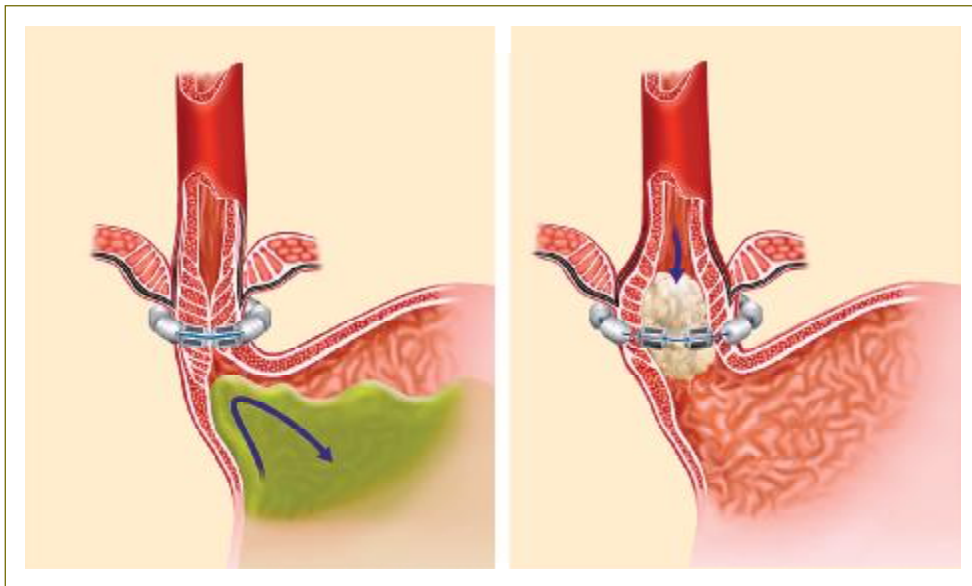




# GIE

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## Use of a magnetic sphincter for the treatment of GERD: a feasibility study

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**Background:** The success of fundoplication surgery varies widely; furthermore, complications after fundoplication can be common. We introduced a new device to treat GERD: biomechanical augmentation of the lower esophageal sphincter (LES) by use of a magnetic reinforcing appliance.

**Objectives:** The aim was to determine whether a magnetic appliance could safely increase LES pressure, maintain a closed sphincter except during swallowing and belching, and increase the gastric yield pressure in a porcine model.

**Design:** Ex vivo work-assessed design variables that would augment the reflux barrier yet still preserve swallow function. Porcine acute and chronic (44 weeks) postimplant studies were also performed. A single animal underwent planned device removal.

**Main Outcome Measurements:** Gastric yield pressure, animal behavior, endoscopy, barium studies, balloon expansion studies, esophageal manometry, and histology.

**Results:** Gastric yield pressure correlated with increasing magnetic forces ( $R^2 = 0.5608$ ,  $P < .001$ ). The sphincter augmentation device was safe in all animals, with no observed effect on eating behavior and normal weight gain. The mucosa of the esophagus appeared normal at all intervals, and there was no device migration or significant tissue inflammation. The average LES pressure rose after implantation ( $P < .005$ ). Balloon and barium studies demonstrated a closed sphincter with normal opening of the gastroesophageal junction during swallowing.

**Conclusions:** Magnetic sphincter augmentation is a novel approach for the treatment of GERD. This study demonstrates the safety and feasibility of such a device in a porcine model. Further investigation of this device for the treatment of GERD in humans seems warranted. (Gastrointest Endosc 2008;67:287-94.)

Since its original description in 1956,<sup>1</sup> the Nissen fundoplication (and variations thereof) has become the most accepted surgical procedure for the treatment of GERD. Since the advent of laparoscopy, the popularity of fundoplication antireflux surgery has soared; as of 1999 there were approximately 35,000 fundoplication procedures performed annually in the United States, mostly by the laparoscopic approach.<sup>2</sup>

Despite its current standing, the success rate of Nissen fundoplication surgery varies widely and appears to be surgeon dependent. DeMeester et al<sup>3</sup> published a case series of 100 consecutive patients with reflux who

underwent open fundoplication at an academic center and reported a 91% success rate in controlling reflux symptoms at 10 years. The same group reported on another 100 patients who had laparoscopic Nissen surgery performed; in this series, 95% of patients considered themselves cured of reflux symptoms at a mean of 21 months of follow-up.<sup>4</sup> In contrast, Vakil et al<sup>5</sup> published laparoscopic fundoplication outcomes from a managed-care organization in Milwaukee, noting that at 20 months, only 61% of 80 patients with reflux were satisfied with the surgical outcome and 32% were still taking medications on a regular basis for heartburn.

