Updates from the MVP Trial

Mesh Vs Pledgets for Paraesophagel Hernia Repair: A randomized, Blinded, Parallel Group Trial

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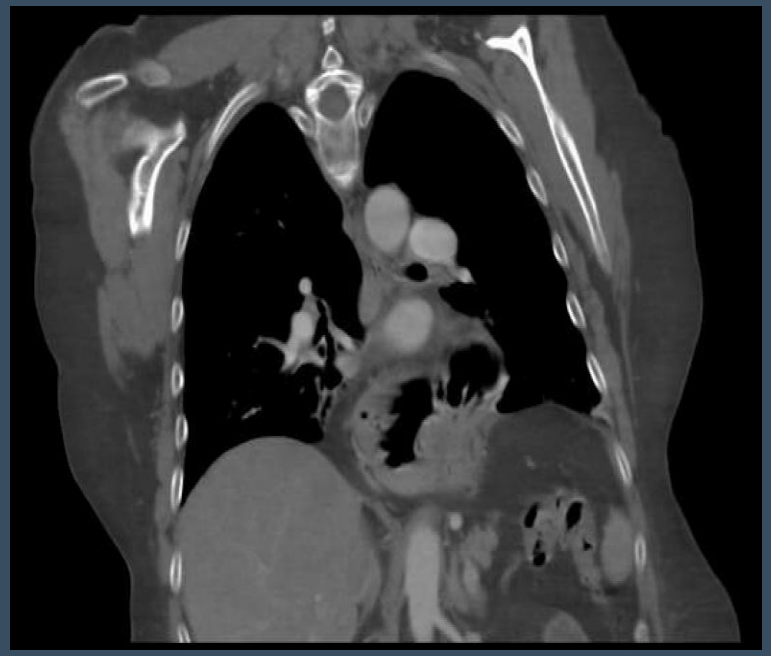
MVP Trial Co-Investigator

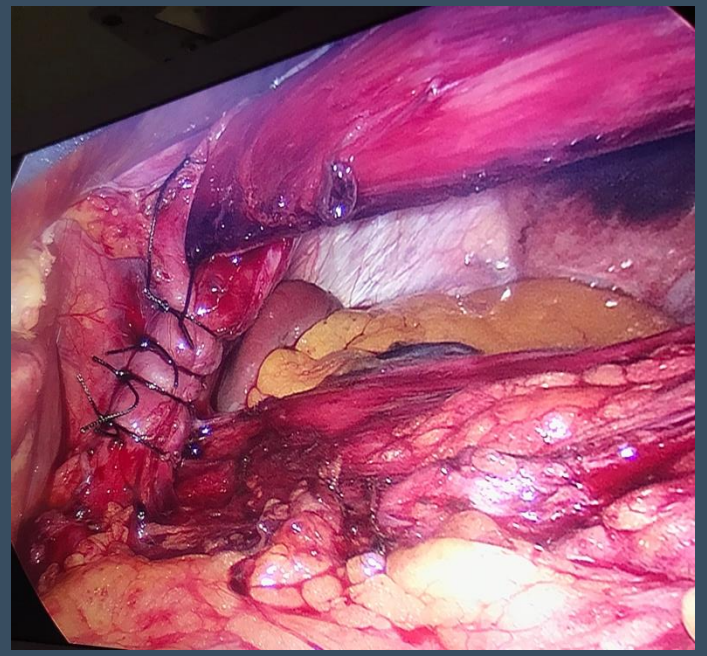
Disclosure

- Consultant for TELA Bio and Advanced Medical Solutions
- Ongoing industry-sponsored RCT

Background

- Peet (1998)
- Diaz (2002)
- Poncet (2010)
- Oelschlager (2011)
- Pallabazzer (2011)
- Daigle (2014)
- Lidor (2015)





Average Recurrence Rate

~ 30%

Background

5 RCTs Evaluating Hiatal Mesh for Paraesophageal Hernia Repair (**PEHR**)

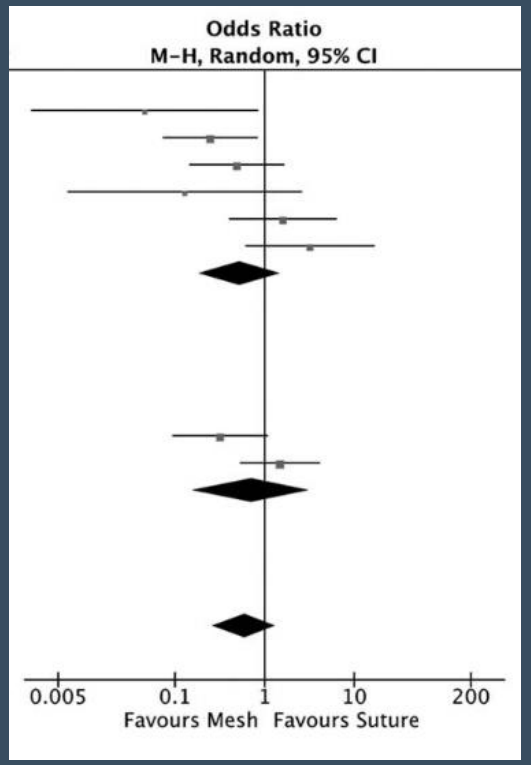
- 2 show benefit
- 2 show short-term benefit
- 1 failed to show benefit

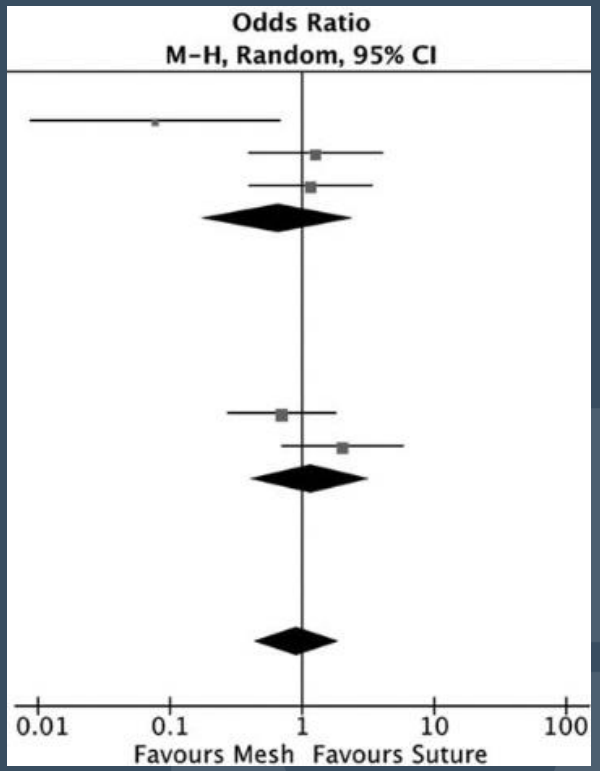
- No RCTs have assessed hybrid reinforcement - OviTex

