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Research Article

Giant Hiatal Hernia and P4HB Phasix TMST Mesh Hiatoplasty Outcomes

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Received date: October 16, 2024; **Accepted date:** October 23, 2024; **Published date:** October 28, 2024

Citation: Yirupaiahgari Viswanath K S, Sharmaine Quake, Bennett C. Peter, Dina Saleh, Phanibhushana C. Munipalle, (2024), Giant hiatal hernia and P4HB Phasix TMST mesh hiatoplasty outcomes, *Clinical Research and Clinical Trials*, 11(1); **DOI:10.31579/2693-4779/238**

Abstract:

Surgical repair of giant hiatal hernia (GHH) and associated high recurrence rate defy technological advances in surgical sciences despite better instrumentation and availability of various mesh prostheses.

Aim: This study evaluates the safety and efficacy of long-lasting biosynthetic absorbable Poly 4 Hydroxybutyrate Phasix TMST mesh outcomes in patients with GHH undergoing hiatal hernia repair.

Methods:

We studied a prospectively maintained database of all patients who underwent GHH repair between September 2020 and October 2023. Primary outcome measures were 30-day mortality and postoperative morbidities. Secondary outcome measures were 90-day readmission rates, patient-reported outcomes derived through modified Visick grading and recurrence of hiatus hernia.

Results:

44 patients were included in this study. Median follow-up is twenty-four months. There was no mortality at 30 days. 4.5% (n=2) experienced significant complications at 30 days. Median length of stay was 3 days. 81% reported clinical improvement with enhanced Visick grade, and proton-pump inhibitor (PPI) cessation rate was 77.4%. There were no readmissions at 90 days. 9.1% who reported symptom recurrence had anatomical hiatus hernia recurrence.

Conclusion:

The study showed laparoscopic hiatoplasty with P4B Phasix TMST mesh has low morbidity and recurrence with medium-term follow-up.

Keywords: Giant hiatus hernia; Phasix TMST mesh; hiatoplasty; paraesophageal hernia; hiatal repair

Abbreviations

GHH – Giant Hiatus Hernia

ST – Sepra Technology

NSM – Non-absorbable Synthetic Mesh

BSM – Bio Synthetic Mesh

Introduction

The surgical management of giant hiatus hernia (GHH) remains a contentious topic about the best repair technique. Despite technological advances, the recurrence rate of hiatus hernia remains high(Zhang et al., 2017). The laparoscopic mesh hiatoplasty is associated with lower recurrence rates and is recommended to repair GHH(Rajkomar et al., 2023; Tam, Winger, & Nason, 2016). A few studies have not shown a consistent advantage of mesh usage over suture repair in the management of GHH. However, the types of mesh to be used – synthetic, biological or biosynthetic – are controversial, with differing opinions among surgeons(Rajkomar et al., 2023; Tam et al., 2016).

The safety profile and complications associated with mesh hiatoplasty have been well studied(Lima et al., 2023; Sathasivam et al., 2019; Zhang et al., 2017). Non-absorbable synthetic meshes (NSM) have lower recurrence rates than biological or biosynthetic meshes (BSM). However, evidence shows that mesh erosion and luminal stenosis occur after NSM repairs of the hiatus, in some cases leading to esophagectomy (Rajkomar et al., 2023). Absorbable biologic meshes are more costly and can be associated with early recurrence due to their early absorption profile (Sathasivam et al., 2019). This led to the development of biosynthetic meshes (BSM), which have delayed resorptive rates while retaining the biological properties of reduced risk of infection and increased compatibility with surrounding viscera (Finch, Mehmood, & Varghese, 2021).

Over the last decade, there has been a growing tendency towards BSM usage in patients with GHH (Tartaglia et al., 2021). This editorial covers the use of biosynthetic Phasix™ ST mesh in managing GHH (>5cm^2 maximum hiatal diameter). Phasix™ ST mesh comprises the natural polymer of transgenic Escherichia coli, Poly-4-hydroxybutyrate(P4HB)

This study assesses patient outcomes following laparoscopic repair of GHH with mesh cruroplasty in the medium-term follow-up. We have reviewed the literature on the role of biological and biosynthetic hiatal meshes to date.

