Clinical overview of hiatal hernia repair

The evolution of hiatal hernia repair

Paraesophageal hernia repair techniques have evolved over the years, but minimizing recurrence rates remains an important concern. During the years of open surgery, sutured crural repair without mesh reinforcement was routine[1]. However, high objective recurrence rates with laparoscopic repair have prompted many surgeons to evaluate the use of mesh at the hiatus given excellent results with mesh at other hernia sites[6]. Two small series using permanent synthetic mesh appeared to reduce hiatal hernia recurrence rates[1] *(table 1)*, however many surgeons are concerned about the potential risk of erosion with permanent synthetic mesh at the hiatus. Subsequently, two randomized trials were conducted using biologic mesh for crural reinforcement. There was no mesh erosion, but the mesh failed to improve hernia recurrence rates compared to suture repair alone[1] *(table 1)*. There is a need for a material that provides a repair without long-term mesh complications.

Range of recurrence rates by mesh type *(based on studies below)*[1]			
	Suture repair	Permanent synthetic	Porcine SIS
Recurrence rate %	22–59%	0–12.8%	30.8–54%

Table 1: Prospective randomized controlled studies evaluating recurrence of PEH after laparoscopic mesh repair[1,2]

	Frantzides et al. 2002	Granderath et al. 2005	Oelschlager et al. 2011	Watson et al. 2015
n=	72	100	60	126
Inclusion criteria Technique: laparoscopic	Hiatal defect >8 cm	Persistent GERD related symptoms Decreased quality of life LES pressure <6mm Hg in combination with pathologic pH values	Hiatal defect >5 cm	Large hiatus hernia; at least 50% of stomach
Procedures	360 nissen fundoplication	360 nissen fundoplication	Nissen fundoplication Collis gastroplasty-discretion of surgeon	Fundoplication *(determined by surgeon)*: Nissen, posterior or anterior partial
Objective follow-up *(mean ± SD, years)*	3.3+– 1.7	1	4.8	0.5
Recurrence rate				
Diagnosis of recurrence	EGD Esophagram	EGD, esophageal manometry, 24-hour pH monitoring, and barium swallow	UGI	Barium meal radiology and endoscopy
Suture repair *(n)*	22% *(8)***	26% *(13)****	59% *(20)****	23.1% *(9)****
Mesh repair *(n)*	PTFE: 0% *(0)***	Polypropylene: 8% *(4)****	SIS biologic: 54% *(14)****	SIS biologic: 30.8% *(12)**** Permanent: 12.8% *(5)****
p-value	<0.006	<0.001	0.7	0.161
Timing of recurrence	All within 6 months	Not described	Within 5 years	All within 6 months
Mesh complications *(n)*	None	None	None	SIS biologic: esophageal perforation[1] Permanent: gastric perforation[1]

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Phasix™ ST Mesh: The only bioresorbable mesh with a proven hydrogel barrier

Primary closure
High recurrence rates[1,2]

Permanent synthetic
Mesh erosion risk[5]

Biologic mesh
High hiatal hernia recurrence rate with high cost[1]

Phasix™ ST Mesh
Early clinical results indicate a strong repair[3,4] and early remodeling[7]

Phasix™ ST Mesh early clinical data

Early outcomes with use of fully bioresorbable poly-4-hydroxybutyrate mesh for reinforcement of crural closure during laparoscopic para-esophageal hernia repair DeMeester et al. 2018[3] *(Poster presented at SAGES 2018)*	
n=	50
Inclusion criteria	≥50% of stomach herniated into chest
Mesh	Phasix™ ST Mesh
Procedures Fundoplication Collis gastroplasty Relaxing incision Partial gastrectomy	**% of patients** 98% 36% 4% 2%
Median follow-up *(months)* *Objective (EGD & UGI)	8.5
Recurrence rate *(n)*	1 *(asymptomatic)*
Mesh complications	None

Retrospective, single center analysis of Phasix™ ST Mesh in laparoscopic hiatal hernia repair DeMeester et al. *(Data currently unpublished)*[4]	
n=	180
Preoperative diagnosis	Gastrointestinal reflux (GERD) Paraesophageal hernia (PEH) Morgagni hernia
Mesh	Phasix™ ST Mesh
Procedures Nissen fundoplication Partial fundoplication Collis gastroplasty Relaxing incision Total or partial gastrectomy LINX implantation	**% of patients** 42.8% 53.3% 29.4% 4.4% 2.2% 1.1%
Mean follow-up *(months)* Median objective follow-up	7 4 *(EGD and Barium Swallow)*
Recurrence rate *(n)*	2 *(asymptomatic)*
Mesh complications	None

The combination of product and technique to address tension while providing early remodeling shows promising early clinical results[3,4]

Indications
Phasix™ ST Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias, including hiatal hernias.

Contraindications
Because Phasix™ ST Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.

Warnings
Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. Use of this device in patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided.

Ensure proper orientation; the coated side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the uncoated mesh side against the bowel. There is a risk for adhesion formation or erosions when the uncoated mesh side is placed in direct contact with the bowel or viscera. (Reference Surface Orientation section of the instructions for use.)

The safety and effectiveness of Phasix™ ST Mesh in bridging repairs has not been evaluated or established.

The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh and it is not recommended.

If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh.

For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended.

For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended.

The safety and effectiveness of Phasix™ ST Mesh in the following applications has not been evaluated or established: pregnant women, pediatric use, neural and cardiovascular tissue.

Precautions
The safety and effectiveness of the mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity.

Adverse Reactions
In preclinical testing, Phasix™ ST Mesh elicited a minimal tissue reaction characteristic of foreign body response to a substance.

The tissue reaction resolved as the mesh was resorbed. Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, allergic reaction, hemorrhage, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect. Possible complications in hiatal hernia repair may include esophageal erosion and dysphagia related to crural fibrosis.

Please consult package insert for more detailed safety information and instructions for use.

1 Kohn GP, et al. Guidelines for the management of hiatal hernia. *Surgical Endoscopy.* 2013:4409-28.
2 Watson DI, et al. Laparoscopic repair of very large hiatus hernia with sutures versus absorbable mesh versus nonabsorbable mesh. *Ann Surg.* 2015;261(2):282-289.
3 DeMeester SR., et al. Use of fully bioresorbable poly-4-hydroxybutyrate mesh for reinforcement of crural closure during para- esophageal hernia repair. Poster presented at The 16th World Congress of Endoscopic Surgery (SAGES); April 11-14, 2018; Seattle, WA.
4 Unpublished clinical data on file at BD.
5 DeMeester TR., et al. Laparoscopic versus open repair of paraesophageal hernia: the second decade. *American College of Surgeons.* 2011;212(5):813-20.
6 Roth JS., et al. Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC lass I/High risk ventral and incisional hernia repair. *Surgical Endoscopy.* 2017; 32(4):1929-1936.
7 Preclinical data on file; results may not correlate to clinical performance in humans.

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** Symptomatic recurrences reported.
*** Asymptomatic and symptomatic recurrences reported.

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