ISSN 2639-8109 | Volume 14

Annals of Clinical and Medical Case Reports®

Case Report Open Access

Phasix™ non-ST Mesh for Giant Paraoesophageal Hernias - The Way of the Future?

Aldenb Lorenzo[1*], Sarah Mahmood[1,2], Kevin Jia[1], Xin Lin[2], David Goltsman[1] and Christophe R Berney[1,2]

[1]Department of Surgery, Bankstown-Lidcombe Hospital, Sydney, Australia
[2]Faculty of Medicine, University of New South Wales, Sydney, Australia

[*]**Corresponding Author:**
Aldenb Lorenzo, BSE, MD, FRACS, Department of Surgery, Bankstown-Lidcombe Hospital, Sydney, Australia

Received: 13 Apr 2025
Accepted: 12 Apr 2025
Published: 26 Apr 2025
J Short Name: ACMCR

Keywords: Hiatus Hernia; Phasix Mesh;Laparoscopic Hiatus Hernia Repair

Citation: A Lorenzo. Phasix™ non-ST Mesh for Giant Paraoesophageal Hernias - The Way of the Future?. Anna Clin Med Case Rep®. 2025; 14(11): 1-5

1. Abstract

1.1 Background

Mesh reinforcement can be used as an adjunct in giant paraoesophagal hernias repairs. The use of synthetic mesh is associated with significant morbidity whereas biologic mesh is associated with higher rates of recurrence. We aim to assess the safety and effectiveness of biosynthetic absorbable Phasix™ non-ST mesh in the repair of giant paraoesophageal hernias.

1.2. Methods

A cohort study of all patients presenting to Bankstown-Lidcombe hospital for elective laparoscopic mesh repair of giant paraoesophageal hernias was prospectively recorded. Preoperative investigations included gastroscopy and CT-scan of the chest and abdomen. Phasix™ non-ST mesh was used in all cases. Clinical follow ups were scheduled at 2- and 6-weeks, 4- and 12-months post-operative. All patients underwent yearly postoperative CT-scan and gastroscopy. Primary endpoint was endoscopic and/or radiological recurrence, and secondary endpoints included length of hospital stay, morbidity, mortality, and symptom recurrence.

1.3. Results

Thirty-two patients were included. Dyspnoea (62.5%) and dysphagia (53.1%) were the most common symptoms. Twenty (62.5%) had type III and five (15.6%) had type IV paraoesophageal hernias. Median length of stay was 3 days (range 2-7) and only minor postoperative complications were recorded in two patients (6.3%). The median follow-up time was 26 months (range 12-53). No mesh-related complications were recorded and 30 patients (93.8%) were symptom-free. There was only one endoscopic and radiological recurrence found in one patient at 18 months post-surgery.

1.4. Conclusion

Phasix™ non-ST mesh reinforcement of the oesophageal hiatus is feasible with satisfactory symptoms improvement and no adverse outcomes. Further RCTs are required to investigate long-term efficacy.