Sutured Versus Mesh-augmented Hiatus Hernia Repair

A Systematic Review and Meta-analysis of Randomized Controlled Trials

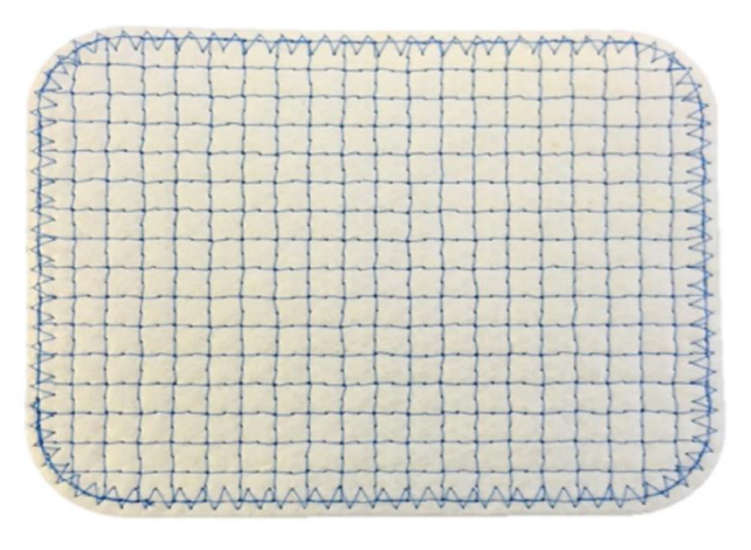
Josipa Petric, MD, BMedSc,†✉ Tim Bright, MBBS, MS, FRACS,†*
David S. Liu, MBBS (Hons), BMedSc, PhD, FRACS,†‡ Melissa Wee Yun, MD, BMedSc,†
and David I. Watson, MBBS, MD, PhD, FRACS, FRCSEd (Hon), FAHMS†*

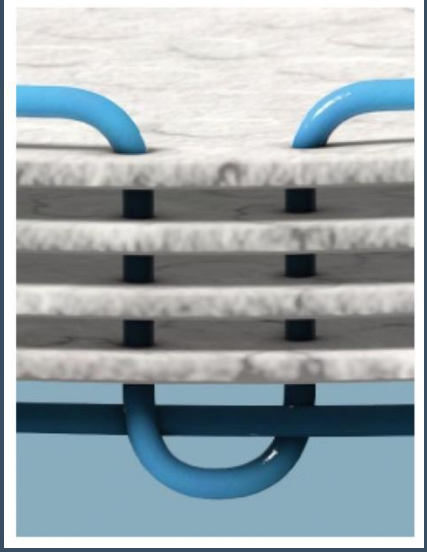




TELA Bio OviTex

- Ovine rumen with interwoven polymer fibers
  - 1 series (n=25) with no recurrences at 14 months

