Health Policy Advisory Committee on Technology

Technology Brief

LINX® Reflux Management System for the treatment of gastro-oesophageal reflux

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ASERNIP-S
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical

Royal Australasian College of Surgeons

HealthPACT
emerging health technology

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Technology, Company and Licensing

Register ID	**WP128**
Technology name	**LINX® Reflux Management System**
Patient indication	**Patients with gastro-oesophageal reflux disease**

Description of the technology

The LINX® Reflux Management System consists of a small flexible and expandable 'bracelet' of titanium beads, with magnetic cores that are linked by independent titanium wires.[1, 2] The device is placed laparoscopically at the gastro-oesophageal junction (Figure 1) to help the lower oesophageal sphincter (LOS) resist opening, thereby preventing stomach contents from entering the oesophagus without affecting the natural physiologic function of the LOS.[1, 3] The LINX® device permits the expansion of the LOS so that swallowing or the release of elevated gastric pressure (associated with belching or vomiting) may take place.[2] This is achieved when the peristaltic pressure of the food bolus, for example, is greater than that of the magnetic attraction between adjacent beads of the LINX® System, causing them to expand and 'open' the device. As the food moves through the oesophagus into the stomach and the peristaltic pressure drops below that of the magnetic attraction between the beads, they are drawn back together and the device 'closes'.[3] The attractive force between the beads comprising the LINX® device range from 40 G (closed) to 7 G (fully expanded).[2] The device comes in different sizes ranging from 12 to 16 beads; the size of the device implanted is determined at the time of placement, using specialised sizing equipment to measure the outer diameter of the oesophagus.[2]

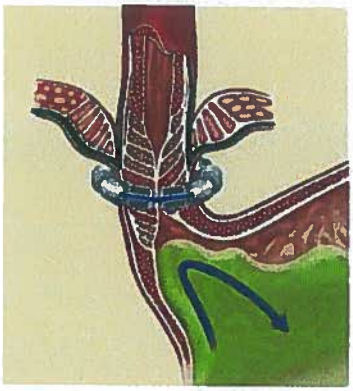

Figure 1 **LINX® device implanted around the oesophagus to assist lower oesophageal sphincter closure (printed with permission).[1]**

Typically, placement of the device occurs under general anaesthesia via five laparoscopic ports. Dissection takes place so that a tunnel may be formed between the posterior oesophageal wall and the posterior vagus nerve. A drain is placed within the tunnel, encircling the oesophagus, to maintain access for the sizing tool and then the LINX® device. Following the insertion of a correctly-sized LINX® device, its ends are secured at the anterior

surface of the oesophagus. Implantation of the LINX® device takes approximately 30 minutes and patients are generally discharged from hospital on the same or the following day. Patients are advised to continue a normal diet, as tolerated, and cease taking acid suppression medication.[2]

The LINX® system is a novel treatment for gastro-oesophageal reflux disease (GORD) in that it is reversible and does not alter the hiatal or gastric anatomy or physiology of the patient. This means that future treatments with other therapies, such as fundoplication, are possible if required.

Company or developer

Torax® Medical, Inc., Minnesota, United States of America (USA).

Reason for assessment

A novel surgical treatment alternative with potentially fewer side effects for managing GORD, a condition which causes a large patient group significant morbidity.

Stage of development in Australia

- ☒ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

Licensing, reimbursement and other approval

The LINX® Reflux Management System received CE Mark approval in April 2010[4] and United States Food and Drug Administration (FDA) pre-market approval in March 2012 (approval umber P100049).[5] The device is not listed on the Australian Register of Therapeutic Goods (ARTG) at this time. Correspondence with Torax® Medical, Inc. indicated that they currently do not plan to seek Therapeutic Goods Administration (TGA) approval.