2. Introduction

Hiatus hernias are relatively common findings in the adult population and often found incidentally on gastroscopy or imaging. We classify hiatus hernias into sliding (type I) and paraoesophageal (types II, III and IV) hernias, with type I hernia being characterised by the displacement of the gastro-oesophageal junction (GOJ) above the diaphragm whilst the fundus remains below. Paraoesophageal hernias (type II-IV) are considered true hernias as they possess a hernia sac and are characterised by the gastric fundus being displaced upwards through a defect in the phreno-oesophageal membrane, with increasing abdominal contents protruding up into the defect. These paraoesophageal hernias comprise 5-10% of all hiatal defects [1]. Patients can be asymptomatic, but often exhibit a broad spectrum of clinical symptoms which can include dyspepsia and reflux, epigastric or chest pain, dysphagia, nausea, regurgitation, shortness of breath, chronic cough, sore throat, and iron deficiency anaemia [2]. Patient may also present with severe complications secondary to paraoesophageal hernias which can include gastrointestinal bleeding, pulmonary aspiration, gastric outlet obstruction, or gastric volvulus. Elective surgical repair is generally indicated in patients with symptomatic paraoesophageal hernias but may be also influenced by other factors including patient age and the severity of existing co-morbidities. Although evidence suggests that there is no indication for intervention in those who are asymptomatic, there is a >10% per year risk to becoming symptomatic [3]. Furthermore, the annual probability of emergency surgery for paraoesophageal hernias in the adult population is around 1%, with a lifetime risk of approximately 18% at 65 years of age [4]. Whilst the mainstay of modern paraesophageal hernia repair is laparoscopic, there remains considerable disparities in the techniques employed including variation in method of hiatal closure and choice of fundoplication, usage and mesh selection. Recurrence rates quoted in literature vary widely, ranging from 4%-66% [5-7]. The severity of recurrence can vary, with the majority being asymptomatic recurrences detected on imaging, whilst others clinically symptomatic requiring re-intervention.Given the potentially high recurrence rates, mesh reinforcement can be considered to circumvent this, however it comes with its own inherent risks. Indeed, permanent synthetic meshes have demonstrated long-term risks of mesh erosion and oesophageal stricture, whereas biological meshes have a hypothetical higher risk for recurrence as they don't integrate well due to limited foreign body response. However, two recent systematic reviews of 7 RCTs demonstrated recurrence rates may be equivocal in both mesh groups (whether synthetic or biological) and could not show any real benefit over simple suture repair.8,9 Conversely, when looking at pooled data from six RCTs and 13 observational studies, Rajkomar et al. [8,9]. Established a significant reduction in large hiatal hernia recurrence rates with use of mesh [10].In recent years, a slowly resorbable biosynthetic mesh has been introduced in Australia. Phasix™ non-ST mesh, or poly-4-hydroxybutyrate (P4HB), is a knitted monofilament mesh that fully resorbs within 12-18 months via hydrolysis. Phasix™ meshes (ST or non-ST) have been widely used worldwide in ventral and incisional hernia repairs. Other biosynthetic or absorbable meshes available include the Gore Bio-A® which has a significantly quicker resorption time of 6-8 months. Those absorbable meshes may reduce the risk of erosion, but hypothetically with the potential long-term cost of hernia recurrence. At present, mesh usage in the

hiatus remains less than 20% in Australia [11]. Due to limited data availability, questions remain as to whether biosynthetic meshes should be routinely used in laparoscopic large hiatus hernia repairs, to improve long-term efficacy (reduced recurrence and complication rates), as well as quality-of-life. Our observational single-institution prospective cohort study aims to assess the feasibility and safety of Phasix™ non-ST mesh with atraumatic fibrin glue fixation (Tisseel) during laparoscopic repair of large sliding hiatus and paraoesophageal hernias.

3. Methods

3.1. Study Design

We conducted an observational single-centre prospective cohort study. All adult patients (aged ≥18 years) admitted to Bankstown-Lidcombe Hospital under the care of one of the co-authors (CB) for elective laparoscopic repair of large (>7cm) sliding (type I) hiatus or paraoesophageal (types II to IV) hernias, using biosynthetic Phasix™ non-ST mesh reinforcement, from September 2019 to March 2022, were included. Data was entered into a prospectively maintained database. We recorded patient demographics, pre-operative symptomatology and ASA score. All patients underwent routine pre-operative clinical assessment, including CT chest and gastroscopy. Selected patients also underwent pre-operative transthoracic echocardiogram (TTE) motivated by chest pain and/or dyspnoea.Our primary outcome of interest was endoscopic recurrence, defined as a recurrence of hiatus hernia measuring >2cm in length, on follow-up gastroscopies, and/or trans-diaphragmatic gastric protrusion on CT-imaging. Secondary outcomes included symptom recurrence, length of hospital admission, post-operative complications and 30-day mortality. This study was approved by the local Institutional Review Board and performed in accordance with the Declaration of Helsinki.