Furthermore, complications after fundoplication surgery can be common; Vakil et al<sup>5</sup> noted that 28% of patients in their series had postoperative dysphagia (11% severe enough to require dilation), 7% underwent repeat surgical procedures, and 48% of patients reported new

*Abbreviations:* GE, gastroesophageal; LES, lower esophageal sphincter.

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symptoms after surgery, including excess flatus or bloating. Patients with those symptoms had significantly lower quality-of-life scores.

Given the variability of fundoplication outcomes and the potential for significant postoperative complications, we have introduced a new method and device designed to treat GERD: biomechanical augmentation of the lower esophageal sphincter (LES) by using a magnetic reinforcing appliance (magnetic sphincter). This study was performed to determine whether a magnetic sphincter device could safely increase LES pressure, maintain a closed sphincter except during swallowing and belching, and increase the gastric yield pressure to potentially improve pathologic reflux.

The magnetic sphincter augmentation device (Torax Medical, Maple Grove, Minn) is an expansible bracelet of magnetic beads designed to be placed surgically around the exterior surface of the distal esophagus in the region of the gastroesophageal (GE) junction. Each bead is composed of a titanium case containing a magnetic core of small disk-shaped magnets. The magnets are coated in parylene and then hermetically sealed inside the cases. The beads are connected by titanium wires of specific lengths that limit the distance any two individual beads can move apart. Each bead has a hollow center that allows the individual beads to slide over the wires for bead approximation (Fig. 1A and B). The device is placed as a necklace around the GE junction and thereby augments the sphincter resistance to reflux. With each peristaltic swallow the individual beads separate, allowing the magnetic and native sphincter to open and a food bolus to pass; after passage of a bolus, the beads reapproximate and augment the closure of the sphincter (Fig. 2). Thus, the magnetic beads have the highest attractive force when closed to augment the sphincter as a barrier to reflux but have a low enough attractive force to allow separation during swallowing for passage of a bolus. By disassociating the barrier force with the swallow/bolus force, it is anticipated that normal swallowing function can be preserved (Fig. 1A and B).

Moreover, the magnetic force between beads can be varied depending on the size, strength, and mass of the magnets within each case, the geometry of the titanium cases, and the length of the wires. The devices used in this study had the following intended performance specifications: (1) the proper magnetic force and the proper length of wire so that, when closed, the magnetic force would augment the sphincter sufficiently to prevent reflux events yet be weak enough to allow peristalsis to open the device; (2) the necklace should partially open to permit belching, to vent a distended stomach; (3) when opened, the lowest attractive force should be strong enough to allow reapproximation of the magnets; (4) the open diameter of the necklace should be at least 60F to allow adequate esophageal distention; (5) the closed magnetic force should be at a level that would not cause dysphagia; (6) the device should be atraumatic, not cause inflammation or erode into adjacent tissue; (7)

### Capsule Summary

#### What is already known on this topic

- Fundoplication for the treatment of GERD is associated with significant postoperative complications, including dysphagia, excessive flatus, and bloating.

#### What this study adds to our knowledge

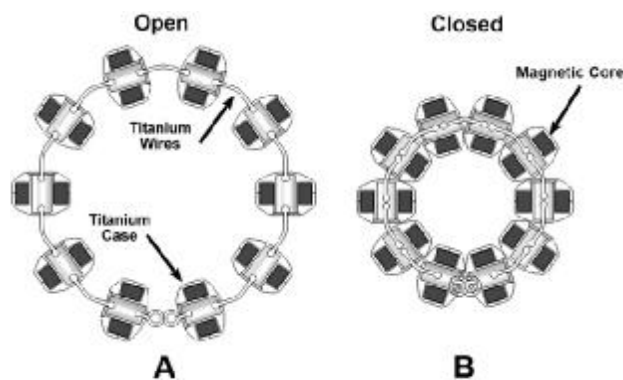
- In a porcine model, esophageal sphincter augmentation with magnetic beads was safe, had no effect on eating behavior or weight gain, did not cause significant tissue inflammation, and increased the lower esophageal sphincter pressure.

the necklace should not migrate after placement; and (8) the necklace could be safely removed if necessary.