Australian Therapeutic Goods Administration approval

- ☐ Yes — ARTG number (s) Not applicable
- ☒ No
- ☐ Not applicable

Technology type	**Device**
Technology use	**Therapeutic**

Patient Indication and Setting

Disease description and associated mortality and morbidity

The oesophagus carries food from the mouth to the stomach. The LOS is a ring of muscle at the bottom of the oesophagus which acts to keep stomach contents from refluxing back into the oesophagus.[6] In some people, the LOS does not work correctly and stomach acids are able to enter the oesophagus causing a burning sensation in the chest or throat known as heartburn.[6] GORD is a common and chronic gastrointestinal disorder where patients experience frequent acid reflux. The main symptoms of GORD are heartburn and acid regurgitation. Other symptoms include nausea, hoarseness, laryngitis, chronic dry cough, asthma, 'lump-in-throat' feeling, sudden excessive saliva, bad breath and chest pain or discomfort.[7] In some cases, GORD may be caused by or associated with hiatal hernia, which occurs when part of the stomach herniates through the diaphragmatic hiatus (the opening in the diaphragm that separates the chest from the abdomen).[8] It is thought that a hiatal hernia may weaken the LOS resulting in GORD.[8] These types of hernia may be repaired at the time of anti-reflux surgery if necessary. Patients with GORD whose symptoms are not well-managed are at risk of developing erosive oesophagitis, Barrett's oesophagus, stricture and adenocarcinoma.[2]

Number of patients

It has been estimated that 10 to 20 per cent of the Western population suffer from chronic GORD.[9] In Australia, it is estimated that approximately nine per cent of the population suffer from GORD, which corresponds to approximately 2.1 million people.[10] A population-based study (n=1,000) conducted in Wellington, New Zealand found that, over a 12-month period, 34 per cent of people had suffered from dyspepsia, 30 per cent had reflux and 45 per cent had both symptoms.[11] The frequency of these symptoms ranged from once a month (48% of people) to several times a week (19%) or daily (6%).[11]

According to the Australian Statistics on Medicines 2010 report, the number of prescriptions for the following PPIs issued in 2010 was as follows: approximately 6.5 million for Esomeprazole, 600, 000 for Lansoprazole, 3.2 million for Omeprazole, 4.3 million for Pantoprazole and 2.5 million for Rabeprazole.[12]

Between 2006 and 2007, 61,049 patients were admitted to hospital with GORD (with or without oesophagitis) in Australia.[13] In addition, GORD is one of the ten most frequently managed problems in general practice.[14] In New Zealand, from 1 July 2010 to 30 June 2011, there were 3,741 discharges from publically-funded hospitals and 202 from privately-funded hospitals for patients with GORD.[15]

A number of patient-related factors have been identified that potentially increase the risk of developing GORD. These include obesity (body mass index, BMI, >30kg/m^2), alcohol

consumption (>7 standard drinks per week), chronic airway disease, intellectual disability, spending prolonged periods in a supine position, and having a first-degree relative who has reflux symptoms.[16]

Speciality	**Upper gastrointestinal surgery**
Technology setting	**General Hospital**

Impact

Alternative and/or complementary technology

The LINX® Reflux Management System is an alternative technology to the current surgical treatment strategies available for patients with GORD. The LINX® system is a reversible surgical intervention that does not interfere with the anatomical or physiological function of the patient's digestive system.

Current technology

Current treatment options for patients with GORD generally include long-term pharmaceutical intervention or surgical alteration of the gastric anatomy.[2] Long-term acid suppression medications, often in the form of proton pump inhibitors (PPIs), work by suppressing the acid produced in the stomach through blocking enzymes on the surface of the acid-producing cells.[17] These drugs are usually an effective first-line therapy; however, a considerable proportion of patients with GORD (up to 40%) have only partial symptom response, particularly those with a mechanically defective LOS.[2, 18]

Surgical intervention for GORD typically involves adding to the bulk of or tightening the LOS.[3] The most common (gold standard) surgical treatment for GORD is Nissen fundoplication.[18] Nissen fundoplication is a surgical procedure whereby the fundus (upper curve of the stomach) is wrapped around the oesophagus so that the lower oesophagus passes through a tunnel of stomach muscle.[19] This acts to reinforce the LOS and restrict the reflux of stomach contents into the oesophagus. The side effects associated with surgical treatments for GORD, which have led to their limited acceptance, include abdominal bloating, increased flatulence, the inability to belch or vomit, and persistent difficulty swallowing.[18]

Diffusion of technology in Australia

The LINX® Reflux Management System is not in use in Australia at this time, and the manufacturer has no plans to seek listing on the ARTG. There are no clinical trials of the device being conducted in an Australian healthcare setting.

