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Magnetic sphincter for anal incontinence: an update

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Abstract

The idea of using magnets to control the esophago-gastro-intestinal flow of contents dates back almost 20 years, from the first bench experiment in 2003, published in 2006, while the first clinical application at the anal level to prevent fecal incontinence took place in 2010 by means of a device called FENIX magnetic anal sphincter augmentation (MAS). The clinical experiences with MAS ranged from satisfactory success to partial failure depending on the various studies. The nonrandomized comparisons of MAS with sacral nerve stimulation (SNS) and artificial bowel sphincter (ABS) showed a similar effectiveness in fecal continence and quality of life, whereas the adverse events were more frequent and severe with MAS compared to SNS. ABS either failed to work or required an explantation for infection in 40% of patients, whereas MAS showed these adverse events in only 20% of cases. The comparison of MAS with anal slings and bulking infiltrations provided similar continence results, although with a shorter duration, whereas MAS showed more adverse events. Recently MAS has been withdrawn from the market, creating major inconveniences for surgeons and patients. Nevertheless, this can represent an opportunity for a system that reinforces the anal sphincter with "two magnetic plaques" to be finally implemented for use in patients after completing animal experimentation. This system offers various advantages compared with MAS: it has simpler operational activity, easier surgical implanting procedure, the possibility of "tailored" sphincter augmentation, and should turn out to cost less.

Keywords: Fecal incontinence, magnetic anal sphincter, FENIX magnetic anal sphincter augmentation, MAS device, fecal incontinence devices

INTRODUCTION

Fecal incontinence (FI) is the involuntary loss of feces, with a prevalence in the general population that can reach up to 15%[1], especially in elderly people living in communities[2]. The key mechanism of this embarrassing disease, whatever may be the cause, is the decrease or absence of tonic contraction of the anal sphincter. Consequently, both surgical and non-surgical treatment is aimed at strengthening the sphincter. The surgical techniques are based on creating an extrinsic constriction of the sphincter, which should keep the lumen sufficiently closed. However, to allow feces and gas passage, the endorectal pressure must overcome that of the extrinsic constriction, which is rather inelastic and yields only partially. Therefore, the constriction can neither be too tight, because it may cause difficulty in evacuation, nor too yielding, because it would not assure an effective anal closure. Thus, a closing device capable of obviating this drawback, opening the lumen to allow the fecal transit and automatically closing immediately thereafter, is necessary. This goal was reached with the use of magnets.

Before updating the events regarding the clinical experience with anal magnets, it could be interesting, and perhaps "instructive" to know how this application of the magnetic force against FI arose, becoming the only real novelty of the last 15 years in the field of surgical therapy of FI, and to assess its contribution to the solution of the FI problem until it was utilized. I had the idea of using magnetic force by observing the application of magnetic devices in gut surgery for a variety of purposes, as recently reviewed by Gagner[3], and in particular the creation of gastrointestinal anastomoses[4-6]. These are carried out by a couple of small magnetic disks applied face-to-face inside the walls of two adjacent portions of the gut. The magnets, attracting each other, cause necrosis of the compressed tissues of the two adjacent walls, creating a "passage" through them, with the aim of bypassing a distal lumen occlusion caused by scarring stenosis or an inoperable cancer. This application of the magnetic force made me think that a couple of magnets with a less powerful attraction force placed face-to-face outside the opposite walls of a sphincter, by attracting each other, could close the lumen without damaging the tissues.

Therefore, in July 2003, I sent to the Journal of Biomechanics[7] a description of a bench experiment [Figure 1][3] in which two magnetic plaques were positioned to attract each other, squeezing as pliers an easily compressible rubber tube, within which water is forced to flow under pressure generated by a pump. If the pressure produced by the two plaques overcomes the pressure inside the tube, the water no longer flows (such as when the anal sphincter is closed), and vice versa if the pressure value of the lumen exceeds the attraction force of the magnetic clamp (such as when the abdominal and rectal musculature push the fecal content). Immediately after the stool has passed, the intraluminal pressure lowers, and the pressure of the magnetic pliers again prevails and closes the anal canal. The force of closure of the magnetic pliers may be chosen by selecting magnets with a more or less powerful force of attraction. This experiment was devised for reinforcing the lower esophageal sphincter (LES) to prevent gastroesophageal reflux (GER), but, as you can well imagine, it may also be applied to the anal sphincter to prevent fecal incontinence. This magnet application, which can be called a "magnetic sphincter", seemed to meet the requirements mentioned above, so that it could be used for a dynamic reinforcement of any weak sphincter. Note that the article with this experiment, sent to the aforesaid journal in 2003, was published in 2006, i.e., three years after its reception.