It is notable that a singular and most unique aspect of an augmentation device based on magnetic force is that, unlike any other type of device design (springs, coils, wraps, elastics, nitinol, etc.), as magnets displace, the attractive force decreases. With all other types of designs the restraining force increases with displacement. Thus with a magnetic sphincter device, progressively larger food boluses should be just as easily swallowed as smaller boluses. Furthermore, magnet forces are permanent and do not decay over time.<sup>6</sup>

## METHODS

The magnetic sphincter augmentation device was bench tested to measure and characterize its various functions. Extensive ex vivo work was conducted to assess key design variables, including the geometry of the titanium cases, magnetic mass, wire lengths, and magnet forces both in closed and expanded position, and to determine the optimal designs that would augment the reflux barrier yet preserve swallow function. For this study we used a cylindrical case design with a 5.85-mm diameter, wire lengths of 2.8 to 6.2 mm, and magnet forces of 0.20 to 0.78 newtons between beads when approximated (closed) and 0.03 to 0.12 newtons when expanded. Preclinical testing was performed to demonstrate that the magnetic sphincter devices, with forces in this range, could be at least partially expanded with balloons at pressures no higher than 20 mm Hg (Numed, Hopkinton, NY). Circumferences of the devices used varied between 3.1 to 4.1 cm closed and 5.3 to 7.5 cm fully expanded. The magnets, composed of neodymium-iron-boron, were manufactured and coated in parylene by Duramagnetics Corporation (Sylvania, Ohio) and then hermetically sealed in the titanium cases. Parylene is a polymeric coating widely used in the medical device industry for its safety, biocompatibility, and acid-base resistance.<sup>7</sup>

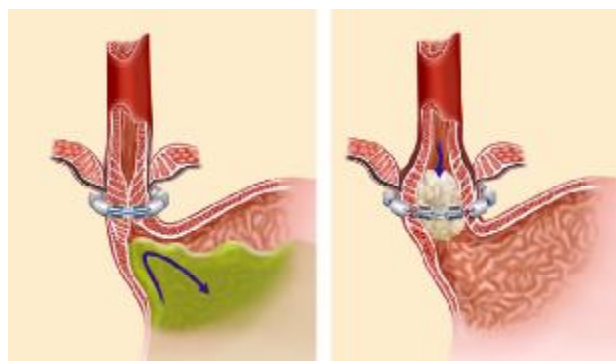


**Figure 1.** Engineering schematic. **A**, Lowest force. **B**, Highest force.

Magnetic forces were measured on a custom-built test apparatus (Torax Medical). A stepper motor-powered linear slide (Compumotor, Rohnert Park, Calif) was used to expand the device at a rate of 1.5 cm/min. Expansion force was measured by a 1-kg force transducer with a strain gauge meter for signal conditioning (Omega Engineering, Stamford, Conn). Expansion distance was measured with a linear variable differential transformer and a process controller for signal conditioning (Omega Engineering). Force and distance measurements were acquired on a computer with a USB-based analog to digital converter (Measurement Computing, Middleboro, Mass) and a custom-written software program. The acquired data were plotted with Microsoft Excel (Microsoft Corp, Redmond, Wash. The overall apparatus was independently calibrated (Kennedy Scales, Minneapolis, Minn).

Ex vivo studies were performed to determine gastric yield pressure (gastric pressure at which the native and augmented lower esophageal sphincter opened). These studies were performed by using a porcine stomach model with the pylorus ligated to prevent opening and the magnetic sphincter device placed circumferentially around the most distal portion of the tubular esophagus at the GE junction region. The devices were placed circumferentially at the GE junction and anchored by tunneling under both trunks of the vagus nerve. Water was perfused into the stomach through a posterior gastrotomy, and yield pressure was measured with an internal manometry catheter (Clinical Innovations, Salt Lake City, Utah) attached to an external transducer (Merit Medical Corp., Salt Lake City, Utah). Twenty consecutive measurements were made. For this portion of the study the magnetic force between beads was varied between 0.20 and 0.78 newtons when approximated, and a correlation plot for yield pressure and magnetic force in newtons was constructed.<sup>8</sup>

Chronic in vivo studies were done in the pig because porcine peristaltic pressures are similar to those in humans<sup>9</sup>; we specifically used Sinclair pigs because adults of this species tend to have less skeletal or internal organ growth than domestic swine over long-term follow-up.