International utilisation

Country	Level of Use		
	Trials underway or completed	Limited use	Widely diffused
Austria	✓		
France	✓		
Germany	✓		
Italy	✓		
Switzerland	✓		
United Kingdom	✓		
United States	✓		

The LINX® Reflux Management System was first used in Europe in 2007 as part of a multicentre feasibility trial.[2] Continued use of the device, on a registry basis, beyond the completion of the trial has taken place.[2] Use of the device in the United States, in two clinical trials, occurred originally under a United States FDA investigational device exception.[2] Correspondence with Torax® Medical, Inc. indicated that approximately 1,000 LINX® systems have been implanted to date, about half of these in Europe and the other half in the USA.

Cost infrastructure and economic consequences

The cost of the LINX® Reflex Management System is A$5,045[1] for the 12 to 16 bead device and A$673 for a pack of five laparoscopic sizing tools. Additional costs would include those related to operative facilities, staff, anaesthesia and hospital stay.

There would also be costs associated with the initial training of surgical staff to undertake the implantation procedure. The LINX® system offers an alternative surgical intervention to patients with GORD, with the potential for fewer side effects. Therefore, it may offer greater economic impact on the healthcare system, with respect to burden of disease, compared with present clinical practice because it gives patients who would otherwise not have considered surgical intervention an option. Despite this, current surgical interventions for GORD are considerably less expensive than the LINX® system. A standard laparoscopic fundoplication procedure (without hernia repair) has a Medicare Benefits Schedule (MBS) fee of $871.30 (75% benefit = $653.50) (MBS item number 31464).[20]

Ethical, cultural or religious considerations

No ethical, cultural or religious issues where identified in the literature.

[1] 1 AUD = 1.68 GBP

Evidence and Policy

A total of four case series studies (level IV Intervention evidence) were eligible for inclusion in this Technology Brief[3, 18, 21, 22], three of which provided short- (3- and 6-month)[22], medium- (1- and 2-year)[21] and long-term (3- and 4-year)[3] follow-up data for the same patient population. Overall, the safety and effectiveness of the LINX® Reflux Management System was evaluated in 144 patients with GORD (Table 1).

Table 1 Study profile of included studies

Study	Ganz et al. 2013[18]	Bonavina et al 2008[22], Bonavina et al 2010[21], Lipham et al 2012[3]
Level of evidence	IV	IV
Number of patients	100	44
Patient details	Patients 18 to 75 years of age, ≥ 6-month history of GORD, partial response to daily PPIs, increased exposure to oesophageal acid confirmed by pH-monitoring	Patients 18 to 75 years of age, candidates for anti-reflux surgery, ≥ 6 months documented history of GORD, incomplete symptom response to daily PPIs, confirmed abnormal oesophageal acid exposure whilst on PPIs, normal contraction amplitude and wave form in oesophageal body
Intervention	LINX System	LINX System
Characteristics of patient population	52% male; median age 53 years; median symptom duration 5 years; median DeMeester score* 36.6.	59% male; mean age 42.3 years; mean BMI 25.7 kg/m²; primary symptom of heartburn; no hernia, n=18; <3 cm sliding hiatal hernia, n=26.
Losses to follow-up	1-year, n=2 2-year, n=10 3-year, n=15	Median 895 days, n=1
Follow-up (time points)	1 week; 3 and 6 months; 1, 2 and 3 years	3 and 6 months; 1, 2, 3 and 4 years
Conflict of interest	Study designed and supported by Torax® Medical, Inc.	Four authors were/are consultants for Torax® Medical, Inc.