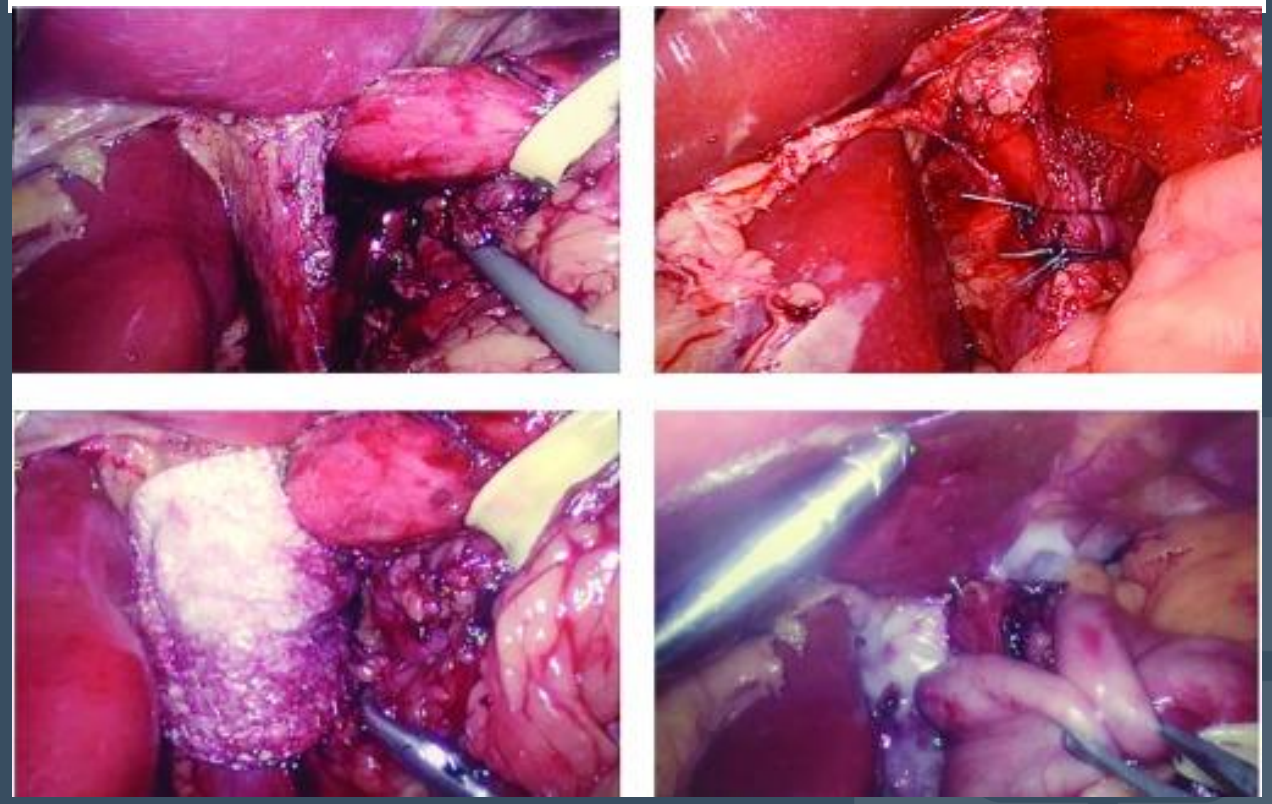




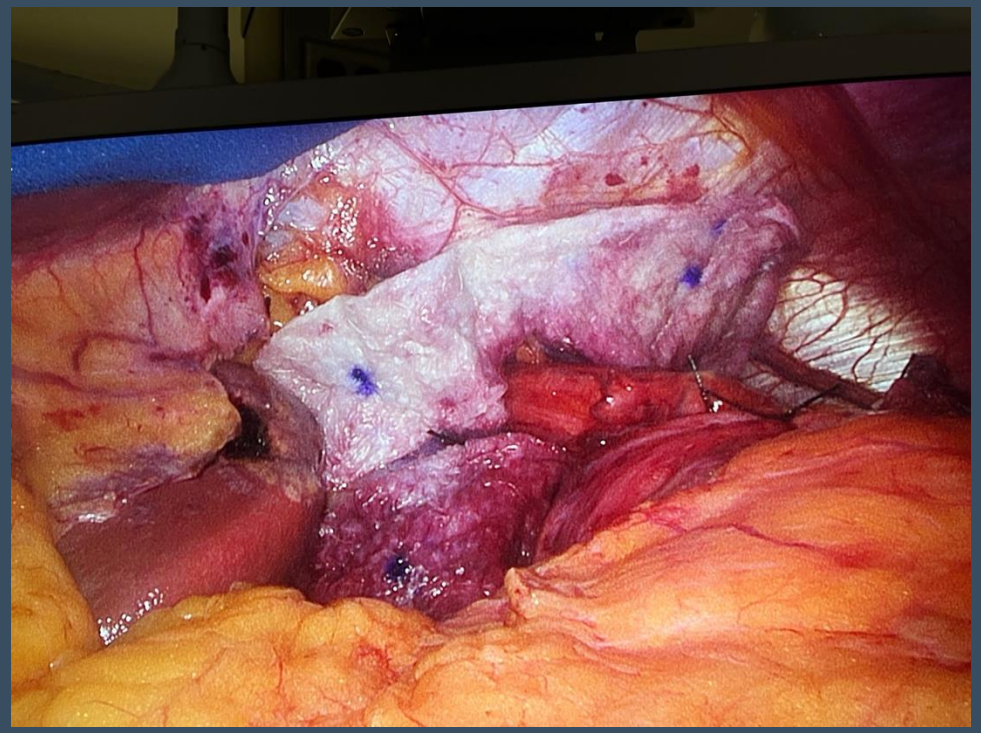
CASE SERIES JSLS

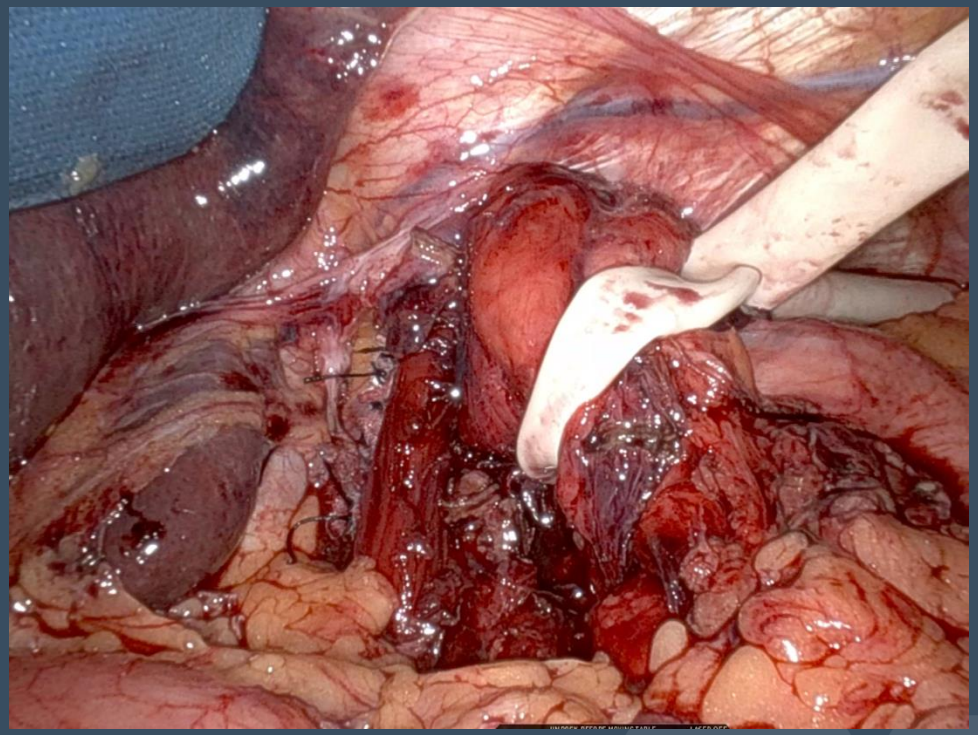
New Ovine Polymer-Reinforced Bioscaffold in Hiatal Hernia Repair