**Figure 2.** Magnetic sphincter simulation.

Ten live male Sinclair pigs, weighing approximately 50 kg, underwent laparotomy under general anesthesia (telazol 6 mg/kg, propofol 1-2 mg/kg), and each was sequentially implanted with a single magnetic sphincter augmentation device over a period of several weeks (Experimental Surgical Services, University of Minnesota). No antibiotics were used. After access to the GE junction was made, a sizing tool was used to determine the optimal number of beads on each necklace per animal; this varied between 8 and 11 magnetic beads, depending on the circumference of the esophagus. Care was taken during the sizing process to ensure that the magnetic sphincter fit closely around the GE junction without compressing the esophagus. This portion of the study was conducted with devices with magnetic forces of 0.17 to 0.57 newtons between beads when approximated (device closed) and 0.03 to 0.12 newtons between beads when apart (device open) (Table 1). (These forces were chosen in part because earlier animal testing with dogs demonstrated canine inability to eat with closed force magnets approximating 0.981 newtons.) Two animals were implanted with magnetic beads and necklaces that had relatively low closed forces (0.17 newtons between beads when approximated) and low open forces (0.03 newtons between beads when apart), 2 with devices that had medium closed forces (0.35-0.36 newtons) and relatively elevated open forces (0.11 newtons), 4 with devices that had elevated closed forces (0.45-0.57 newtons) and low open forces (0.04-0.05 newtons), and 2 with devices with elevated closed forces (0.48 newtons) and elevated open forces (0.12 newtons) (Table 1).

The devices were positioned in the region of the GE junction, at the most distal section of the tubular esophagus and below the crus of the diaphragm, similar to where a Nissen fundoplication would be placed, and were anchored by tunneling under both the anterior and posterior vagus nerves and through the adherent perineural tissue. The implant time varied between 10 and 30 minutes. LES pressure was measured at baseline and after implant by a standard pull-through technique. Animals were

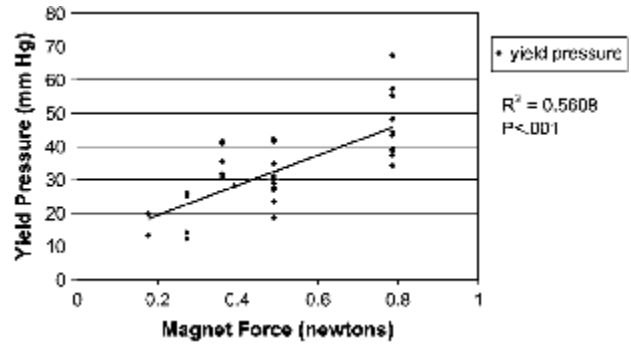
**TABLE 1. Magnet force categories**

Animal No.	Closed force (N)	Open force (N)	Category closed/open force
1	0.17	0.03	Low/low
2	0.17	0.03	Low/low
3	0.36	0.11	Medium/elevated
4	0.35	0.11	Medium/elevated
5	0.45	0.05	Elevated/low
6	0.45	0.04	Elevated/low
7	0.49	0.05	Elevated/low
8	0.57	0.05	Elevated/low
9	0.48	0.12	Elevated/elevated
10	0.48	0.12	Elevated/elevated

followed closely for 20 to 44 weeks. Animals were given food and water and were allowed to eat ad libitum. Animal eating was observed daily for changes or adverse events, and animal weights were monitored monthly. Endoscopy, balloon expansion studies (Numed 25 mm balloon), and barium swallow studies with thin barium and mixed food were performed at baseline and at monthly intervals after implant. Endoscopy was performed to assess for device migration, inflammation, erosion, or obstruction of the GE junction. Balloon expansion and barium boluses of contrast and food were used to assess opening and closing of both the devices and the GE junction. The barium swallows were done with a nonsedated animal, sitting or standing while in a clear acrylic box, with a portable C-arm placed over the top of the box, to record a cine loop while the pig swallowed barium boluses of canned dog food (Science Diet; Hill's Pet Nutrition, Inc, Topeka, Kan) rolled in ground corn meal. The volume of the bolus was not predefined but was large enough to create a bolus several inches in length as it traveled through the esophagus. Balloon inflations were done on a sedated supine pig under portable C-arm fluoroscopic visualization.

Animals were arbitrarily euthanized at 20, 30, and 44 weeks to determine device migration, obstruction, or tissue inflammation/erosion. After necropsy, the esophagogastric block was sectioned in the area of interest to evaluate the chronic healing response at the implant site. Tissues were fixed in neutral buffered formaldehyde (Formaldefresh, Fisher, Fairlawn, NJ) and histologic evaluation was performed (Charles River Laboratories, Frederick, Md) by an independent veterinary pathologist.