GORD: gastro-oesophageal reflux disease; PPIs: proton pump inhibitors; BMI: body mass index.
*DeMeester score: composite score of factors measured during 24 to 48 hour pH study; including percentage of time pH < 4 in various positions, total number of reflux episodes, number of reflux episodes lasting >5 minutes and duration of longest reflux episode. A score ≥14.7 indicates abnormal reflux.

Safety and effectiveness

Ganz et al 2013[18]

This industry-sponsored, prospective, multicentre (13 centres in the USA and one centre in the Netherlands) case series study enrolled 100 patients with GORD between January and September 2009 to be implanted with the LINX® device. Patients were excluded if they had evidence of a large hiatal hernia, oesophagitis of Los Angeles classification[2] Grade C or D, BMI > 35 kg/m², Barrett's oesophagus, a motility disorder, dysphagia more than three times per week, or an allergy to any of the materials in the LINX® device. Baseline screening of patients included endoscopy, pH monitoring (off PPIs), barium oesophagography and manometry. These tests, along with chest radiography, were repeated at the 1- and 2-year

[2] Los Angeles classification of oesophagitis[18]
Grade A: ≥1 mucosal break(s) ≤5 mm in length; Grade B: ≥ 1 mucosal break(s) >5 mm in length; Grade C: mucosal breaks that extend between ≥2 mucosal folds but involve <75 per cent of the circumference of the oesophagus; Grade D: mucosal breaks involving ≥ 75 per cent of the circumference of the oesophagus.

follow-up. The use of PPIs was assessed at baseline, one week after treatment, three and six months after treatment, and yearly thereafter. Quality of life (QoL) was measured using the Gastroesophageal Reflux Disease–Health Related QoL Questionnaire (range 0 [good]–50 [poor]). The LINX® device was implanted laparoscopically, but the exact surgical technique was not described.

The primary effectiveness endpoint reported was the proportion of patients with either normalised oesophageal acid exposure (≤4.5% of a 24-hour period with pH <4) or at least a 50 per cent reduction in the proportion of time pH was less than 4 (without PPIs), compared with baseline. Secondary endpoints included at least a 50 per cent reduction in QoL questionnaire score and daily PPI dose, compared with baseline measurements. Inclusion criteria and baseline patient demographics are summarised in Table 1.

Safety

There were no intraoperative or device-related complications reported. All adverse events and incidences of device removal are reported in Table 2.

Major complications occurred in six of the 100 patients (6%), four of whom required device removal. Three of the four device removals occurred in the early postoperative period due to persistent dysphagia (at 21, 31 and 93 days after implantation), while the fourth device removal occurred 357 days after treatment due to intermittent vomiting, which continued after the removal of the device. The remaining two patients experienced nausea and vomiting that required hospitalisation; both cases were resolved with conservative treatment. Two additional devices were removed as part of each patient's "disease management": one patient experienced persistent reflux symptoms, while the other had persistent chest pain. Three of the six patients who had their devices removed underwent uncomplicated Nissen fundoplication.

Oesophageal dilation was undertaken in 19 patients to treat the most common complication of dysphagia, which occurred in a total of 68 patients (68%). Eighty-four per cent (16/19) of these patients experienced improvement in their dysphagia symptoms. The proportion of patients with Grade A and B oesophagitis decreased significantly, from 40 per cent at baseline to 12 per cent at the 1-year follow-up and 11 per cent at the 2-year follow-up ($p<0.001$).

Table 2 Adverse events reported by Ganz et al. (2013)[18]

Adverse event	Patients (n=100)	Level of intensity (%)			Device removal
		Mild	Moderate	Severe	
Dysphagia	68	47	16	5	3
Bloating	14	12	2	0	0
Pain	25	7	13	5	1
Painful swallowing	8	4	3	1	0
Hiccups	8	7	1	0	0
Nausea	7	3	2	2	0
Inability to belch or vomit	6	5	1	0	0
Decreased appetite	4	4	0	0	0
Flatulence	2	2	0	0	0
Belching	2	2	0	0	0
Weight loss	2	2	0	0	0
Food impaction	1	0	1	0	0
'Lump in throat' sensation	1	1	0	0	0
Irritable bowel syndrome or dyspepsia	1	1	0	0	0
Regurgitation of sticky mucus	1	0	1	0	0
Uncomfortable feeling in chest	1	1	0	0	0
Vomiting	1	0	1	0	1
Persistent gastro-oesophageal reflux disease symptoms	1	0	1	0	1

Effectiveness

The median time taken to implant the LINX® device (measured from placement of the last laparoscopic port to removal of the first laparoscopic port) was 36 minutes (range 7–125 minutes). All patients were discharged within one day of the operation.