Methods:

We aimed to evaluate patient outcomes following laparoscopic repair of hiatus hernia with mesh hernioplasty using resorbable Phasix™ ST mesh. This is an observational cohort study at our tertiary Upper GI centre, North of England, UK. Patients who underwent laparoscopic repair of giant hiatal hernias between September 2020 and October 2023 were identified from a prospectively maintained database at our institution. Giant hiatal hernia was defined as hiatal width >5cm^2 determined intra-operatively irrespective of the type of hiatus hernia.

Adults >18 years old undergoing laparoscopic repair of giant hiatal hernias with mesh hernioplasty for both primary and revisional procedures were included. Patients with incomplete data collection or who underwent suture cruroplasty alone were excluded from the study.

Primary outcome measures are 30-day mortality and significant post-operative morbidities (Clavien-Dindo grades III to V). Secondary outcome measures include 90-day readmission rates, clinical outcomes reported during follow-up and recurrence of hiatus hernia. Clinical outcomes were recorded using a modified Visick grade (Watson et al., 2004) (Table 1). The recurrence of hiatus hernia was defined as patient-reported symptoms, with objective evidence of anatomical recurrence of >2cm supported by endoscopic and radiological investigations. Data was analysed using descriptive statistics.

MODIFIED VISICK GRADING	
Grade 1	No symptoms
Grade 2	Mild symptoms, easily controlled by simple measures such as avoiding certain foods
Grade 3	Moderate symptoms not controlled by simple measures, but not interfering with social or economic life
Grade 4	Moderate symptoms interfering with social or economic life
Grade 5	Symptoms bad or worse than preoperatively

Table 1: Modified Visick grading system

At our tertiary institution in the United Kingdom, upper gastrointestinal surgeons have standardized the laparoscopic approach to repair GHH with mesh hernioplasty. The patient is supine, secured with two straps, and placed in the reverse Trendelenburg position. Five trocars were used, including one for liver retraction. Pneumoperitoneum was induced, with pressure set at 12-15mm Hg. The whole hernia sac and associated contents are dissected free and reduced into the abdomen with adequate esophageal mobilization. The target was to achieve at least 3 cm tension-free esophagus below the diaphragm. Most of the sac was excised, and short gastric vessel division was performed where necessary. Care was taken to avoid injury to mediastinal structures and both Vagi nerves. A transabdominal large bore Robinson mediastinal drain was placed in selected cases where pleural breach occurred, which was removed after 48 hours.

The Crura were approximated with Ethibond sutures (Ethibond 2-0, Ethicon, Zug, Switzerland) posteriorly, and in selected, an additional anterior suture was taken, depending on the hiatal morphology. We use the monofilament Phasix™ ST mesh (BD, Allschwil, Switzerland) made of poly-4-hydroxybutyrate with a hydrogel barrier. We performed On-lay crural reinforcement with the mesh following the primary closure of the hiatal defect. The Phasix™ ST mesh was prepared as 'U-shaped' and secured with intracorporeal absorbable tackers on the crural area and atraumatic fixation of tissue glue or suture to secure the outer mesh perimeter. For sizing the mesh hiatus, we used fully opened laparoscopic Johann graspers, and the mesh hiatus was trimmed accordingly. Partial fundoplication (anterior or Toupet) is performed after the combined mesh and suture cruroplasty. All patients are advised on the liquid to a soft diet for six weeks postoperatively.