3.2. Surgical Technique

Overweight or obese patients received preoperative low calorie and high protein diet of Optifast to reduce liver size. All patients received preoperative IV antibiotics and DVT prophylaxis with sequential calf compressors and 20mg subcutaneous enoxaparin, as well as an indwelling catheter to monitor urine output and a temporary nasogastric tube to decompress the stomach. They are placed in lithotomy and anti-Trendelenburg position. Pneumoperitoneum is created via closed Veress entry at Palmer's point. Four ports are inserted in the upper abdomen under direct vision and a Nathanson liver retractor is preferentially used. Dissection begins at the lesser curvature at the level of the pars flaccida of the gastrohepatic ligament with identification of the caudate lobe, inferior vena cava, and right crus. Hernia sac is opened and progressively dissected off the mediastinal space, with identification of the left crus. The hernia sac is completely reduced into the abdomen and excised using an ultrasonic dissection device. This is followed by circumferential mobilisation of the lower oesophagus, after careful dissection of the perioesophageal congenital adhesions within the hiatus. A nylon tape is placed around the oesophagus to aid in gentle lateral, downwards and upwards tractions. The distal oesophagus is mobilised into the mediastinum to approximately 7cm or until GOJ can be easily reduced 2-3 cm below the diaphragm without tension (Image 1). Collis gastroplasty or diaphragm relaxing incisions were not utilised. A bougie was also not utilised. Both pleurae are visualized and preserved. Diaphragmatic crura are primarily closed posteriorly with continuous size 1 Stratafix™ (Ethicon) suture and the phreno-oesophageal ligament is re-created using two interrupted 2/0 PDS sutures on both sides.Repair is reinforced with a Phasix™ non-ST mesh cut into a standardized U-shaped 7x10cm configuration, placed posteriorly and secured on the crura with 4mls of Tisseel fibrin glue (Image 2). Posterior gastropexy (close to the GOJ) to the left crus and partial 120o-150o anterior fundoplication (modified Dor) is completed with interrupted 2/0 Ethibond sutures. An intra-abdominal drain is only used when indicated. The nasogastric tube is routinely removed at the end of the procedure and patients receive regular postoperative intravenous

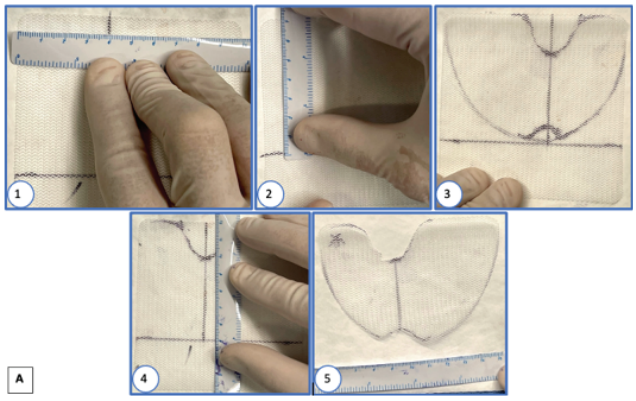

Image 1: A nylon tape is placed around the oesophagus to aid in gentle lateral, downwards and upwards tractions. The distal oesophagus is mobilised into the mediastinum to approximately 7cm or until GOJ can be easily reduced 2-3 cm below the diaphragm without tension.

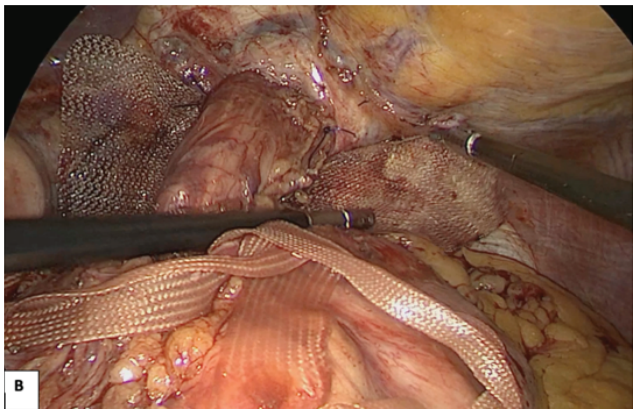

Image 2: Repair is reinforced with a Phasix™ non-ST mesh cut into a standardized U-shaped 7x10cm configuration, placed posteriorly and secured on the crura with 4mls of Tisseel fibrin glue.

antiemetics of Ondansetron 4mg and Dexamethasone 8mg. A post-operative TTE is routinely performed the following day in HDU to exclude cardiac tamponade, and the patient is commenced on a puree diet before discharge home.