The primary effectiveness endpoints of normalised oesophageal acid exposure or a reduction of at least 50 per cent in oesophageal acid exposure (compared with baseline) was achieved in 67 per cent (64/96 patients) and 58 per cent (56/96) of patients, respectively. Collectively, 67 per cent of patients achieved the primary effectiveness endpoint. All components of the DeMeester score/pH monitoring (described previously) were significantly improved at 1-year follow-up ($p<0.001$ for all components), compared with baseline.

The secondary effectiveness endpoints of at least a 50 per cent reduction in QoL score and daily PPI dose was achieved in 92 per cent (95% confidence interval [CI] [85, 97]) and 93 per cent (95% CI [86, 97]) of patients respectively. Statistical analyses found significant improvements in median QoL scores after LINX® implantation at 1-, 2- and 3-year follow-up, with or without PPIs, compared with baseline ($p<0.005$). Eighty-seven per cent of patients

reported continued PPI cessation at 3-year follow-up. Regurgitation symptoms, measured using the Foregut Symptom Questionnaire, were significantly improved at 1-, 2- and 3-year follow-up for all severity grades (mild, moderate and severe; $p<0.001$).

Bonavina et al 2008[22], Bonavina et al 2010[21], Lipham et al 2012[3]

This multicentre (four centres across the USA and Europe), prospective case series study enrolled patients with GORD between February 2007 and October 2008 for treatment with the LINX® device. The earliest study reported that 38 of 41 enrolled patients were implanted with the LINX® device (the remaining three were unable to undergo implantation for the reasons stated below under the Safety subheading); however, the latter two studies reported a total of 44 patients were implanted with the LINX® device. It is unclear why the patient number differs between the studies.

Patients were ineligible for inclusion in this study if they had any of the following: a hiatal hernia of at least 3 cm; a history of abdominal surgery or endoscopic anti-reflux procedures; erosive oesophagitis Grade B, C or D (Los Angeles Classification); a BMI greater than 35 kg/m^2; Barrett's oesophagus; motility disorders; gross oesophageal anatomic abnormalities; or known allergies to any of the materials that comprise the LINX® device. Baseline screening included a symptom questionnaire (Gastroesophageal Reflux Disease–Health Related QoL Questionnaire), endoscopy, Barium swallow, oesophageal manometry and pH monitoring. These, in addition to chest x-rays and a modified Barium swallow on postoperative day one, were repeated at 3-month, 1-year and 2-year follow-up. Oesophageal manometry and pH monitoring was performed at 3-month and 1-year follow-up only, with the exception of one European centre which performed pH monitoring at 2- and 3-year follow-up also. Symptom questionnaires and recording of adverse events were the only long-term (4-year) follow-up reported. Insertion of the LINX® device occurred via five laparoscopic ports, in a procedure similar to that described previously in this Technology Brief. Inclusion criteria and patient demographics at baseline are summarised in Table 1.

Safety

Three patients were unable to undergo implantation with the LINX® device. One was converted to Nissen fundoplication because of a hiatal hernia (>3 cm) and a leiomyoma at the oesophagogastric junction, another withdrew consent prior to surgery, and the third patient was found to have insufficient peristalsis (motility disorder). There were no intraoperative or device-related complications reported beyond one year.