Meanwhile, a sophisticated magnetic device to reinforce the lower esophageal sphincter based on the same mechanism was manufactured, which appeared on the clinical scene in 2008. It was experimented on patients with gastroesophageal reflux by Bonavina *et al.*, under the name of LINX magnetic sphincter augmentation (MSA), produced by TORAX Medical, Inc. Share View, Minnesota, USA[8]. Subsequently, in 2010, Lehur *et al.* published an article concerning the treatment of patients with fecal incontinence by

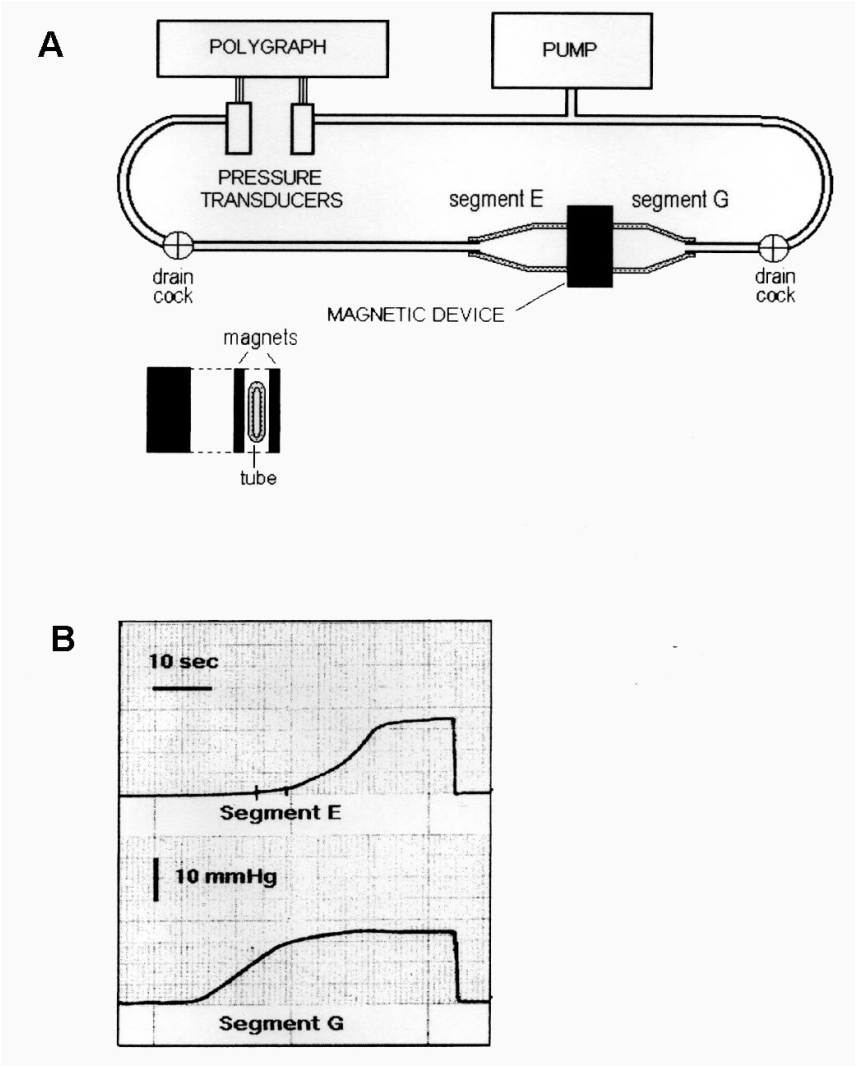

Figure 1. (A) Schematic illustration of the bench model used to study the new antireflux device based on magnets. On the right, there is a flaccid polyethylene tube 2.8 cm in diameter, mimicking the gastroesophageal junction. It is squeezed perpendicularly by two rectangular magnets made of plastoferrite (Flexo) 2 cm × 4 cm × 0.5 cm with an attraction force of 0.36 N/cm^2 when put in contact and 0.16 N/cm^2 at 7 mm distance. It creates a high-pressure zone 2 cm wide that divides the tube into Segments E (esophagus) and G (stomach). The tube is perfused with water by a pump, and the pressure variations of each segment are detected with two pressure transducers and recorded by a polygraph. (B) Intraluminal pressure variations in Segments G (bottom) and E (top). The pressure of Segment G (stomach) was progressively increased by the pump, and, when it reached the value of about 11.5 mmHg, the magnets, simulating the sphincter, were detached, so that the pressure in Segment E (esophagus) started to increase, mimicking gastroesophageal reflux and reaching the level of Segment G. Once the pump stopped, the pressure dropped and the magnets adhered again, closing the passage. Exchanging the Segment E for G and Segment G for E, this sequence of events may represent the passage of a bolus through the zone squeezed by the magnets. From: Ref.[7] (Reprinted with permission).

means of a magnetic device named FENIX magnetic anal sphincter augmentation (MAS) produced by the same company, which was similar to the previous one[9].