Michael A. J. Sawyer, MD



Hypothesis



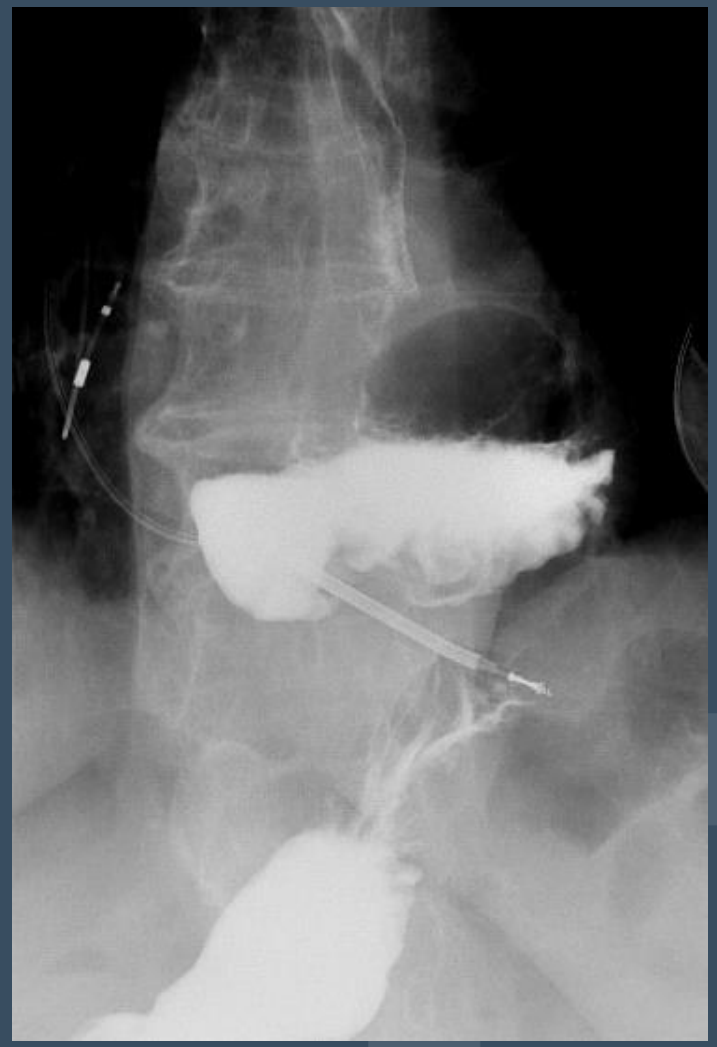


OviTex hiatal reinforcement is superior to pledgeted crural repair in regard to 2-year recurrence

Objectives

- **Primary Objective**
  - **Compare 2-year recurrence rates following PEHR**

- Secondary Objectives
  - Compare PROs
    - Pain
    - QoL
    - Regret



Outcome Measurements

Outcome	Measurement	Scale	Better
Recurrence	**CT A/P, UGI, MRI – 2/3 Reviewer Consensus**	**≥2cm**	**No**
Pain	VAS	0-10	
GERD	GERD-HQRL	0-50	
Atypical Symptoms	Additional Foregut Q&A	0-80	
Regret about pursuing surgery	Decision Regret Scale	0-100	

Decision Regret Scale

Please think about the decision you made about _____ after talking to your [doctor, surgeon, nurse, health professional, etc.]. Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).

1.	It was the right decision	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
2.	I regret the choice that was made	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
3.	I would go for the same choice if I had to do it over again	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
4.	The choice did me a lot of harm	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree
5.	The decision was a wise one	1 Strongly Agree	2 Agree	3 Neither Agree Nor Disagree	4 Disagree	5 Strongly Disagree

Methods

Prospective

Registry-Embedded

ACHQC

REDCap

Two-arm

Double-Blinded

Superiority Trial

Methods

- Power Calculation
  - 25% Difference (15% vs 40% baseline)
  - α 0.025, β 0.9
  - 65/arm = 130
  - 20% loss to follow-up
  - **82/arm = 164**
- Accrual
  - Estimated 24 months of accrual
  - Estimated 4 years until completion

Inclusion

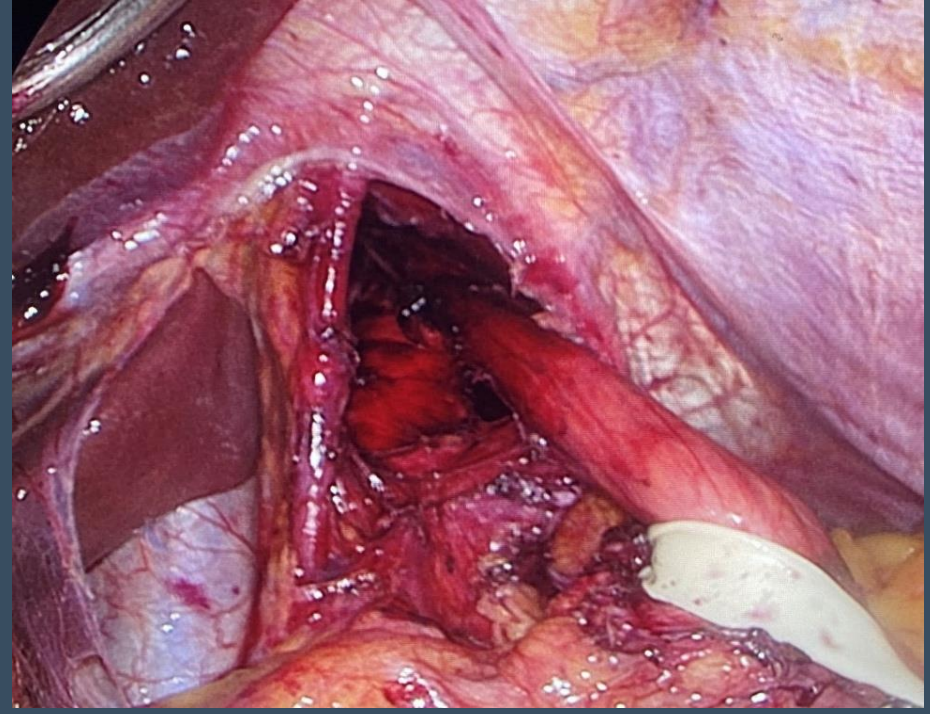
- ≥18
- Willing and able to provide consent
- Willing and able to follow-up
- Type II, III, or IV hiatal hernia >5cm via UGI, CT, or MRI
- Intraoperative confirmation of >5cm intrathoracic size