A single animal underwent planned device removal at 40 weeks postimplant to determine ease of removal of the device. This animal was followed after removal of the device for 4 weeks and was then euthanized. The study design and method followed Institutional Animal Care



**Figure 3.** Yield pressure versus magnet strength. Closed circles, Yield pressure.  $R^2 = 0.5608$ ;  $P < .001$ .

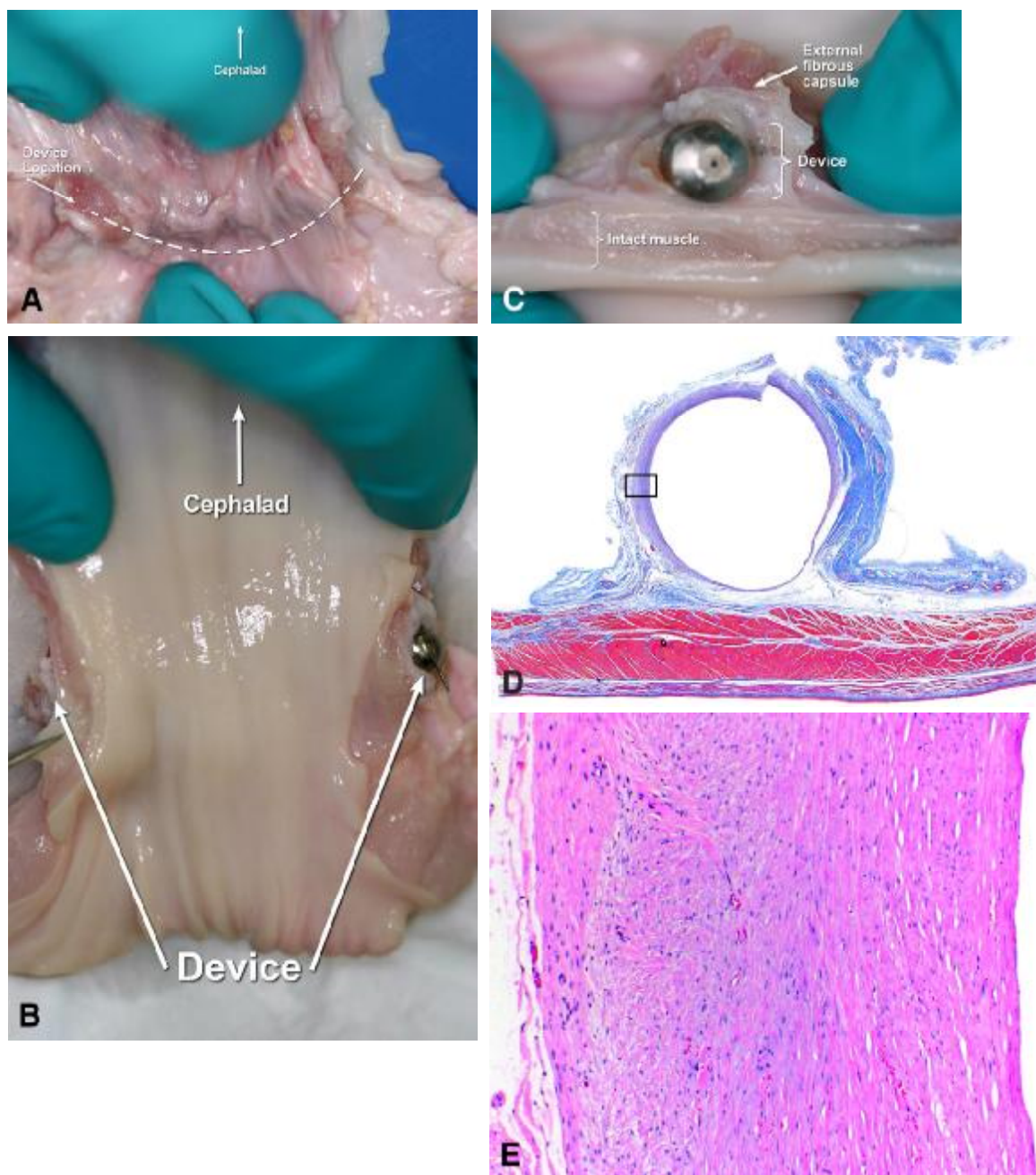
and Use Committee guidelines; the entire study, including all procedures and outcome measures, was approved by the University of Minnesota Institutional Animal Care and Use Committee.

## RESULTS

The ex vivo gastric yield pressure studies showed that gastric yield pressure directly correlated with increasing magnet forces. The mean baseline yield pressure was 10 mm Hg. At a magnet force of .20 newtons between closed beads, the mean yield pressure was 18 mm Hg, rising to a mean yield pressure of 46 mm Hg at a magnet force of .78 newtons ( $R^2 = 0.5608$ ,  $P < .001$ , Fig. 3).

The chronic in vivo studies showed that after placement of the sphincter augmentation device all the animals exhibited a normal eating pattern and consumed normal amounts of food. There were no observed effects on eating behavior or weight gain in any of the animals, even at the maximal magnetic force. The average weight of the animals at death or last follow-up period was 155% of the preimplant weight, with a maximal weight gain of 188% and a minimum weight gain of 126%. All the animals appeared healthy at the time of death.