In the years following, many other studies with MAS were performed, and today the time has come to assess the successes and failures of this device, as well as its drawbacks and complications, before considering the present perspective.

THE MAS "MAGNETIC COLLAR" ANTI-INCONTINENCE SYSTEM

The magnetic anal sphincter[10] is made up of a series of titanium beads with magnetic cores connected with a flexible titanium wire along which they may slide one against the other, being attracted by their magnetic force [Figure 2][9]. This string of beads, also called a "magnetic collar", is surgically placed in a tunnel around the anal canal, adapting the number of magnets to the previously measured circumference to surround and tighten[11]. The increase in pressure inside the anal lumen during the evacuation moves the beads away along the wire, widening the collar and consequently the anal lumen, thus enabling the passage of feces. After evacuation, the endoluminal pressure decreases and the collar tightens again, closing the lumen.

Effectiveness of the MAS device in preventing fecal incontinence

The first report of the effects of this "magnetic collar" on fecal incontinence[9] was not very satisfactory, as it showed an improvement at six months in only 5 of 14 patients (all females). In these patients, the number of FI episodes/week decreased from 7.2 to 0.7 and the Wexner Continence Score from 17.2 to 7.8, whereas the FI Quality of Life Score (FIQoL) improved in all domains. After the first slightly disappointing study, in the subsequent years, there were others [Table 1], some of which with satisfactory results[12,13] and others completely negative[14], whereas another with favorable results[15] was demoted by numerous adverse events. More recently, a single-center study was published by Kim *et al.* collecting 45 patients (43 females) with a mean follow-up of 36 months (range 6-84 months), some of whom had been included in other publications and the MOS-STIC trial (MOS, Magnets Or Stimulation; STIC, "Soutien aux Technologies Innovantes et Coûteuses")[9,15-17]. This study did not add significantly better results regarding Cleveland Clinic Incontinence Score (CCIS) and FIQoL with respect to those of the previous studies, but it established an interesting correlation between patient satisfaction and a reduction of FI episodes of ≥ 50% or a postoperative decrease by ≥ 5.5 points of CCIS. In this study, 48% of patients declared they were satisfied in correlation with the postoperative decrease of CCIS by ≥ 5.5 points. Furthermore, the authors performed an analysis of the causes of success or failure in patients implanted with MAS. They concluded that factors such as the origin of FI, previous damage to the sphincter, and its manometric values did not influence the outcome, whereas the only independent predictive factor for success after MAS implantation was no previous FI surgery. To better evaluate the results of MAS treatment, it was deemed necessary to compare them to those of other surgical therapies for FI.

The comparison of MAS with Acticon Neosphincter to artificial bowel sphincter (ABS) and sacral nerve stimulation (SNS), albeit carried out in two small nonrandomized studies by Wong *et al.* [Table 2], showed that MAS did not obtain significantly better improvements in continence and quality of life as compared with the two other groups[18,19]. The only differences of MAS with ABS were in the lower number of devices "gone out of action" and in the fewer cases with fecal impaction and constipation. In the comparison with SNS, similar adverse events were observed in both groups. However, the follow-up of patients with ABS was about three times longer than those with MAS. Furthermore, it is important to observe that continence results similar to those of MAS with fewer adverse events have also been obtained by some anal canal narrowing techniques, such as anal slings[20] and bulking infiltrations[21] [Table 3]. However, most of these studies were characterized by follow-ups shorter than those of MAS and by patients with less severe FI. Consequently, these anal canal narrowing techniques require other prospective, randomized controlled studies to be considered as an alternative to MAS. Finally, a comparison between the two FI treatments MAS and SNS was the target of two multicenter, prospective, randomized, interventional, controlled trials announced in 2016, the French MOS-STIC[17] and the English SaFaRI[22]. The English SaFaRI trial in 2021 concluded that the success of FENIX was lower than previously reported, with high postoperative morbidity[23], whereas I have not been able to find the outcome of the other trial.

Table 1. Clinical effectiveness against FI and adverse events reported in a series of the most representative single- and multicenter studies after MAS implantation

	Barussaud *et al.*, 2013[12]	Bridoux *et al.*, 2014[14]	Pakravan *et al.*, 2015[13]	Sugrue *et al.*, 2017[15]
Patients number and mean age	23 (all females) 64 years (35-78)	7 (6 females) 57 years (31-65)	18 (15 females) 69 years (31-91)	35 (34 females)
Mean follow-up with range (months)	17.6 (6-36)	9 (1-20)	12-24.6	60 (6-72)
CCF-IS (average score)	From 15.2 to 6.9[a,]*		From 17.5 to 7.3[a]	From 15.7 to 7*
FIQoL median index (average of 4 scales)	From 1.97 to 3.19[a,]*	No significant improvement in all 4 domains[a]	Significant improvement in all 4 domains	From 8.2 to 12.8*
Wexner score		From 16 to 14.2[a] NS None reached > 50% reduction		
Patient satisfaction	69%	none	all	53%
Device explantation or expulsion	13%	71%	0	20%
Stoma creation			1	1
Difficulty in evacuation	17%			20%
Rectal perforation during surgery	1		1	
Local pain	14%	29%	29%	14%
Infection		43%	5	11%
Bleeding				9%

