

Case Report

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The Case of the Broken Linx[®] System in a Sleeve Gastrectomy Patient

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Abstract

De novo breaking of the LINX[®] system inside the patient's body has not been reported. The LINX[®] system was introduced in 2012 after FDA approval as a device to control reflux symptoms in the general population. Its use was expanded into the bariatric population in 2015. Until now the only complication known to occur due to the device itself is erosion into the esophagus. Our case report is the first to show the possibility of such break to occur in the connecting wire between the magnetic beads in a patient after sleeve gastrectomy without MRI exposure.

Keywords: LINX[®] Device; Reflux; Sleeve Gastrectomy; Complications.

Case history

The patient is a 60-year-old female who had a Sleeve Gastrectomy in June 2011. The patient had a history of reflux before the sleeve surgery, which was not confirmed by pH study. Her preoperative upper endoscopy revealed a DeMeester score of 3.9 (normal=14.7), although her Upper Gastrointestinal (UGI) contrast study did show a small hiatal hernia with moderate reflux. Her initial weight was 236 lbs. with a body mass index (BMI) of 40 kg/m². The patient did well initially after her SG with improvement in her reflux symptoms while bringing her weight down to 180 lbs. with BMI of 30 kg/m².

The patient started to gain weight and experienced increase in her reflux symptoms three years after her SG. She started taking H2-Blocker once a day due to continued progression of her symp-

toms. She was then transitioned to proton pump inhibitor (PPI) about three months later with minimal improvement in her symptoms. Her weight increased to 197 lbs. with a BMI of 33 kg/m². She expressed interest in surgical intervention for treatment of her reflux as medical management was not controlling her symptoms. She underwent pre-operative work up including an EGD with bravo capsule (GIVIN imaging, Duluth, GA) placement in June 2015. Her EGD revealed gastritis and a small one centimeter hiatal hernia. Her DeMeester score was 106 (normal=14.7). The H. Pylori studies were negative. Her UGI contrast study in June 2015 revealed moderate reflux and confirmed a one centimeter hiatal hernia. Esophageal motility studies were within normal range. We used the GERD- Health Related Quality of Life (GERD-HRQL) questionnaire to evaluate the patient's symptoms and follow her progress. Her pre LINX total score was 60/75 (Table 1).

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Table 1: GERD-Health Related Quality of Life Score.

GERD-HRQL	Total 75 points	Heartburn 30 points	Dysphagia & Medication 15 points	Regurgitation 30 points
Pre LINX®	60	27	6	27
1 year post LINX®	13	3	1	9
3 years post LINX®	30	11	3	16
6 years post LINX®	44	18	5	21

Results

The patient declined the RYGB as an option to treat her reflux. She consented to having laparoscopic hiatal hernia repair and placement of the LINX® device which was done in November 2015 after IRB approval. The hiatal hernia was repaired around a 40-French bougie with posterior approximation of the crura with nonabsorbable sutures. A size 15 mm LINX® device was placed according to the company's instructions of using a device of 2 sizes above the esophageal size. The operative time was 65 minutes and there were no intraoperative or post operative complications. The patient did well post operatively. On post operative day one she underwent an UGI that revealed the device to be in good position with no reflux or hiatal hernia present (Figure 1).

On the same post-operative day, the patient was started on regular diet with small meals to exercise the LINX®. The patient reported resolution of her reflux immediately after the operation and stopped using her PPI within a week of placement. She was seen in the clinic after one week and again after three months. Her one year post LINX® device placement GERD-HRQL total score dropped to 13/75 with the largest drop was in the heartburn score, which dropped from 27/30 to 3/30. Unfortunately, the patient was lost to follow up. In a phone contact with the patient in September 2018, three years after the LINX® placement, she stated a recurrence in her reflux and reported an increase in her GERD-HRQL total score to 30/75. On her revisit in September 2019, four years after LINX® placement, she reported the recurrence of her reflux and that she was on PPI again, which started about a year after her LINX® placement. An UGI was ordered which was done at a different institution. The UGI report stated that there was recurrent reflux with the LINX® to be in good position with no mention of the status of the LINX®'s beads or circular integrity. We did not have access to these films for personal review at that time. The patient was lost to follow up again and she presented to the our office two years later, in October 2021, six years after her LINX® device placement. The patient was accompanied by her sister who stated that the patient has been struggling with drug addiction for the last five years. At this time the patient had lost more weight. Her weight was 136 lbs. with BMI 22.6 kg/m². She continued to report worsening of her reflux and regurgitation symptoms affecting her eating and contributing to her weight loss. She increased her antacid medications to a high dose PPI twice daily with mild control of her symptoms. Her GERD-HRQL score revealed an increase in total score from 13/75 post operatively to 44/75, with increase in the heartburn symptoms from 3/30 to 18/30. In addition there was an increase in the other two categories of the GERD-HRQL scores as shown in (Table 1). The patient denied any recent viral infection or episodes of emesis around this time. She denied any overt change in symptoms except for the gradual recurrence of



Figure 1: Post-operative UGI November 2015.

