probably give an insight into the factors for the failure of the FENIX system in the treatment of fecal incontinence.

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Authors' Contributions Jean-Luc Faucheron: Conception, design, analysis and interpretation, manuscript author, drafted the article and revised it critically for important intellectual content, provided care for study patient, final approval of the version to be published.

Bertrand Trilling: Data acquisition, analysis and interpretation, provided criticism of the manuscript, revised it critically for intellectual content, final approval of the version to be published, and agreed to be accountable for all aspects of the work.

Pierre-Yves Sage: Data acquisition, analysis and interpretation, provided care for study patients, provided criticism of the manuscript, revised it critically for intellectual content, final approval of the version to be published, agreed to be accountable for all aspects of the work.

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