At the 4-year follow-up, 95 per cent (42/44) of patients were free from major complications related to the LINX® device or the implantation procedure. The most common minor complication encountered was mild dysphagia, which occurred in 20 patients (43%) and resolved without the need for intervention within two months. In one case, persistent

dysphagia and oesophageal acid exposure resulted in device removal at eight months. Another patient was hospitalised for chest pain 22 days after implantation, which resolved completely by two months. It was not reported whether the chest pain was related to the LINX® device or implantation procedure. Two other patients underwent device removal: one at 18 months due to the need for magnetic resonance imaging (MRI) and the other elected to undergo Nissen fundoplication due to persistent GORD symptoms. All patients were able to belch and vomit following implantation with the LINX® device.

Effectiveness

The median operative time (measured from the time all laparoscopic ports were placed to when the first port was removed) was 40 minutes (range 19–104 minutes). Discharge from hospital occurred within 48-hours for 98 per cent (43/44) of patients.

The proportion of patients who remained off daily PPIs at the 3-month and 1- and 2-year follow-ups were as follows: 89, 90 and 86 per cent, respectively. The mean QoL score was significantly lower at three months (4.6, $p<0.005$), one year (3.8) and two years (2.4) after treatment ($p<0.0001$), compared with baseline (25.7). All patients (n=23) had a reduction in QoL scores of at least 50 per cent at the 4-year follow-up (Table 3).

Table 3 Mean Gastroesophageal Reflux Disease–Health Related QoL Questionnaire score reported by Lipham et al[3]

	Follow-up time point (mean score)					
QoL questionnaire	Baseline n=44	3-month n=37	1-year n=39	2-year n=35	3-year n=31	4-year n=23
How bad is your heartburn?	3.7	0.6	0.6	0.4	0.6	0.5
Heartburn when lying down?	3.1	0.3	0.4	0.3	0.4	0.2
Heartburn when standing up?	3.3	0.4	0.4	0.2	0.3	0.3
Heartburn after meals?	3.6	0.6	0.6	0.4	0.6	0.7
Does heartburn change your diet?	3.1	0.5	0.2	0.3	0.6	0.5
Does heartburn wake you from sleep?	2.5	0.0	0.3	0.1	0.3	0.0
Do you have difficulty swallowing?	1.2	0.7	0.6	0.3	0.3	0.4
Do you have bloating and gassy feelings?	2.9	0.8	0.5	0.5	0.4	0.4
Do you have pain with swallowing?	0.6	0.4	0.1	0.0	0.1	0.0
If you take medication, does this affect your daily life?	2.0	0.2	0.2	0.1	0.5	0.2
% of patients satisfied with their present condition?	0%	84%	87%	86%	88%	87%

There were no significant changes in manometric parameters (including LOS resting tone, LOS length, abdominal length, relaxation and swallowing effectiveness) at the 3-month and 1-year follow up, compared with baseline, with the exception of a significant increase in LOS resting pressure (6.5 to 14.6 mmHg) at one year in nine patients with hypertensive LOS pressure ($p<0.005$).

Oesophageal acid exposure returned to normal in 79 per cent (19/24) of patients at the 3-month follow-up and remained normalised at the 1-, 2- and 3-year follow-up in 77 per cent, 90 per cent and 80 per cent of patients respectively. Overall, all components of the DeMeester score/pH monitoring were significantly improved at the 3-month follow-up, compared with baseline, and remained significantly improved at the 1- and 2-year follow-up.

An additional 'article-in-press' was identified after the August HealthPACT committee meeting and is briefly summarised here.[23] This study was published by the same group of authors as Bonavina et al and reports the 6-year clinical outcomes of 100 consecutive patients with GORD implanted with the LINX® device in a single centre in Milan, Italy (some patient overlap is apparent). This article found median total acid exposure time was significantly reduced post-implant, as was GORD- related QoL. Independence from PPIs was achieved in 85% of patients and there were no long-term complications. Three patients required device removal due to consistent GORD symptoms. Overall, this study describes similar findings to those included in the Technology Brief and looks at a similar patient population (specifically those without significant hiatal hernia or esophagitis).

Economic evaluation

There were no economic evaluations identified for the use of the LINX® Reflux Management System.