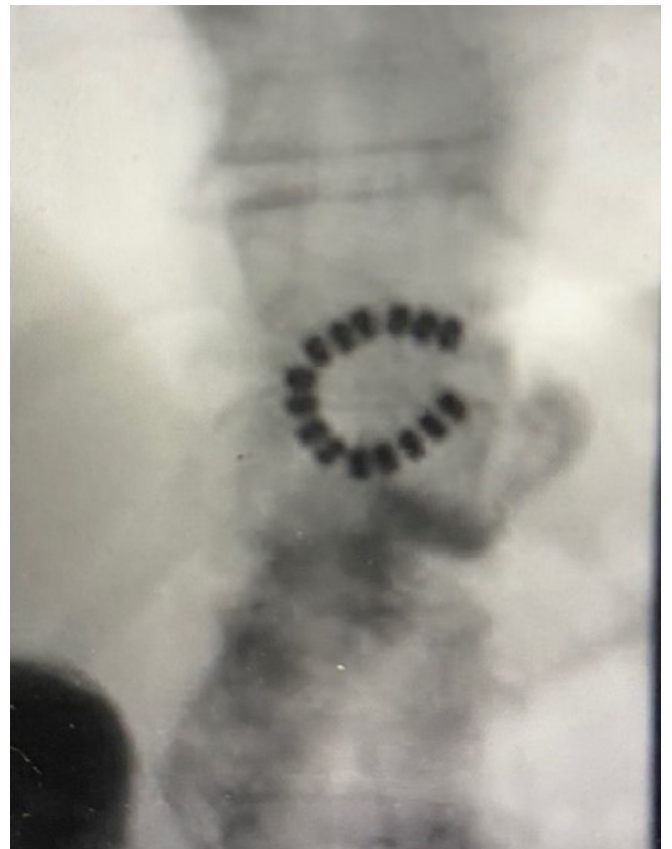


Figure 2: UGI showing LINX® device broken October 2021. The buckle is closed at 11 o'clock location with the break in the wire at 3 o'clock location.

her reflux symptoms in January 2017, which was over one year from placement of the LINX® device. She denied having an MRI since her surgery. She was dissatisfied with the LINX® device outcome.

We requested a repeat UGI, which was done in November 2021. The findings were negative for reflux or a hiatal hernia, however, the LINX® device was reported to be broken with evidence of a disconnected ring at the 3 o'clock location while the buckle was still closed. The device was no longer completely encircling the lower esophageal sphincter (Figure 2). A retrospective access to the patient's records from her other institution revealed chest X-rays from 2016 and 2018 which showed the LINX® device to be intact. The UGI which was done in September 2019, however, showed a break in the LINX® device, similar to the finding of November 2021 which unfortunately was not mentioned in the dictated report. In addition there was a chest X-ray in June 2021 which also showed the device to be broken but the radiologist did not address that in the dictated report as well (Figure 3). Since we became aware of this complication we were unable to schedule the patient for an EGD to evaluate her esophagus. She had cancelled multiple attempts to schedule her endoscopy due to transportation problem according to the patient.

Discussion

The LINX® system was developed in 2002 and received FDA approval in March 2012 [5]. First reports on using the LINX® system after sleeve gastrectomy appeared in 2015 [2]. The success of the device in controlling reflux in the general population and its low device risk of erosion lead a handful of bariatric surgeons to offer it to post sleeve gastrectomy patients to manage their reflux as an alternative to the standard procedure of RYGB [6]. The absence of the fundus after SG to be used as a wrap and the higher surgical and medical risks associated with the conversion to RYGB makes the LINX® an attractive alternative that is worth investigating. It was even used as an option in controlling reflux after RYGB [7].

The mechanism of action of the LINX® is by providing augmentation to the lower esophageal sphincter by placement of magnetic beads configured in a flexible and expandable ring around the gastroesophageal junction. It consists of a series of titanium beads, each with a magnetic core, connected together with titanium wires to form a ring shape (Figure 4).

Erosion of the device into the esophagus of 1.2% is the only risk reported related to the device = itself. The use of the smaller size (12 mm) contributed approximately to 62% of this problem [8]. This was corrected by the company eliminating the devices with smaller sizes and standardizing the placement of the device size to be two sizes above the calibration of the esophagus [8]. A de novo breaking of the LINX® device connecting wire inside a patient's body has not been reported until now.

Intentional breaking of the connecting wire between the beads has been reported when removing the eroded LINX®, either endoscopically or laparoscopically, using the harmonic scissors [8]. Our case report is the first case of a de novo breaking of the connecting wire occurring inside the patient's body. We are not sure if our patient's LINX® device was from the first generation of devices which were designed to tolerate the 0.7 Tesla MRI or the second generation. The reports of the ability of the surgeons to remove



Figure 3: A chest X-ray June 2021 with evidence of a broken LINX®.



Figure 4: LINX® Reflux Management Device.

the eroded LINX® devices using the harmonic scissors in cutting the connecting wire between the magnetic beads is possible to have been from this first generation of devices [9]. Since then the company introduced the newer generation of LINX® devices which is supposed to withstand the 1.5 Tesla MRI due to its stronger alloy [5]. This change gives us hope that this type of complication may not be seen in the patients who had implantation of the second generation of LINX® devices. The fact that there were two radiologic studies that showed the break in the LINX® device connecting wire without being reported, behooves the surgeons to review these films by themselves, especially in patients who are complaining of recurrent reflux. It is also our duty to educate the radiologists about the possibility of the breaking of these wires that can occur in these devices.

Conclusion

Using the LINX® device in treating reflux after SG is gaining wide acceptance as an alternative to the standard conversion to the RYGB. It could also be useful in controlling reflux after RYGB. De novo breaking of the LINX® device connecting wire has not been reported yet. Our patient's case is the first report of such complication. A recall of all patients who had placement of the first generation LINX® devices may be considered to find out if any of them had developed this type of complication, especially if they had recurrence of their reflux symptoms.

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