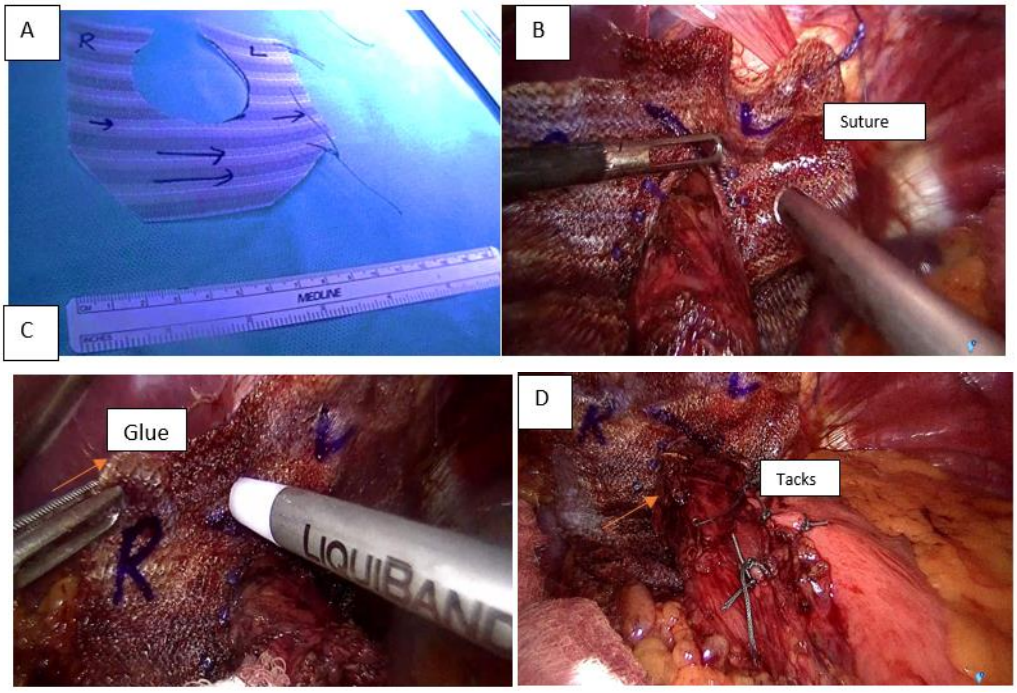


Figure 1 A: Phasix ST mesh prepared as 'U-shaped' mesh. B and C: on-lay crural reinforcement of Phasix ST mesh with intracorporeal tackers and tissue glue. D: The final outcome of combined mesh and suture cruroplasty with partial fundoplication.

Results:

Forty-four patients underwent laparoscopic repair of hiatus hernia with Phasix™ ST mesh hernioplasty for giant hiatal hernia between September 2020 and October 2023. 77% were females, and the median age was 68 years old (IQR 16, range 33 – 86). The majority (88.6%) performed as primary procedures (88.6%) and in elective settings (97.7%), with five patients undergoing the above procedure for recurrent hiatus hernia. All procedures were completed laparoscopically without needing conversion to open procedure. All (100%) patients followed up with a median follow-up period of twenty-four months (IQR 13, range 3-41).

Primary outcome measures

There was no mortality (0%) at 30 days. 4.5% (n=2) of patients experienced major complications at 30 days, defined as Clavien-Dindo grades III – V, with one patient requiring return to theatre for suspected viscus perforation (Table 2). In this patient, there was oedema and florid inflammatory changes, secondary to a small, localized perforation, with no features of a frank perforation at re-laparoscopy. The perforation was managed conservatively with drains and antibiotics. The median length of stay was 3 days (IQR 5, 1-69).

Clavien-Dindo classification	Percentages of patient post-operative complications (%)	
Grade I	6.8%	Acute kidney injury n=2, Pneumonia n=1
Grade II	2.3%	Atrial fibrillation n=1
Grade IIIa	2.3%	Pneumothorax n=1
Grade IIIb	2.3%	Suspected viscus perforation n=1
Grade IV	0%	
Grade V	0%	

Table 2: Post-operative complication rates according to Clavien-Dindo classification.

Secondary outcome measures

The majority (81%) reported clinical improvement in their symptoms with better Visick grades during the follow-up period, with a proton-pump inhibitor (PPI) cessation rate of 77.4% - see Table 3 & Figure *2.* There were no readmissions at 90 days**.** Endoscopic and radiological investigations were performed in patients with recurrent or persistent symptoms. These reported anatomical recurrences greater than 2cm with symptoms in 9.1% of patients at a median follow-up length of twenty-four months. These patients are being treated with pharmacotherapy with a continued follow-up in the future. Altogether, around 19% did not report clinical improvement and were all managed non-operatively, with pharmacotherapy except one patient, who had re-laparoscopy during return to theatre for suspected viscus perforation, due to complex type 3/4 hiatus hernia needing extensive hiatal dissection secondary to adhesions. To date, there are no reports of mesh-related complications. There was no hiatal hernia recurrence in patients with persistent or unchanged symptoms after surgery on imaging or endoscopy.