*Statistically significant; [a]at six months; NS: statistically not significant; FI: fecal incontinence; MAS: magnetic anal sphincter; FIQoL: fecal incontinence quality of life; CCF-IS: Cleveland Clinic Florida Incontinence Severity.

Table 2. Comparison between the clinical outcomes of patients undergoing magnetic anal sphincter and artificial bowel sphincter implantations drawn from the study by Wong *et al.* (2011)[18] and a comparison between those of magnetic anal sphincter and sacral nerve stimulation from the study by Wong *et al.* (2012)[19]

	Magnetic anal sphincter	Artificial bowel sphincter	Magnetic anal sphincter	Sacral nerve stimulation
Number of patients	10 (10 women)	10 (10 women)	12	16
Mean follow-up (months)	8 (range, 6-13)	22.5 (range, 6-72)	18 (range, 8-30)	22 (range, 10-28)
Jorge Waxner median score	From 17 to 6*	From 16 to 4*	From 16.5 to 6*	From 15 to 11.5*
FIQoL median score	From 2.03 to 3.51*	From 1.80 to 3.63*	Significant improvement in all 4 components	Significant improvement in all 4 components
Resting anal pressure cm H_2O (median)	From 35 to 58.5*	From 34 to 75*	From 42.5 to 54*	From 34 to 33
Device explantation, extrusion, or stopped working	1 extrusion (spontaneous) 1 stopped working	4 revisions 2 explantations 2 stopped working	1 extrusion (spontaneous)	1 explantation
Fecal impaction, constipation, or anti-diarrheal	1 impaction 1 constipation	2 impactions 4 constipations	1 impaction 1 constipation 2 antidiarrheals	1 constipation 6 antidiarrheals
Infections		1		1
Bleeding	2		2	
Pain		1		

*Statistically significant; FIQoL: fecal incontinence quality of life. Note: The scores of incontinence severity and of FIQoL represent the mean values measured before intervention followed by those observed at the end of the study. From: Ref.[41] (Reprinted with permission).

Adverse events and malfunctions of MAS

The assessment of the causes of adverse events and the analysis of malfunctioning mechanisms of MAS may be useful, not only to characterize this device but also to conceive an alternative to this magnetic sphincter

Table 3. Comparison of the clinical outcomes after MAS device implantation from the study by Sugrue[15], the insertion of perianal elastic band from the study by Devesa *et al.*[20], the intra-anal injection of collagen from the study by Maslekar *et al.*[21]

	Magnetic anal sphincter	Elastic band perianal sling	Collagen intra-anal injection
Number of patients	35 (34 women)	33 (20 women)	100 (70 women)
Mean follow-up (months)	60	65	36
Symptom subjective improvement	53%	97%	68%
Incontinence severity (average scores)	From 15.7 to 7* (Cleveland Clinic Incontinence Score)	From 15 to 7* (Jorge-Wexner Score)	From 14 to 8* (Cleveland Clinic Incontinence Score)
FIQoL median index (average of the 4 scales)	From 8.2 to 12.8*	From 7.8 to 14.3*	Not done
Device explantation or reoperation	7 explantations (infections, erosions, and ineffectiveness) 1 creation of stoma for fecal impaction	13 sling removals (sling breakage, infections, and erosions), with 10 reinsertions and further removals in 3	38%: 2nd injection 15%: 3rd injection
Adverse events (total)	30	13	None
Difficulty in evacuation	20%	None	None
Pain	14%	None	None
Erosion	11%	6%	None
Infection	11%	12%	None
Bleeding	9%	None	None

*Statistically significant; MAS: magnetic anal sphincter. Note: The scores of incontinence severity and FIQoL represent the mean values measured before intervention followed by those observed at the end of the study. From: Ref.[41] (Reprinted with permission).