The mucosa of the esophagus appeared normal at all interval endoscopies, with no evident obstruction, stenosis, or stricture formation. No mucosal breaks were identified in any animal. At necropsy, all the magnetic devices were confined to the adventitia adjacent to the muscular wall of the esophagus and were encapsulated in fibrous tissue; individual beads were contained within pockets of connective tissue. The individual beads were able to approximate despite the fibrous capsulization surrounding each bead. As the beads approximated, some of the fibrous tissue was displaced. Device or individual bead erosion into esophageal muscle was not observed. There was no device migration and no proximal or distal movement identified in any case; all the necklaces remained in their original circumferential position as determined by gross visualization.

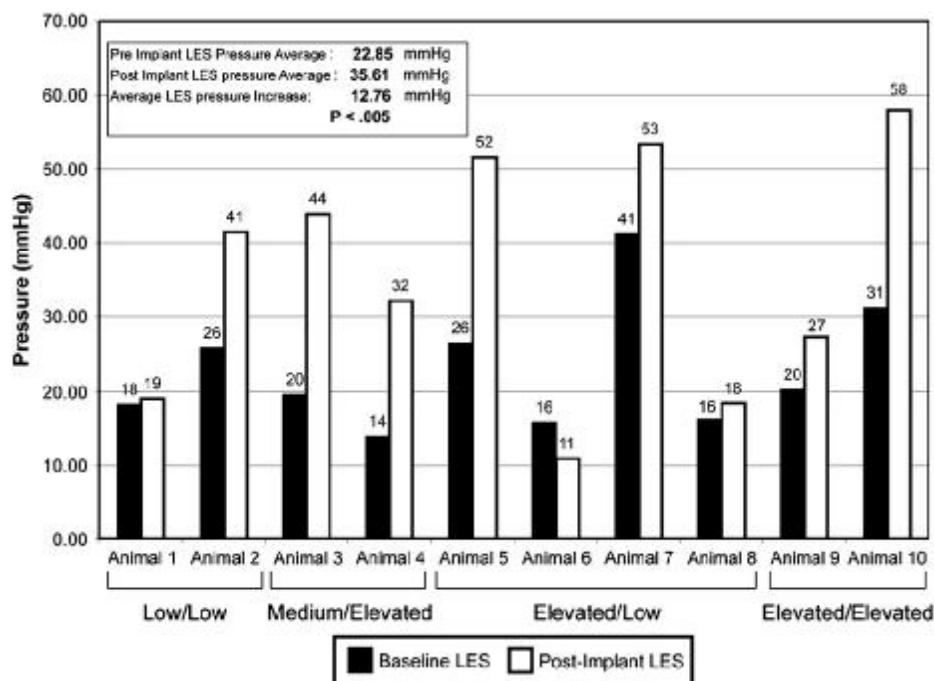


**Figure 4.** **A**, Ex vivo implant. Adventitial aspect at the GE junction. **B**, Ex vivo implant. Mucosal aspect at the GE junction. **C**, Ex vivo implant showing a bead in section. **D**, Histologic section of a fibrous capsulization of a bead space (H&E, orig. mag.  $\times 40$ ). **E**, Histologic section of fibrous capsule showing minimal inflammation (H&E, orig. mag.  $\times 40$ ).

Histologic examination revealed minimal cellular inflammation within the fibrous pockets consistent with a typical foreign body response; there was no inflammation of the muscle layer. (Fig. 4A to E).

The LES pressures for the group, before surgery, averaged 22.85 mm Hg and rose to 35.61 mm Hg after implan-

tation ( $P < .005$ , Fig. 5). The increase in LES pressure occurred at the lowest closed forces; however, some animals with similar force devices showed no change in LES pressure. The rise in LES pressure did not correlate with stronger closed magnetic forces. Esophageal peristaltic pressures were adequate to consistently open the



**Figure 5.** Feasibility LES pressure summary. *Closed bars*, Baseline LES; *open bars*, postimplant LES.

augmented sphincter, without changes in eating behavior, even at 0.59 newtons, the highest closed magnetic force tested.

GE junction and partial device opening was seen with minimal balloon pressures and complete device expansion was noted with all balloon inflations by 40 mm Hg. With mixed barium and food swallows there was consistent GE junction opening, and at least partial device opening occurred with every bolus. The number of beads that separated on swallowing a mixed barium or food bolus depended on the bolus size. Pooling of contrast or food in the esophagus was not observed.

Surgical removal of a device at 40 weeks revealed some adhesions but was accomplished without difficulty or significant dissection. After removal, the animal ate and behaved normally with no observed adverse sequelae and appeared healthy when euthanized at 44 weeks.