	Presurgery	Postsurgery
Visick Grade 1	0	20
Visick Grade 2	0	15
Visick Grade 3	14	6
Visick Grade 4	30	2
Visick Grade 5	0	1

Table 3: Visick Grades before and after Phasix Hiatoplasty

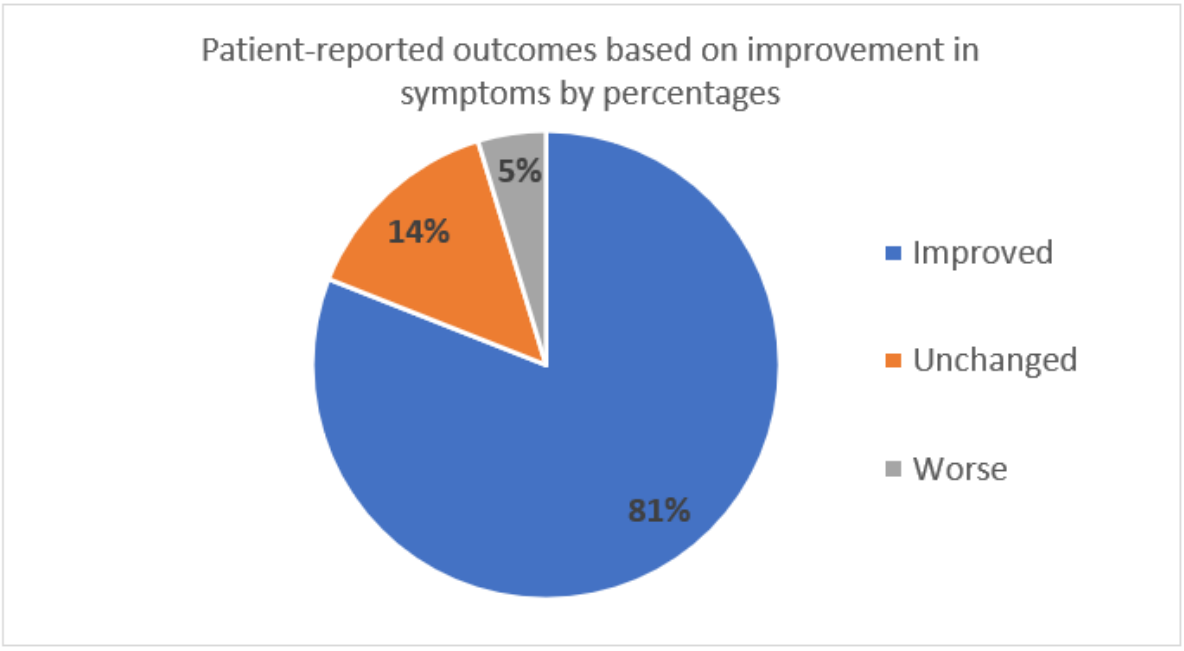
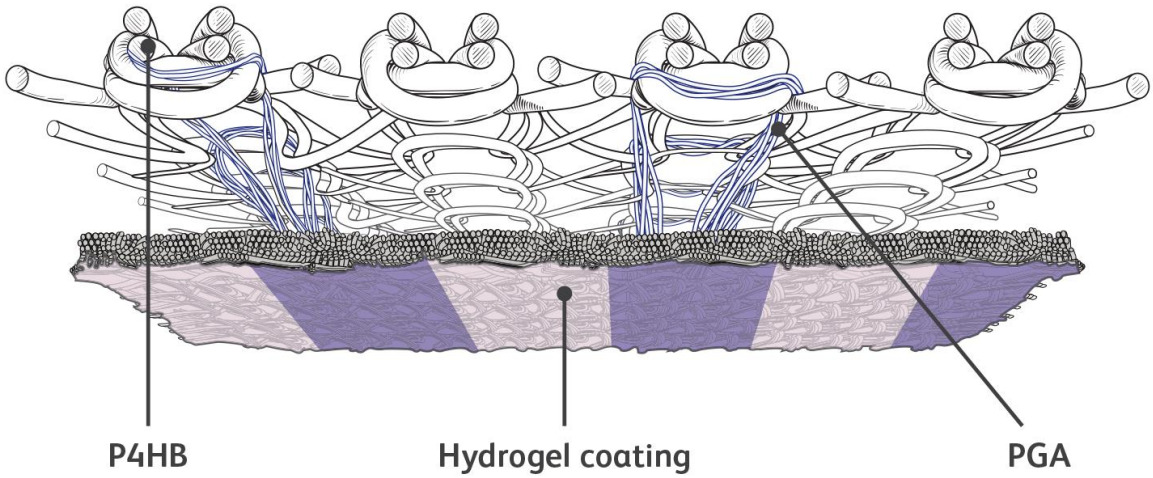