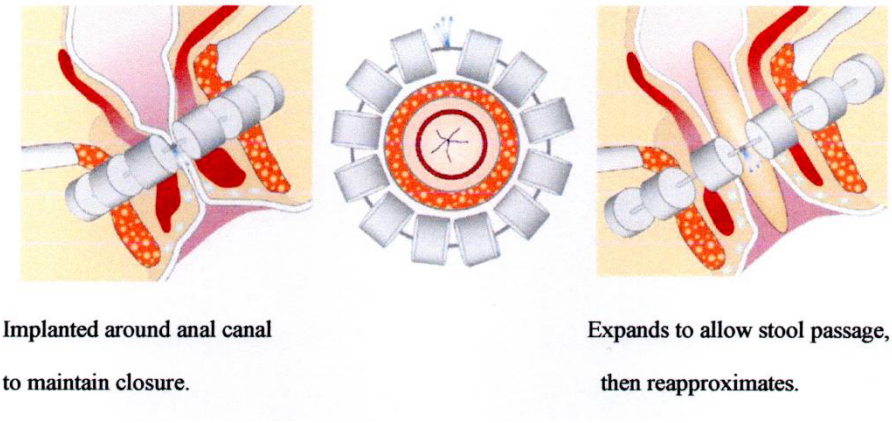

Figure 2. Magnetic anal sphincter augmentation device: closed (left); and open (right). From: Ref.[9] (Reprinted with permission).

devoid of its flaws. The rate of major complications that led to explantations and extrusions of the device and stoma creations reported in various studies[9,12-16,18,19] may reach a mean value of 18.3%, which is higher than that after SNS (5%)[24] but less than after ABS (24%)[25]. Patients with previous anorectal surgery may have a higher incidence of adverse events, for which Kim *et al.* suggested that these patients should be excluded from the MAS implantation by protocol[16]. During the creation of the tunnel around the anal sphincter, there is a risk of rectal perforation, which prevents device implantation[12,13], whereas after explantation, the defecatory function is compromised and a stoma creation is sometimes necessary[9,15]. In some cases, the useless device was left "in situ" and a stoma was created to avoid further complications[15].

Another complication is represented by the erosions of the anorectal wall, whose frequency is much higher than that after the "magnetic collar" LINX implantation for GER[26]. These erosions are likely caused by the padding of the "magnetic collar" FENIX against the rectal wall, together with the constriction due to the attraction of the magnets. In some cases, the deepening of the erosion up to the mucosa may cause frequent bleedings and can lead to the device penetrating into the rectal lumen, followed in rare cases by its spontaneous expulsion[9,12]. The device sometimes may harm the tissues so much that not only it is impossible to insert into another one, but it becomes necessary to make a stoma[9,12,15].

The appearance or worsening of incontinence and constipation, up to fecal obstruction, which begins to manifest itself some time after insertion, is likely due to an intervening malfunctioning of the device. In fact, although the working mechanism of MAS for closing and opening the anal canal denotes a high engineering skill and the device on the bench works perfectly, once implanted in an organism, it has to deal with the biological reaction of the tissues. Fibrotic production takes place around the device, as demonstrated by the necropsy carried out after 44 weeks in pigs with a similar "magnetic collar" implanted, which appeared encapsulated in fibrous tissue[27]. This phenomenon was also confirmed in some patients in whom the LINX device for LES was explanted for serious complications[28,29]. The fibrosis around the device could likely, in some way, hamper the detachment and reattachment of the magnetic beads, which must slip along the wires to open and close the rectal lumen[30]. The anal "magnetic collar" also inevitably follows the same destiny of being encapsulated in fibrous tissue, as observed in a series of studies in dogs[9]. Furthermore, the fibrous tissue becomes increasingly hard and rigid over time, and it is reasonable to suppose that in some cases, it could interfere with the movements of the magnetic beads of the device in an open or closed position, leading to incontinence or defecation difficulty, respectively. This phenomenon could explain the cases of worsening incontinence as well as the appearance of defecatory dysfunctions complained of by some patients. However, if, by hypothesis, the MAS device is completely blocked in the opening state by fibrosis, it could still be able to prevent the loss of feces. In fact, the "magnetic collar" could pad the wall of the anal canal, mimicking the anti-incontinence effect of a sling or a bulking agent. On the other hand, if this padding against the canal wall becomes too strong, an impairment of the evacuation and other complications described above could take place. A defecatory dysfunction or incontinence could also occur as a result of an incorrect length of the "magnetic collar" placed inside the tunnel around the anal sphincter. If the device is too tight, an obstruction or a difficult defecation could take place, whereas if it is too large, a liquid leakage may occur. The same phenomenon could also occur during device insertion. When adding a bead, the collar comes out too wide, giving rise to leakage; conversely, by not adding it, the collar becomes too tight, causing difficulty in evacuation. The decision can be taken based on the consistency of the stool: adding the bead with a solid stool and avoiding it with soft stool[9,12].