## DISCUSSION

The sphincter augmentation device is a novel and unexplored therapeutic approach for the treatment of chronic GERD. This study has shown the safety and feasibility of such a device in a live porcine model. There were no adverse effects on long-term follow-up; specifically, there was no observed effect on eating behavior, and no migration or erosion related to the device. Histologic inflammation was minimal, consistent with a normal foreign body response. Separation and reapproximation of the mag-

netic beads continued on a long-term basis despite the encapsulation of individual beads in fibrous tissue. The necklace was encased in fibrous tissue, but individual beads remained movable and were able to actuate and support closure of the LES.

In this pilot study, a range of open and closed magnetic forces was explored in an effort to find the lowest closed force that could potentially augment the reflux barrier yet avoid dysphagia, along with the highest achievable open force that would allow consistent bead reapproximation after bolus transport. Although preliminary, it appears that in this porcine model esophageal peristaltic pressures were adequate to open the magnetic necklace and GE junction, at least partially, on a consistent basis, and to prevent changes in eating behavior even at 0.59 newtons, which was the highest closed magnetic force tested. Furthermore, the pig model is a reasonable approximation of human esophageal LES and peristaltic pressures; thus, the requirements and findings in this study should reasonably translate to those needed in patients with GERD.<sup>9</sup>

The sphincter augmentation device increases gastric yield pressure. The degree to which this occurs is dependent on the magnetic attraction force between beads. Overall, the LES pressures rose, although this effect was inconsistent and not based on magnetic force alone. The inconsistency may be due to the technique of implantation, the position of the device on placement, or other factors including dissection, manipulation, and edema involved in placement.<sup>10</sup> Thus the rise in LES pressure appears to be, at least in part, an issue of device placement

and may have less to do with magnetic force than does the yield pressure effect.

The sphincter augmentation device may have some theoretic differences compared with a Nissen fundoplication. Although not explicitly measured, the beaded design could allow for variable and partial opening of the GE junction and could permit a patient to open his sphincter to belch. Lack of the ability to belch can be a significant problem with Nissen surgery, leading to gas-bloat syndrome.<sup>11</sup> In addition, post-Nissen dysphagia is a common postoperative complication occurring in as many as one third of patients.<sup>11,12</sup> The etiology of postoperative Nissen dysphagia is multifactorial and includes the type of surgery performed, length and tightness of the wrap—particularly the subdiaphragmatic component, rigidity of the wrap, and whether the wrap slips or remains in position.<sup>11,13</sup> Moreover, the relative rigidity of a Nissen wrap leads to increasing wrap resistance (and potential dysphagia) with progressively larger food boluses<sup>13</sup>; the sphincter augmentation device may obviate this problem by using a design of wired magnets whose attraction force falls as they separate.<sup>6</sup> Consequently, the device could have minimal effects on esophageal peristalsis. The ease of insertion of this device with limited dissection and minimal alteration of hiatal anatomy may provide a more consistent and less variable outcome in the control of reflux than does the Nissen fundoplication.

Previous experience with circumferential artificial prostheses for GERD, in particular the Angelchik prosthesis, has been mixed.<sup>14</sup> The Angelchik prosthesis was successful in controlling reflux, either in large series of refractory reflux patients or in randomized, prospective trials comparing the Angelchik prosthesis with Nissen fundoplication; however, the procedure was plagued by various complications including migration, erosion into adjacent organs, and dysphagia.<sup>15-18</sup> Two separate animal models determined that the antireflux mechanism of action of the Angelchik prosthesis was to increase functional LES length, decrease compliance, and increase gastric yield pressure at the GE junction.<sup>19,20</sup>

Although similar conceptually in that both the Angelchik prosthesis and the sphincter augmentation device studied here are placed around the GE junction, functionally they are very different devices. The mechanisms of function of the sphincter augmentation device are specifically intended to overcome the previous problems of the Angelchik prosthesis: (1) A magnetic sphincter augmentation device provides a reflux barrier by magnetic force, not bulk as with the Angelchik. The volume of the Angelchik device was approximately 50 mL versus 1.2 mL for the currently tested augmentation device. (2) The augmentation device opens for food bolus transport (its opening area can increase more than the esophagus) and exhibits progressively less force the larger the bolus compared with the Angelchik prosthesis, which had a rigid, Silastic silicone rubber (Dow Corning, Midland, Mich) design

and created a fixed diameter around the esophagus, allowing for little or no device distention. The Angelchik prosthesis would create progressive resistance to swallowing (ie, the greater the distention of the esophagus the greater the resistance). (3) The sphincter augmentation device uses independent beads to create a very pliable, flexible, and expansible implant intended to mimic the physiologic motion of the esophagus. The body of the Angelchik prosthesis had a large rigid structure that would resist motion of the esophagus and compress adjacent organs and tissue.<sup>20</sup> It is anticipated that these differences in design and mechanism of action will provide beneficial effects and should result in an improved safety profile for magnetic sphincter augmentation. On the basis of the results of this study, further investigation of this device for the treatment of GERD in humans seems warranted.