3.3. Follow-Up

Perioperative complications were defined in accordance with the modified Clavien-Dindo classification [12]. Patients were followed up at 2- and 6-weeks, and 4- and 12-months after discharge from hospital. Routine gastroscopy and CT chest for evaluation of hernia recurrence were scheduled at 12 months post-surgery, and then yearly.

4. Results

A total of 32 patients (mean age 68.8 years) underwent laparoscopic repair of large sliding hiatus or paraoesophageal hernias with modified anterior Dor fundoplication, using a Phasix™ non-ST mesh for crura reinforcement. Commonly reported preoperative symptoms included dyspnoea (62.5%), dysphagia (53.1%), epigastric pain (46.9%) and chest pain (43.7%). Mild reflux symptoms were reported in 56.3% of cases. Seven patients (21.9%) were diagnosed with a large type I sliding hiatus hernia (measuring >7cm in length), 20 with a type III paraoesophageal hernia (62.5%) and five with a type IV paraoesophageal hernia (15.6%). No patients had a type II paraoesophageal hernia. Pre-operatively, three patients were ASA class I, ten were ASA class II, 18 were ASA class III, and one ASA class IV. Patient demographics and pre-operative characteristics are described in Table 1. All the procedures were completed laparoscopically and there were no intra-operative complications

recorded during our study. The median hospital length of stay was 3 days (range 2-7 days) and the overall post-operative complication rate was 6.3% (n=2). Both complications were recorded as grade I (one asthma attack and one basal lung atelectasis) according to the modified Clavien-Dindo scale. There were no major complications and no post-operative mortality at 30 days (Table 2).The median follow-up time was 26 months (range 12-53). No patients were lost to follow-up at the 2-year mark. No mesh-related complications were recorded and 93.8% of patients (n=30) remained symptom-free. There was only one endoscopic and radiological recurrence found in one patient at 18 months post-surgery, who was immunosuppressed on steroids for severe asthma and suffered chronic cough from bronchiectasis.

5. Discussion

In 1919, the first open hiatus hernia repair was described by Soresi[13]. Many years passed until Cuschieri described laparoscopic repair of large hiatus hernias, paving the way for considerable advances in the surgical approaches to paraoesophageal hernia repair [14]. These hernias are characterized by significant displacement of the gastric fundus in the mediastinum, and occasionally the entire stomach and other abdominal viscera through a large defect in the phreno-oesophageal membrane. They may pose various significant and potentially life-threatening complications such as gastric volvulus, total gastric obstruction, pulmonary aspiration, and bleeding [15-16]. Surgical intervention is therefore recommended for most symptomatic patients, provided they are fit for surgery. A laparoscopic approach is now considered the gold-standard management for symptomatic paraoesophageal hernias, especially in reducing post-operative pain, length of hospital admission, and faster recovery. Despite this, the repair of giant paraoesophageal hernias remains a challenging surgical endeavour with high incidence of recurrence reported between 4%-66% in the literature.5-7 This remains a rather nuanced issue as most recurrences tend to be radiological in nature, with a minority resulting in symptom recurrence.Traditionally, surgical repair of paraoesophageal hernias has relied on primary suture hiatal repair which, unfortunately, has shown relatively high recurrence rates [17]. Case series evaluating modified surgical techniques such as excision of the hernia sac and simple anterior gastropexy show a variable 0%-16% recurrence rate at 24 months [18-20]. Mesh reinforcement has emerged as an alternative approach to reduce recurrence rates by reinforcing the hiatus and improving durability of the repair. While early evidence suggested a significant reduction in hernia recurrence rates, recent studies have not consistently demonstrated the superiority of mesh over primary suture hiatal repair [21]. Different types of prostheses have been used. Synthetic meshes are made of polypropylene, polyester or ePTFE, but have unfortunately demonstrated a long-term risk of oesophageal erosion or stricture [22,23]. A recent systematic review which included 35 case reports and 20 observational studies demonstrated synthetic mesh is more frequently implicated in mesh erosion, with the majority of incidences occurring within 5 years of surgery [24]. Although biological meshes (porcine small intestinal submucosal, bovine pericardium or allograft dermal matrix) do not have the same long-term risk of erosion, they have been shown to have no long-term benefit in term of hernia recurrence compared to synthetic meshes.8,9 Biosynthetic meshes such as Gore Bio-A®, a polyglycolide and trimethylene carbonate polymer which resorbs in 6-8 months, have been utilised with varying degrees of recurrence from 2%-18% [25,26].The emergence of new biosynthetic meshes, such as Phasix™, may present a promising alternative in paraoesophageal hernia repair. Phasix™ mesh is a knitted monofilament mesh which fully resorbs within 12-18 months, which is longer than other comparable biosynthetic meshes available. This offers potential advantages in terms of reducing the risk of erosion associated with synthetic meshes, while avoiding the potential long-term recurrence risk observed with some other biological and biosynthetic meshes as it resorption time is slower compared to other similar meshes [27-29]. A recent 5-year outcome prospective study