Comment on the results of MAS treatment

As previously reported, the clinical effectiveness of MAS is comparable to that of other methods of treatment, such as ABS[18] and SNS[19]. All these techniques, however, are unable to prevent minimal loss of stool, especially liquid stool, and even flatus[13,16]. Considering the causes of success or failure after MAS implantation, only previous surgical interventions, such as those of SNS, ABS, and injection of bulking agents, may prognosticate a negative result[13,16]. Furthermore, Pakravan *et al.* argued that implantation of MAS in patients, e.g., those of Bridoux *et al.*, who are younger and more dynamic, with respect to those of their own study, may lead to worst results[13,14]. They concluded that better results with MAS implantation are obtained with older patients and those with a sedentary lifestyle.

Despite the lackluster performance of MAS treatment and the not negligible number and severity of adverse events, the MAS system was approved by US Food and Drug Administration (FDA) as a Humanitarian Device Exemption for its use in patients with FI who do not respond to SNS. Consequently, the

implantation of MAS should not precede that of SNS, whereas the latter has been proposed as a surgical treatment in selected patients with end-stage FI[9,12,13]. However, the indication for patients with idiopathic moderate to severe FI remained uncertain, also because other surgical managements with fairly good effectiveness and a low or null risk of serious complications present themselves as valid candidates. The insertion of silastic slings[20] or the local infiltration of bulking agents, such as collagen[21] and Gatekeeper[31], proved to be valid in the comparison with MAS [Table 3], not only for anti-incontinence efficacy, whose shorter duration in the long term is offset by easy repeatability, but also for the scarcity of adverse events, simplicity of realization, and low cost. Bulking agent injection or perianal elastic slings could compete with MAS in the treatment of borderline severe FI, whereas MAS was considered for patients with severe incontinence refractory to other major surgical treatments[16].

However, while the indications for MAS were being discussed and other studies were being conducted and planned to compare MAS and SNS, as mentioned above, bombshell news arrived that took everyone aback and disrupted those programs. Torax Medical, part of the group Ethicon Johnson and Johnson, decided to discontinue sales and clinical studies on the FENIX continence restoration system, i.e., MAS. A severe protest was raised by Lehur *et al.* in an Editorial published in 2020[32], complaining that the industry would, practically speaking, deprive all incontinent patients worldwide of an effective possibility to efficaciously fight severe fecal incontinence, being the result of the ABS device lower than expectations, mostly due to a high rate of complications. He concluded that, given the fact that the artificial anal sphincter is practically in a deadlock, it is time to (re)develop a reliable artificial anal sphincter device. On the grounds of the decision to suspend the FENIX availability, one may wonder if the magnetic solution for FI has reached a dead-end. I do not believe that, but I am certain that MAS was only an inadequate realization of a good idea, as I wrote in 2015[33], and that another type of magnetic device, more efficient and with a lower risk of complications, could be realized, as explained below.

THE NEW ERA OF THE "TWO PLAQUES" ANTI-INCONTINENCE

For the reasons expressed above, I believe that this is the moment to develop another anti-incontinence magnetic device following the original idea with two magnetic plaques to reinforce the incontinent anal sphincter.

This new anti-incontinence system consists of two small plaques, which are to be placed between the external and internal muscle bundles [Figure 3][34], or outside them, positioned on the antero-posterior and longitudinal plan, with the opposite polarities face to face in order to attract each other, squeezing the anal canal as pliers. These two plaques covered by a biocompatible and soft material must be fixed to the surrounding tissues with suture thread passing through appropriate holes of the plaques. When the endoluminal pressure increase induced by defecation exceeds the attraction force of the magnets, they become detached, thereby opening the anal lumen. When the stools have been expelled, the endoluminal pressure reduces to a level lower than the force of attraction of the two plaques, which approach again, closing the lumen.

The force of this magnetic closure was evaluated in a pilot study[34] in a series of porcine anatomical preparations weighing from 25 to 35 kg. The three pairs of magnets tested in the experiment were ovoidal in shape and showed a diameter of 20-30 mm, a thickness of 1.5-2.5 mm, and were made of different magnetic materials that had different forces of attraction: one was *neodymium*, which is stronger than *ferrite* and more powerful than *plastoferrite*, the other two materials. The endoanal pressure was measured manometrically, averaging the values of three pull-throughs of a slight side-hole catheter perfused by means of a pump and joined to a Statham P23 Db pressure transducer and a Beckman R 612 polygraph to record