Figure 2: Patient-reported outcomes based on improvement in symptoms during follow-up, according to percentages.



P4HB; Poly 4 Hydroxy Butyric Acid, PGA; Poly Glycolic Acid.

Figure 3: P4HB Phasix™ ST Mesh, the image used with permission from BD.

Discussion

To our knowledge, this is the first study in the United Kingdom reporting on patient outcomes in the medium-term follow-up after laparoscopic repair of GHH using biosynthetic Phasix™ ST mesh. Phasix™ ST mesh is made up of an interwoven sheet of hydrogel coating with poly 4 hydroxy butyric acid (Figure 3). As per our study, there was no mortality in our cohort of patients. In a 2023 European study conducted by Tonucci et al, 8.2% patients had reported post-operative morbidities which is similar to our findings of 4.5%(n=2) major morbidities post-operatively. Additionally, there were no Phasix™ ST mesh related complications in the study, similar to our current findings (Panici Tonucci, Asti, Sironi, Ferrari, & Bonavina, 2020; Ukegjini, Vetter, Dirr, & Gutschow, 2023).

The majority (81%) of our cohort reported improvement in their symptoms during the follow-up period; this is objectively reflected in the rates of PPI cessation (77.4%) and improvement in their Visick scores. In a study of 50 patients with 1 year follow up conducted by Abdelmoaty et al, 8% of patients had a recurrence of hiatus hernia (Abdelmoaty et al., 2020). In another, more recent observational study conducted by Aiolfi et al. the recurrence rates reported following a 2-year median follow up was 8.8% (Aiolfi et al., 2022). These are comparable to our finding of 9.1% recurrence as part of 2-year median follow-up.

The median time to recurrence in this cohort of patients was seven months. In comparison, the absorption rate of Phasix™ ST mesh was reported to be 12-18 months in animal models (Martin et al., 2013). Early recurrence in our subgroup of patients before the average time of Phasix mesh resorption suggests that other risk factors, such as patient and technical-related factors, play a role in the recurrence of hiatus hernia (Ellis et al., 2019; Saad & Velanovich, 2020).

In literature, mesh augmentation is a highly controversial and debated topic of hiatus hernia (HH) surgery; several types of repairs have been employed in this context. More recently, different prosthetic vs biological mesh materials have been used to repair the defect (Sathasivam et al., 2019).

The ideal material for mesh cruroplasty should aim to provide enough tensile strength to aid reinforcement of the hiatus and hence reduce the risk of recurrent herniation whilst avoiding mesh erosion into the viscera and post-operative dysphagia. Employment of a synthetic mesh at the oesophageal hiatus differs from that of inguinal or ventral hernia repairs due to the dynamic nature of the hiatal defect. The continuous diaphragmatic respiratory motion results in the friction effect of the mesh at the esophageal and stomach interface around the hiatus. This has resulted in some cases of mesh erosion into the oesophagus and migration into the stomach (Sathasivam et al., 2019). The latter can result in catastrophic complications, including esophageal resection. Standardizing the mesh fixation techniques used in hiatal hernia surgery is essential. Different centres have used various methods such as sutures, metallic tacks, absorbable tacks, and glue. In our unit, we fix the mesh with glue (Liquiband Cyanoacrylate) and or absorbable tacks for crural edge (Figure 1). In selected cases, absorbable sutures are added. However, for consistency and best practices, it is necessary to establish a standard protocol for mesh fixation.