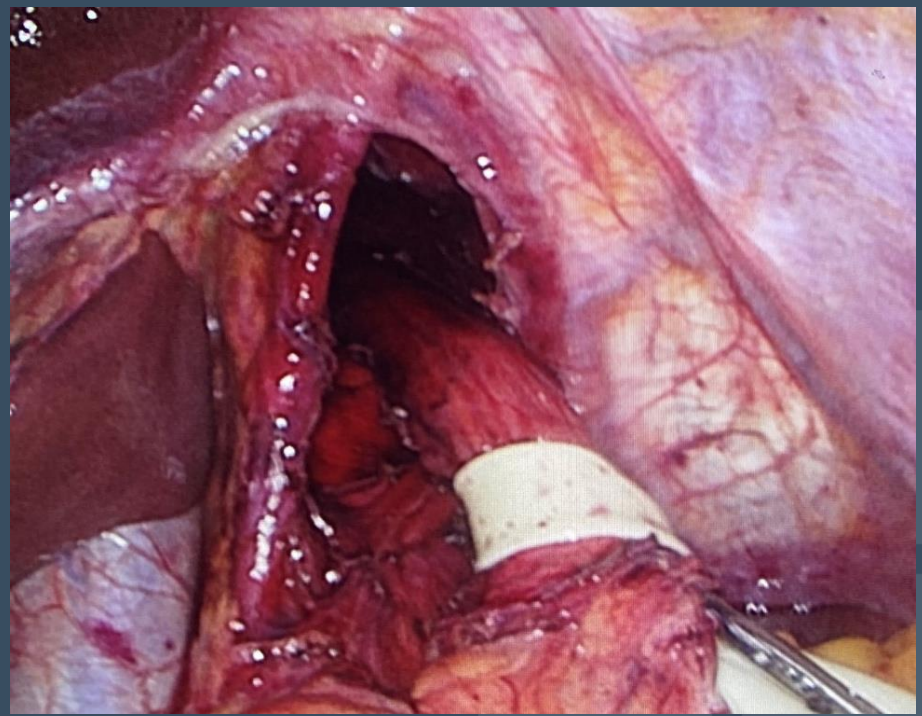
Exclusion

- Pregnancy
- BMI >45cm
- Allergy to any mesh component
- Concurrent bariatric procedure
  - Sleeve gastrectomy
  - RYGB, DS, Single-anastomosis GB
  - Partial/total gastrectomy
- Prior hiatal hernia repair

Procedure

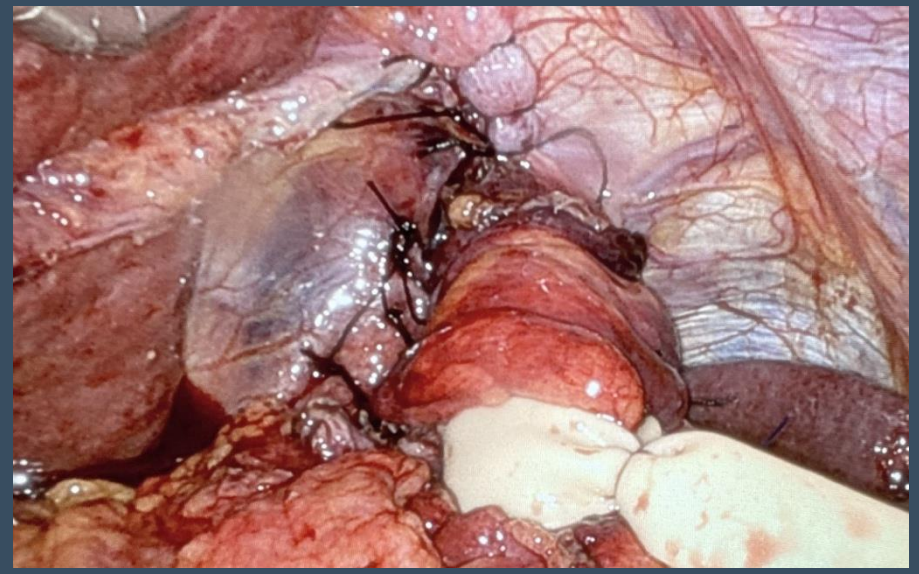
1. Confirm ≥5cm PEH
2. Excision of hernia sac from mediastinum
3. Reduction of hernia contents/restoration of normal anatomy
4. Restore ≥2cm of intrabdominal esophagus
5. Measure H/W Hiatus
6. Photo w/wo tension
7. Randomize