Table 1: Characteristics of patients who underwent laparoscopic repair of large hiatus & para-oesophageal hernias with Phasix™ non-ST mesh reinforcement.

	n
Mean age (years)	68.8 (range 38-87)
Sex	
Male	10
Female	22
Symptoms†	***n***
Heartburn or reflux	18
Regurgitation or vomiting	8
Epigastric or retrosternal pain	15
Dysphagia or swallowing difficulty	17
Abdominal bloating	2
Nausea	1
Chest pain	14
Dry cough	3
Burping	2
Iron deficiency anaemia	7
Breathing difficulties or breathlessness	20
Dizziness	6
Pre-operative investigations‡	
Gastroscopy	32
Oesophageal manometry	1
Computed tomography (CT)	32
Barium swallow	1
Echocardiogram	12
Coronary angiogram	2
Hernia classification	
Type I	7
Type II	0
Type III	20
Type IV§	5
ASA class	
ASA I	3
ASA II	10
ASA III	18
ASA IV	1

† Note that numbers do not add up to 32 as some patients reported >1 symptom.
‡ Note that numbers do not add up to 32 as some patients underwent >1 pre-operative investigation.
§ Three greater omentum and two transverse colon.

Table 2: Post-operative follow up results.

	n
Post-operative complications	
Major	0
Minor†	2
Follow-up	
30-day mortality	0
Median length of stay (days)	3 (range 2-7)
Median follow-up (months)	26 (range 12-53)
Symptom-free on last follow-up	30
Endoscopic recurrence at 12 months‡	0
Endoscopic recurrence at 24 months§	1
Chest CT recurrence at 12 months	0
Chest CT recurrence at 24 months§	1

† Minor complications included lung atelectasis and asthma.
‡ Interruption of endoscopies due to COVID-19.
§Hernia recurrence in the same patient.