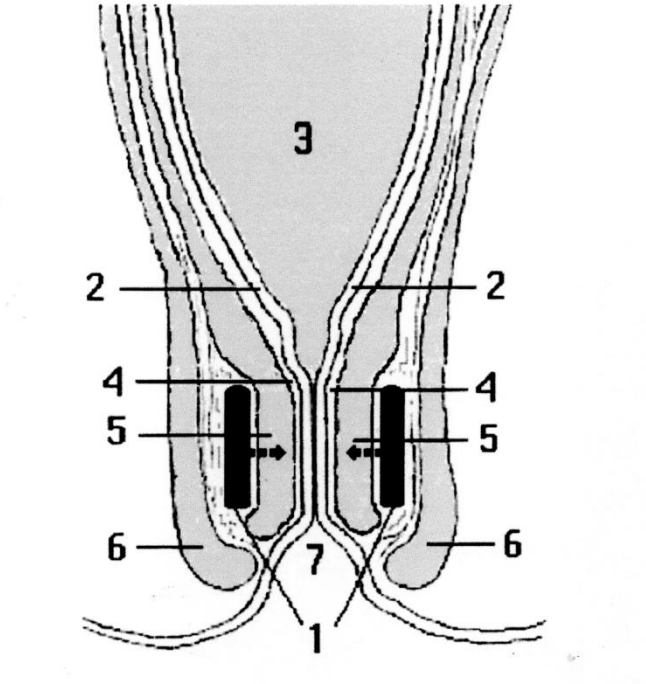

Figure 3. Schematic section following a vertical frontal plane of the recto-anal region showing the pair of magnets in profile (1) inserted between the muscular bundles of the internal (5) and external (6) anal sphincters, with the opposite polarities face to face attracting each other. Note: (2) mucosa; (3) rectal ampulla; (4) submucosa; (7) anus. From: Ref.[34] (Reprinted with permission).

the pressure values. The mean endoanal pressures obtained before and after implantation of each magnetic couple were compared with the basal value by means of the Student t-test. The results are reported in Figure 4. The pair of *neodymium* magnets showed an endoanal pressure of 79.7 ± 13.1 mmHg (mean ± SD), whereas those of *ferrite* and *plastoferrite* displayed values of 42.1 ± 5.6 and 21.6 ± 4.6 mmHg, respectively. All of these values of endoanal pressure were significantly higher than the basal value of 1.72 ± 0.71 mmHg. The results of this experiment demonstrate that we may choose a pair of magnets that, when implanted outside the anal canal, creates a local zone of high pressure with values higher than the previously measured value of the patient with fecal incontinence.

Advantages of the "two-plaque" system

As explained above, unlike the other anti-incontinence systems that narrow more or less consistently and continuously the anal lumen and create an obstacle to the passage of stool during defecation, the "two-plaque" magnetic system realizes a "dynamic closure" of the anus. In the basal condition, the two plaques keep the anus closed, whereas during defecation, they detach, leaving an easy passage of feces. Furthermore, this system possesses several theoretical advantages over the MSA system consisting of a collar of magnets. As explained above, the latter device, albeit denoting a skillful engineering quality and operating perfectly at the workbench, once placed into an organism, is progressively wrapped by a coating of fibrous tissue, which with time becomes stiffer and could cause its dysfunction in some cases. On the contrary, the "two-plaque" system does not have mechanical sliding parts that could be blocked by fibrin deposition and, therefore, is not subjected to this drawback. In fact, the fibrin coating around each magnetic plaque does not hinder the attraction force that acts through the lumen of the anal canal, so that the magnetic plaques are free to approach and separate. Moreover, the fibrin encapsulation, instead of impeding their operative activity, may contribute to securing them in their cranny of the rectal wall, in addition to other fixing systems (hooks, anchors, suture stitches, biological glue, etc.), to avoid their expulsion.