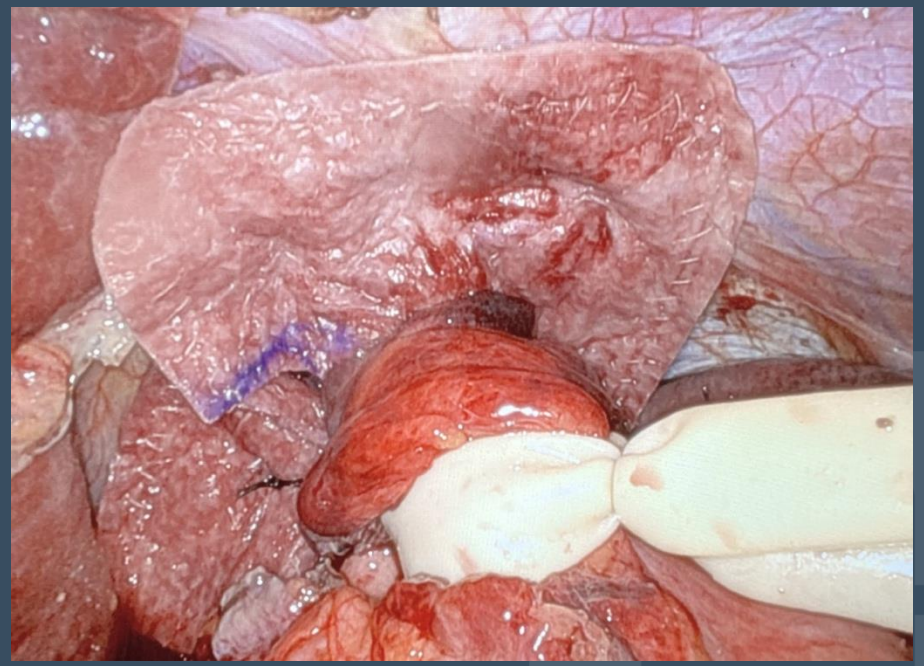




Procedure

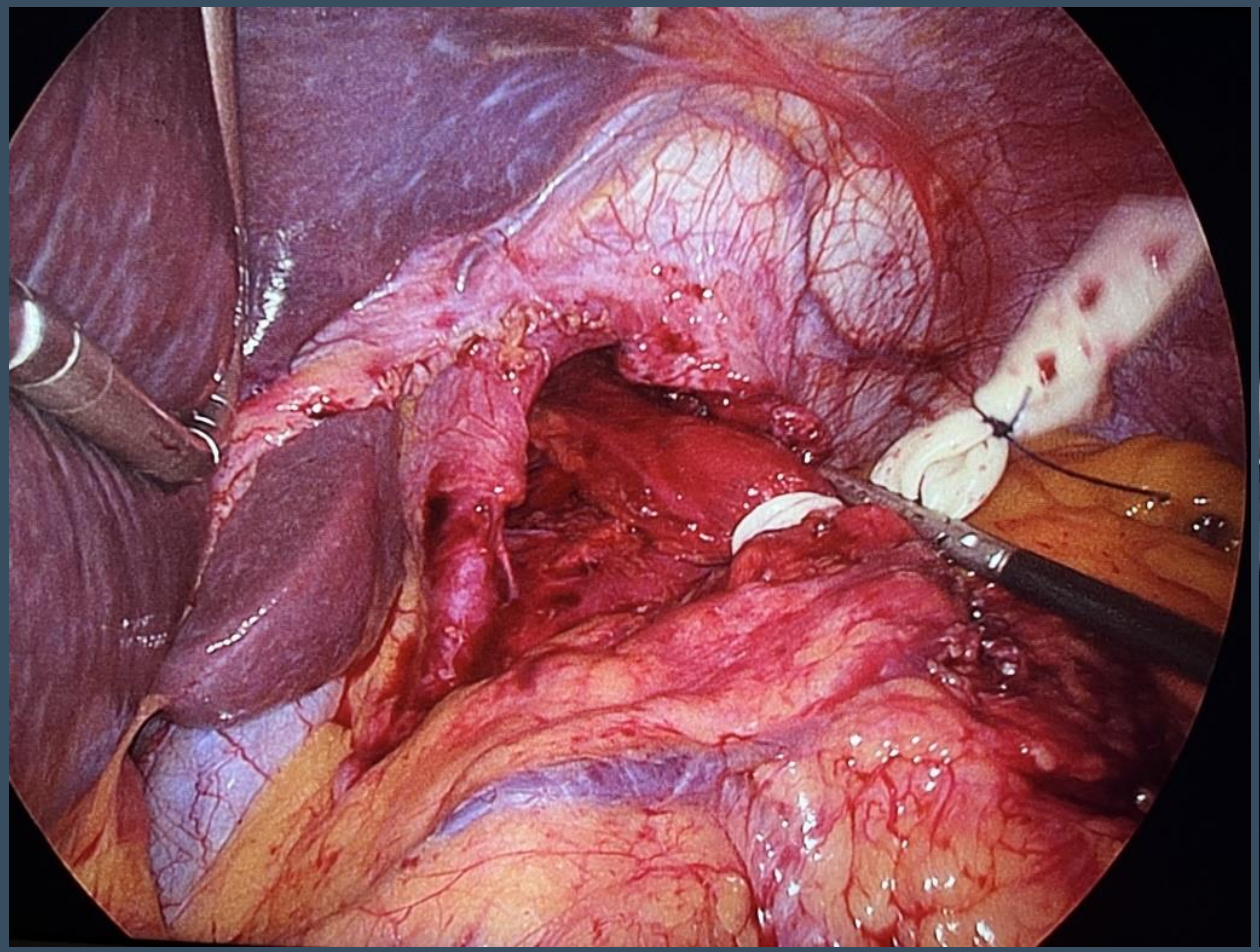
8. Closure of crural defect
   +/- PLEDGETS
   - Measure and record intraabdominal esophageal length
9. +/- Fundoplication (Surgeon Pref)
   +/- OviTex Placement
10. Anterior gastropexy for all repairs
    - Two 2-0 transfascial prolene sutures