## DISCLOSURE

*The authors report the following conflicts: Grant support: Torax Medical, Inc., Maple Grove, Minn. R. A. Ganz is a consultant to Torax Medical, Inc and has an equity position in the company. C. J. Gostout is a consultant to Torax Medical, Inc and receives research funding support. T. R. DeMeester is a consultant to Torax Medical, Inc and has an equity position in the company and receives research funding support. J. Grudem and W. Swanson are engineers employed by the company and have equity positions. T. Berg is the company CEO.*

## REFERENCES

1. Nissen R. Eine einfache operation zur beeinflussung der refluxoesophagitis. *Schweiz Med Wochenschr* 1956;86:590-2.
2. Pappasavas P, Yeane W, Landreneau R, et al. Reoperative laparoscopic fundoplication for the treatment of failed fundoplication. *J Thorac Cardiovasc Surg* 2004;128:509-16.
3. DeMeester T, Bonavina L, Albertucci M. Nissen fundoplication for gastroesophageal reflux disease: evaluation of primary repair in 100 consecutive patients. *Ann Surg* 1986;204:9-20.
4. Peters J, DeMeester T, Crookes P, et al. The treatment of gastroesophageal reflux disease with laparoscopic Nissen fundoplication. *Ann Surg* 1998;228:40-50.
5. Vakili N, Shaw M, Kirby R. Clinical effectiveness of laparoscopic fundoplication in a US community. *Am J Med* 2003;114:1-5.
6. Darendeliler M, Darendeliler A, Mandurino M. Clinical applications of magnets in orthodontics and biological implications: a review. *Eur J Orthod* 1997;19:431-42.
7. V&P Scientific, Inc. Parylene properties and characteristics. Available at: [http://www.vp-scientific.com/parylene\\_properties.htm](http://www.vp-scientific.com/parylene_properties.htm). Accessed October 25, 2007.
8. Mason R, Hughes M, Lehman G, et al. Endoscopic augmentation of the cardia with a biocompatible injectable polymer in a porcine model. *Surg Endosc* 2002;16:386-91.
9. Utley D, Kim M, Vierra M, et al. Augmentation of lower esophageal sphincter pressure and gastric yield pressure after radiofrequency energy delivery to the gastroesophageal junction: a porcine model. *Gastrointest Endosc* 2000;52:81-6.
10. Mittal R, Balaban D. The esophagogastric junction. *N Engl J Med* 1997;336:924-32.

11. Thor K, Silander T. A long-term randomized prospective trial of the Nissen procedure versus a modified Toupet procedure. *Ann Surg* 1989;210:719-24.
12. Hunter JG, Swanstrom L, Waring P. Dysphagia after laparoscopic anti-reflux surgery: the impact of operative technique. *Ann Surg* 1996;224:51-7.
13. Kahrilas P, Lin S, Manka M, et al. Esophagogastric junction pressure topography after fundoplication. *Surgery* 2000;127:200-8.
14. Kozarek R, Brayko C, Sanowski R, et al. Evaluation of the Angelchik antireflux prosthesis: long-term results. *Dig Dis Sci* 1985;30:723-32.
15. Eyre-Brook IA, Codling B, Gear M. Results of a prospective Randomized trial of the Angelchik prosthesis and of a consecutive series of 119 patients. *Br J Surg* 1993;80:602-4.
16. Wale R, Royston C, Bennett J, et al. Prospective study of the Angelchik anti-reflux prosthesis. *Br J Surg* 1985;72:520-4.
17. Stuart R, Dawson K, Keeling P, et al. A prospective randomized trial of the Angelchik prosthesis versus Nissen fundoplication. *Br J Surg* 1989;76:86-9.
18. Cohen D, Benjamin S, Graeber G, et al. Evaluation of the Angelchik antireflux prosthesis using a model for esophageal reflux in rhesus monkeys. *Ann Thor Surg* 1986;41:135-42.
19. Bonavina L, DeMeester T, Mason R, et al. Mechanical effect of the Angelchik prosthesis on the competency of the gastric cardia: pathologic physiologic implications and surgical perspectives. *Dis Esoph* 1997;10:115-8.
20. Battaglini J, Schorlemmer G, Frantz P. Intractable dysphagia following placement of Angelchik prosthesis for reflux esophagitis. *Ann Thor Surg* 1983;35:551-2.

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