published by DeMeester's group reported a 25% recurrence rate (8/32 patients) following laparoscopic paraoesophageal hernia repair with composite Phasix™ ST mesh reinforcement that comprises a hydrogel barrier on the intraabdominal side [30]. In this study, Nissen fundoplication was the treatment of choice, which doesn't secure the stomach to the diaphragm, compared to Dor fundoplication. Furthermore, they preferentially secured the mesh to the crura using absorbable tacks, which isn't without risk of vascular injury [31]. Similarly, following a median follow-up of 27 months Aiolfi et al. [32]. Reported a lower hernia recurrence rate of 8.8% (6/68) using the same mesh with a 270o Toupet fundoplication, while Panici Tonucci and coll. published a 3.2% recurrence rate (2/62) after a median follow-up of 17 months, with Toupet fundoplication, which is almost comparable to our findings (3.1% recurrence after a median follow-up of 26 months) [32,33]. None of those three series reported any mesh-related complications.We evaluated the feasibility of Phasix™ non-ST mesh for the repair of giant paraoesophageal hernias. Similar to Gore Bio-A®, Phasix™ non-ST mesh lacks a hydrogel barrier thus promoting adhesion formation on both sides. The aim is to purposely promote stronger connections between the hiatal repair and the posterior gastric wall, which should theoretically ensure permanent reinforcement of the repair long after the mesh has been reabsorbed, and we hypothesise that recurrence rate could be favourably reduced. Our study recorded no mesh-related complications and 93.8% of patients remained symptom-free at median 26 months follow-up, with only one demonstrating hernia recurrence (3.1%). To our knowledge, this is the first study investigating the feasibility of Phasix™ non-ST over a median >2-year follow up for large hiatal/paraoesophageal hernia repairs. Although still too early to draw any conclusion, our results compare favourably to the previously mentioned studies using Phasix™ ST mesh. Only extended follow up will allow us to determine if Phasix™ non-ST can still improve long-term outcome, following laparoscopic paraoesophageal hernia repair compared to Phasix™ ST mesh.Re-do hiatal hernia repairs are technically challenging procedures with a higher risk of postoperative morbidity compared to native hiatal hernia repairs. A recent retrospective study by Liu et al. [34].Analysed 346 patients undergoing revision hiatal surgery, of which [35] had pre-existing mesh, and noted longer operative times and higher risk of intraoperative complications such as bleeding and injury to surrounding lung, liver, and pleura (48.6 vs 22.5%) compared to the non-mesh group [34]. Of importance, this risk was only seen with non-absorbable mesh; absorbable mesh was not associated with an increased risk of complications in revisional surgery, however the retrospective review only included 9 cases with pre-existing absorbable mesh and may not have sufficient sample to draw strong conclusions [34]. Another study by Barazanchi et al. [35] had similar findings with increased risks associated with revisional hiatus surgery with pre-existing mesh [35]. However, this study only had one patient that had a pre-existing absorbable mesh. Thus, more research is needed to see if absorbable meshes have the same risk profile as non-absorbable meshes in relation to revisional hiatus hernia surgery. The Phasix™ non-ST mesh lacks a hydrogel barrier and theoretically promotes adhesions on both sides of the device, with the goal being to prevent recurrence. If a hernia were to still re-occur despite the Phasix non-ST mesh, risk of complications for a re-do should be similar to the Phasix™ ST mesh.

6. Limitations

We conducted an observational prospective cohort study at a single metropolitan hospital in Sydney, Australia. We recognise the risk of introduced bias as the population of patients undergoing paraoesophageal hernia repair is, by nature, inhomogeneous. Owing the nature of our single-centre study we can at least guarantee the consistency of the surgical technique performed throughout the entire cohort study group. We were also limited by a relatively small sample size as Phasix™ mesh only became available in Australia in 2019 and consequently the study may not have sufficient power to detect long-term mesh related complications as they tend to be uncommon.

7. Conclusion

Our single-centre early experience seems promising for medium-to-long term outcomes with Phasix™ non-ST mesh reinforcement of the oesophageal hiatus. More studies with a larger sample size and longer follow up duration are needed to further evaluate the safety profile and efficacy of this mesh in paraoesophageal hernia repairs. Due to the potentially limited number of recruited patients per specialist centre, we would recommend further collaborative prospective multi-centre randomised clinical trials involving the use of biosynthetic mesh to establish its definitive role and potential preferred option in complex hiatus hernia repair strategies, including choice of fundoplication as Nissen doesn't secure the stomach to the diaphragm, compared to Dor fundoplication.

Future research should also emphasize assessing quality-of-life outcomes related to biosynthetic mesh usage, understanding the long-term durability, and potential benefits in reducing recurrence rates beyond the observed follow-up in our study. Moreover, comparisons between different types of biosynthetic meshes, including Phasix™ ST and Phasix™ non-ST, but also other biosynthetic mesh variants, would provide valuable insights into the most optimal mesh choice for paraoesophageal hernia repair, as the debate is still opened..

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