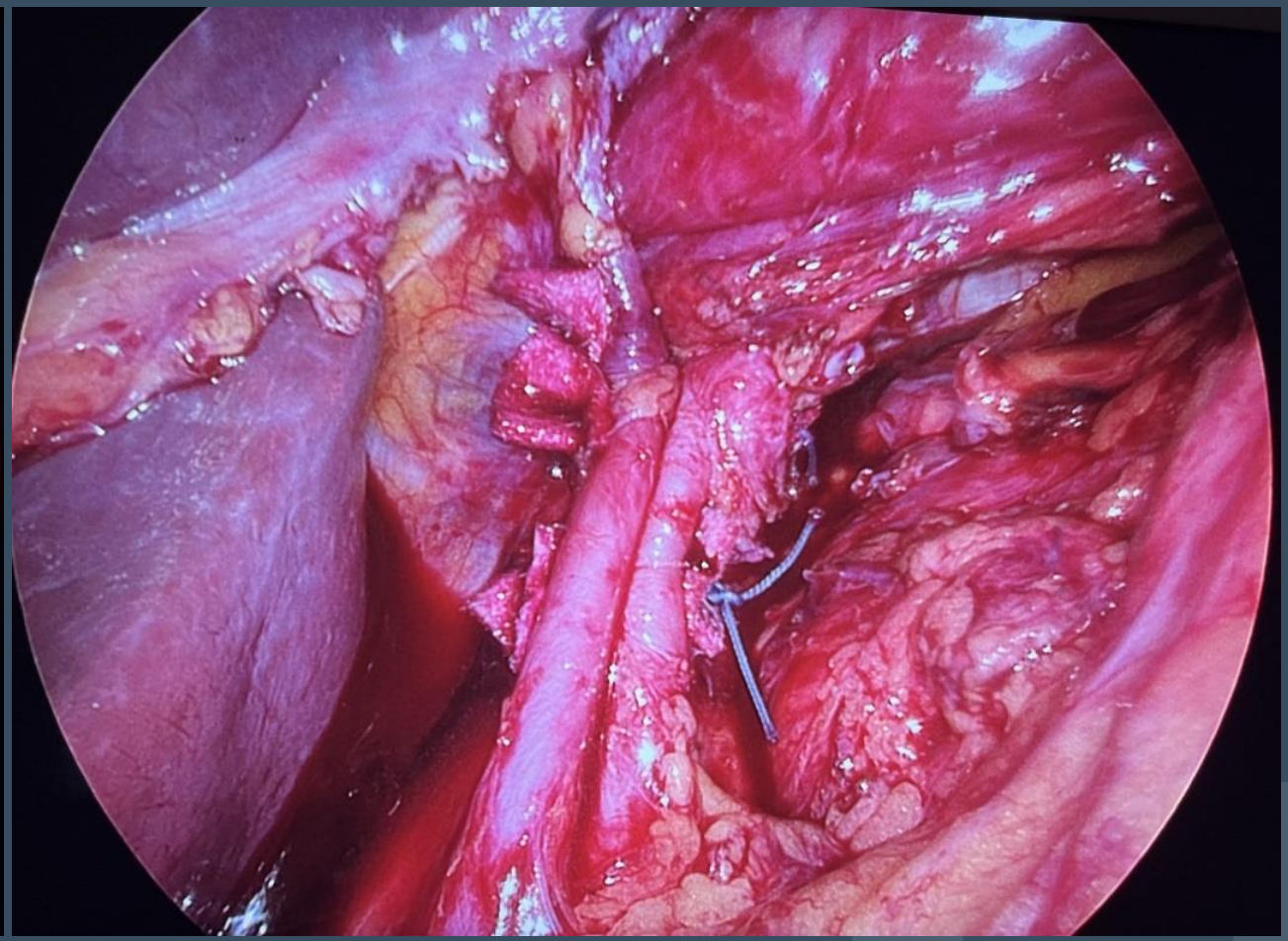




Pledgeted Suture Repair

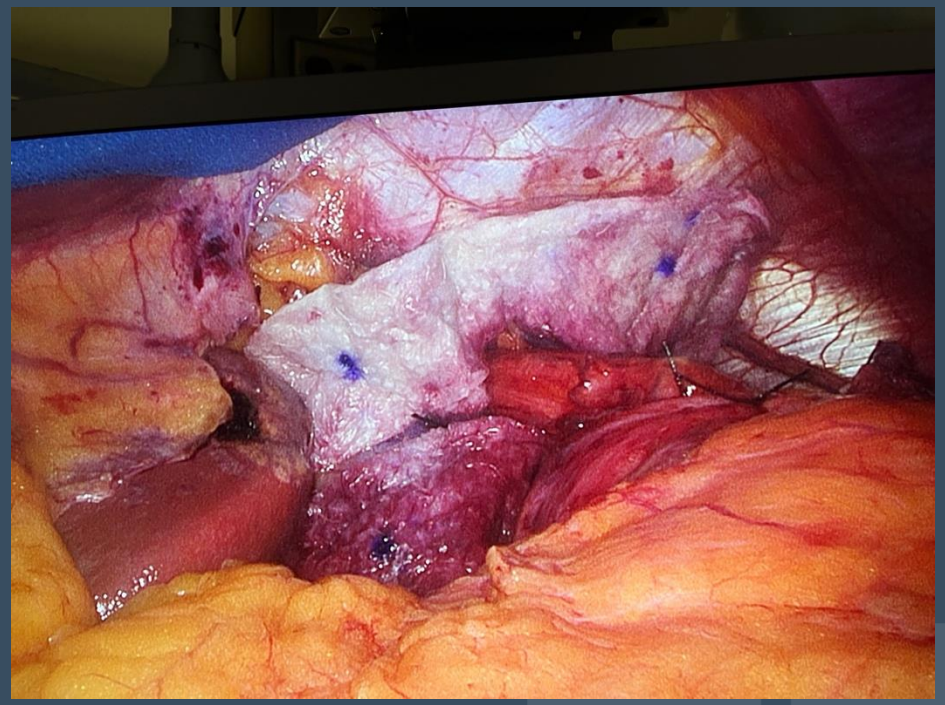
- “Standard Treatment”
  - Interrupted 0 polyester-type braided sutures placed in a vertical mattress over 1cm x 1cm PTFE pledgets
- Crural repair via posterior approach
  - Posterior stitches must be pledgeted
  - Anterior and lateral stitches allowed, not mandated to pledgets
- Repairs are photographed for subsequent review

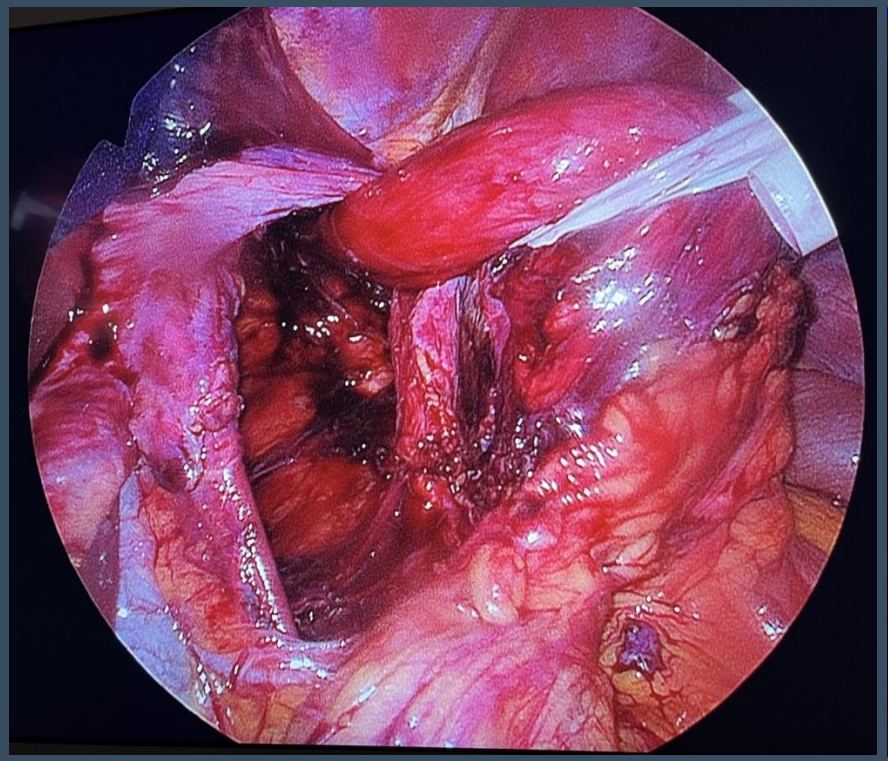
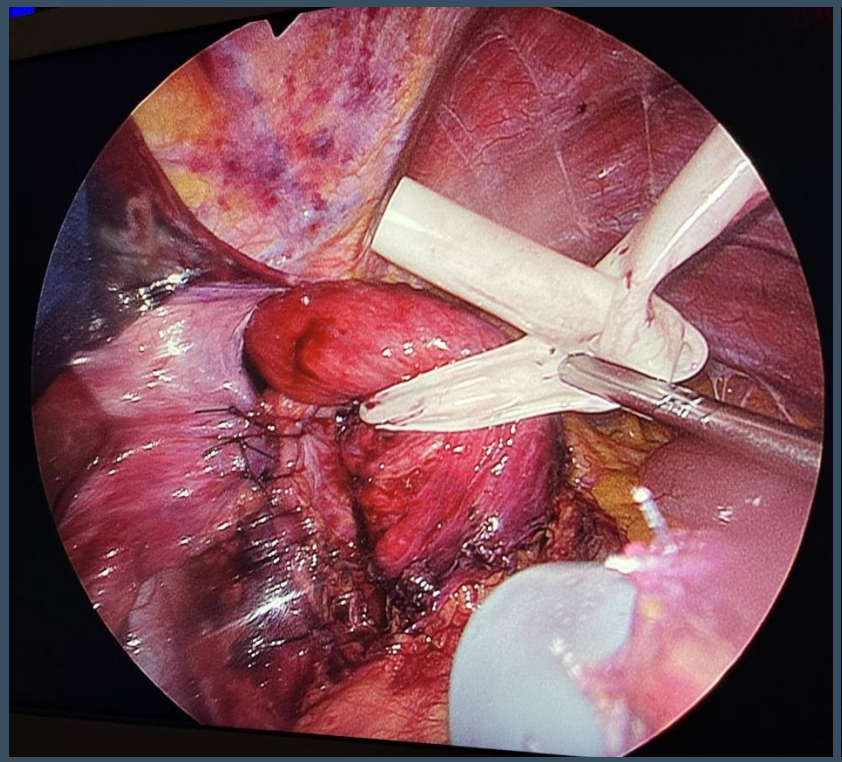
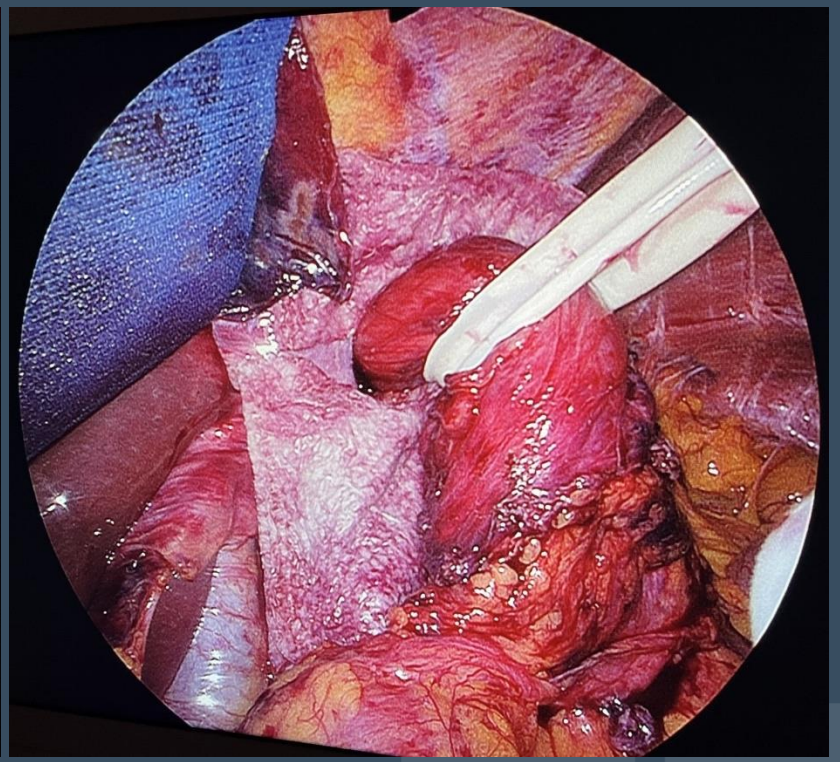