Ongoing research

There were four ongoing trials identified from ClinicalTrials.gov and the Australian and New Zealand Clinical Trails Register, all of which had industry sponsorship and only one of which was comparative (Table 4).

Table 4 Ongoing trials for LINX Reflux Management System

Trial Identifier	Country	Trial Status	N	Study Design	Interventions	Estimated completion date
NCT00776997	United States, Netherlands	Ongoing but not recruiting	100	Case series	LINX	October 2014
NCT01058070	United States	Ongoing but not recruiting	14	Case series	LINX	October 2013
NCT01057992	Italy	Ongoing but not recruiting	31	Case series	LINX	October 2013
NCT01624506	Austria, Germany, Italy, United Kingdom	Recruiting	800	Non-randomised comparative	LINX versus laparoscopic fundoplication	January 2016

Like the current evidence base, these trials are being conducted in Europe and the USA and are examining similar treatment outcomes, including oesophageal acid exposure and the incidence of adverse events, in similar patient populations.

Other issues

- To date, all of the peer-reviewed literature looking at the safety and effectiveness of the LINX® Reflux Management System has been designed or sponsored by the manufacturer of the device. This is most likely a reflection of the stage of development of the device.
- The studies included in this Technology Brief had stringent inclusion and exclusion criteria, namely excluding those patients with significant oesophagitis and hiatal hernia, which makes it difficult to extrapolate the findings to the broader GORD population.
- Given the small number of patients implanted with the LINX® device in each of the included studies (i.e. Ganz et al enrolled 100 patients across 14 centres and Bonavina et al enrolled 44 patients across four centres) there is likely to have been a learning curve observed. It is possible that as the surgical team preforming LINX® implantation becomes more experienced in doing so it will impact the patient outcomes seen.
- The reversibility of the LINX® procedure must also be considered. Apart from reporting that patients who underwent device removal were able to undergo Nissan fundoplication, it is not clear from the included studies what complications, if any, were associated with device removal (for example, fibrosis).
- Device slippage/migration is also an issue. At this stage, there was no incidence of device migration in the included studies; however, as was the case for an earlier anti-reflux prosthesis (Angelchik™), migration is a potential problem that should continue to be monitored in long-term follow-up studies.
- It is important to note that patients implanted with the LINX® Reflux Management System will be unable to undergo MRI. Given the increased utilisation of MRI as a diagnostic tool, this is a significant consideration in regards to the suitability of this technology. Use of the device is also not recommended in patients with existing electrical implants (such as pacemakers and implantable defibrillators) or in those patients with metallic abdominal implants.[24]

Summary of findings

The findings of the two clinical trials reported in this Technology Brief illustrate promising results for the use of the LINX® Reflux Management System in treating patients with GORD. In particular, the device's ability to be removed if required and the lower rate of side effects, compared with conventional surgical intervention, make the device a favourable treatment alternative (provided its utility in patients with significant oesophagitis and hiatal hernia can

be determined). However, the evidence base for this technology is in its infancy and it is not currently possible to determine the safety and effectiveness of the LINX® device. Future studies should be comparative (ideally randomised), with broader patient populations and without industry sponsorship. Particular outcomes of interest for future studies should include the durability of the device (i.e. the lifespan of the magnets), its ability to reduce the likelihood of complications of GORD (i.e., Barrett's oesophagus and cancer) and patient QoL. In addition, regulatory approval of the LINX® Reflux Management System in Australia does not appear to be imminent, and the cost of the device is likely to be a barrier to its uptake in clinical practice at this time.

HealthPACT assessment

The LINX® Reflux Management System shows promising results. Given the unlikelihood of new evidence becoming available in the near future, it is recommended that the technology be monitored for a period of 36 months. In this time it is hoped that the device will be closer to implementation in Australia, its cost may no longer be preclusive and its evidence base will be more developed.

Number of studies included

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

Total number of studies 4

Total number of Level IV intervention evidence studies 4

References

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Search criteria to be used (MeSH terms)

LINX reflux management system

Magnetic AND gastroesophageal reflux

Magnetic AND sphincter augmentation

Sphincter augmentation AND gastroesophageal reflux