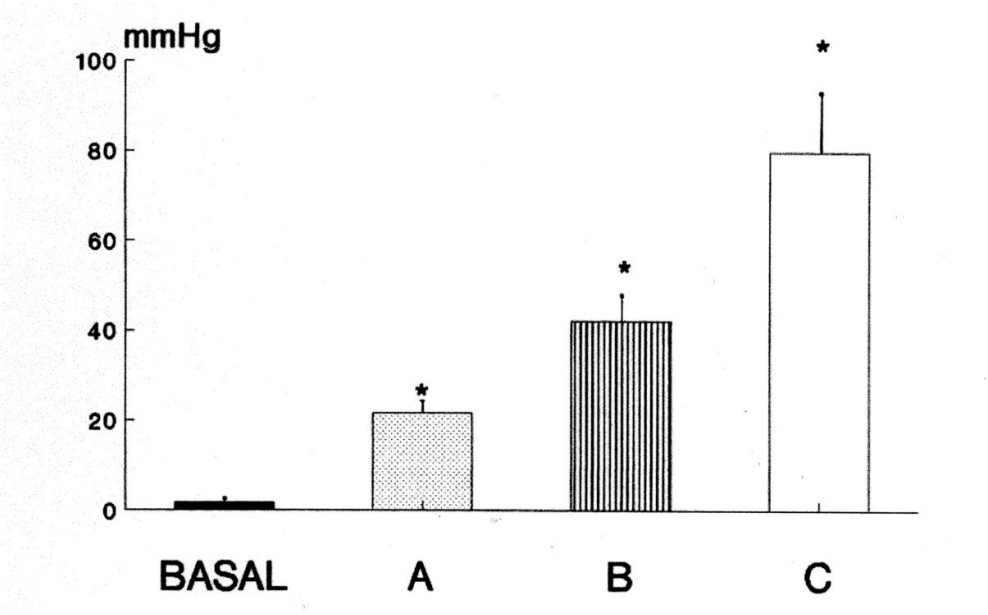

Figure 4. Anal pressure measured manometrically in basal conditions and after the insertion of the magnets made of: plastoferrite (A); ferrite (B); and neodymium (C). * $P < 0.05$. The endoanal pressure after the insertion of neodymium magnets was 79.7 ± 13.1 mmHg (mean ± SD), after ferrite magnets 42.1 ± 5.6 mmHg, and after plastoferrite magnets 21.6 ± 4.6 mmHg, all of them significantly higher than the pressure recorded in basal conditions (1.72 ± 0.71 mmHg). From: Ref.[34] (Reprinted with permission).

Another advantage of this method, unlike the "magnetic collar", lies in the possibility of adapting the force of closure to the local characteristics of each patient by choosing magnets with different attraction forces and sizes. In fact, the distance between the two plaques due to interposed tissues may vary from one patient to another, the force of attraction of the magnets varies with the square of the distance, and the weakness entity of the anal sphincter may also vary from one patient to another. Consequently, plaques with greater attraction force are required for greater distances and for weaker sphincters, and vice versa. The choice of magnets may be oriented by measuring with a manometric probe or other systems before implantation, as suggested by Bharucha *et al.*, the anal sphincter tone, or better, during the magnet implantation, the endoanal pressure produced by magnets[35]. In this way, by choosing the magnets with the most suitable attraction force, a "tailored augmentation" of the anal sphincter can be obtained, on the one hand sufficiently high to prevent fecal incontinence and fluid leakage at rest[36] and on the other hand sufficiently low to be overcome by the endorectal pressure increase during defecation. This system of intraoperative manometric measurement and choice of the plaques more suitable by force of attraction, together with shapes that better fit their anatomical position and coverage with a soft bio-compatible material on the face towards the anal lumen, should avoid the complication of ischemia and erosions of the compressed tissues.

A further, not insignificant advantage is represented by the fact that the surgical procedure for implanting the plaques is presumably less complex with respect to that of the "magnetic collar", which requires both the laborious creation of a tunnel around the anal canal, a procedure that may expose to rectal perforation[13], and the measure of its circumference with a sizing tool[11].

Furthermore, the plaques can be easily disinfected and sterilized, thus making the appearance of local infections more difficult, a not uncommon complication during this kind of operation for fecal incontinence.

Finally, the "two-plaque" system would cost less than the "magnetic collar" system, as regards both the device and the complexity and duration of the intervention.

This "two-plaque" system may be applied to reinforce any other gut sphincter that has lost its tone and function, for example, the LES, with the aim of preventing gastroesophageal reflux, as it has already been devised and experimented in *ex vivo*[37] and *in vivo*[38] animals.

FINAL CONSIDERATIONS

Nowadays, the disappearance from the market of the FENIX magnetic anal sphincter has left a void that must be filled with another device capable of adequately treating patients with severe FI, once an SNS or sacral nerve modulation (SNM)[39] attempt has failed. Indeed, the Acticon Neosphincter ABS, although it works satisfactorily, has some limitations and has turned out to be over time below expectations, especially as regards the adverse events[40]. Thus, it is desirable to develop a more reliable device whose performance must closely resemble that of a natural sphincter. To achieve this, researchers have to consider the development of a device based on magnetic activity. However, it is not worthwhile to waste time and money to restore a device similar to MAS after the negative conclusion of the English SaFaRI trial[23] and in view of the assessment of its mediocre effectiveness with too many adverse events, as highlighted in the present study. Considering the good results of the magnetic plaques, which have proved capable of augmenting LES pressure in animals, both *ex vivo* and *in vivo,* it would be right to move forward in this direction with experiments *in vivo* also for the anal sphincter, given the good results already obtained in animals *ex vivo*[33]. In addition, as described above, this magnetic system presents some plausible advantages as compared with the MAS system. It has simpler and presumably more reliable operational activity with an easier surgical procedure for implanting the plaques; it provides the chance to choose the most suitable plaques for each patient regarding the force of attraction, shape, and dimensions, guaranteeing the possibility of a higher level of sterilization; and it should be less expensive.

The development of this kind of magnetic device requires cooperation between researchers and a manufacturing company eager to fill this gap in the market while being aware that this new road is a long and arduous one, but worthwhile undertakingas, already claimed in a previous article[41].

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The author contributed solely to the article.

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