A variety of non-absorbable and absorbable meshes are utilized in literature worldwide. PTFE was the first mesh documented in the literature and used by Frantzides and Gouvas et al. (Sathasivam et al., 2019). No mesh-related complications were reported in the PTFE group. Partially absorbable mesh (Poliglecaprone- 25/Polypropylene composite was used in one study (Panici Tonucci et al., 2020).

Other options included absorbable (biodegradable) material that acts as a scaffolding for significant tissue growth for persistent reinforcement. Ringley et al. used a Human acellular dermal matrix (ACDM) patch to reinforce the hiatal closure during laparoscopic hiatal hernia repair (Sathasivam et al., 2019). Oelschlager et al. used porcine small intestinal submucosa for laparoscopic repair of large para esophageal hernias. However, the layered nature of this material made it more challenging to suture to the hiatus during laparoscopic cruroplasty and hence the initial tensile strength before tissue in-growth (Panici Tonucci et al., 2020).

The current scientific evidence remains unclear, and even experts disagree on indications and surgical techniques. Biosynthetic long-term resorbable meshes (BSM) such as Phasix have been developed to avoid the downsides of both non-resorbable synthetic and short term resorbable biological meshes. They are becoming increasingly popular and have been cited in previous studies (Sathasivam et al., 2019).

Absorbable allogenic and xenogeneic materials ("bio meshes") have been introduced and widely promoted to overcome the undesirable characteristics of permanent synthetic meshes. P4HB Phasix™ ST Biomesh is a biosynthetic mesh that gets revascularized and reincorporated with added advantage of having high resistance to bacterial contamination (Panici Tonucci et al., 2020).

Such new-generation long-term absorbable biosynthetic meshes (BSM) have recently been developed to combine the advantages and avoid the downsides of synthetic materials and bio meshes. Phasix ST® (BD, Allschwil, Switzerland) is made from poly-4-hydroxybutyrate (P4HB), a material that handles well laparoscopically, absorbs and remodels to native host tissue within 18 months, and hence carries a lower risk of long-term complications. The mesh provides a monofilament scaffold allowing rapid incorporation with enhanced tissue strength along with remodelling characteristics of a biological prosthesis (Figure 4).

Hiatal Hernia repair with the Phasix bioabsorbable mesh, crural reinforcement, and appropriate tension-reducing techniques is associated with a low early hernia recurrence rate and no mesh-related complications. However, as we stand now, more studies are required to elaborate on using this mesh to confirm long-term efficacy (Sathasivam et al., 2019).

Although promising in concept, few studies have reported clinical outcomes after P4HB reinforcement in HH repair (Panici Tonucci et al., 2020)

Limitations and Strengths

Invariably, COVID-19 impacted our elective operating capacity in the United Kingdom. Therefore, our sample size is smaller than expected for a consecutive period of thirty-seven months. A long-term follow-up would determine whether the overall recurrence in patients undergoing P4HB Phasix™ ST hiatoplasty is less than primary suture repair. Additionally, this is a single centre study and warrants recruitment of other hospitals to increase generalization and understand the outcomes of the study.

One of the major strengths of this study is the application of the modified Visick grading system, standardizing the clinical outcomes of the patients. Additionally, the procedure for all patients were standardized and hence gives a more robust understanding of the outcomes of mesh hernioplasty pertaining to the operative procedure.

Conclusion

We conducted a study on Laparoscopic Hiatoplasty using Biosynthetic Phasix™ ST Mesh in patients with GHH. The study showed this procedure has low morbidity and recurrence with medium-term follow-up. Aside, it also affirms that patients sustain symptomatic improvement along with an improved quality of life. The study results are comparable to a few studies published earlier. We intend to continue following these patients as part of a continued long-term observational study.

Despite the positive outcomes, determining what type and when to use a mesh in patients with giant hiatal hernia remains challenging. For all technological advances and surgical endeavours, the quest by foregut surgeons in the world to standardize the procedure continues. Further randomized control studies need to be conducted to understand the outcomes of using different types BSM for the repair of GHH. Additional research needs to be done to create the ideal mesh for complete repair of GHH.

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DOI:10.31579/2693-4779/238