OviTex Repair

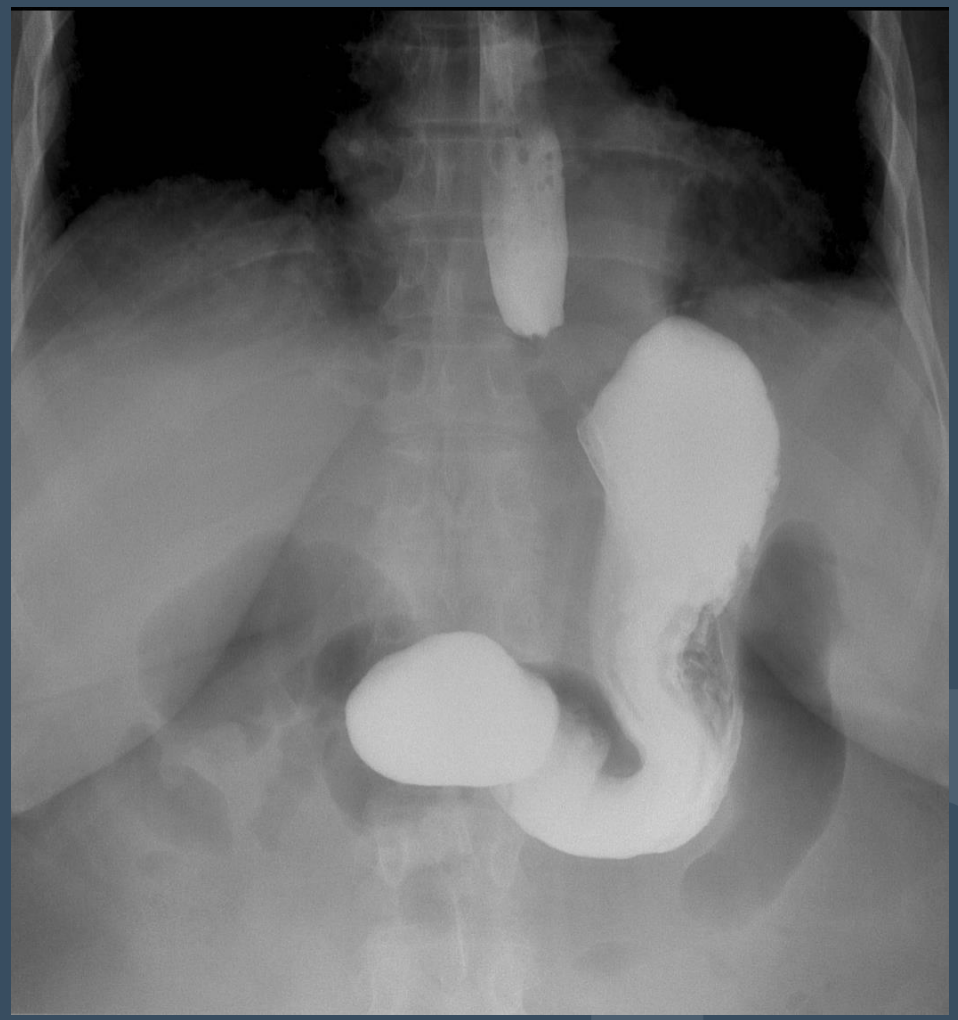
- “Experimental Treatment”
  - Primary crural closure with interrupted 0 polyester-type braided sutures
  - Posterior closure; anterior and left lateral sutures allowed.
- 1S OviTex applied as an onlay in a reverse “C” configuration opening toward patient-right
    - Fixation per surgeon
- OviTex repairs will be photographed



Post-Operative Care

- POD 1 UGI
- Initiation of liquid diet
- Routine care per surgeon
- Subjects may be discharged after
  - Toleration of PO intake
  - Ambulation
  - Adequate pain control



Follow-Up

	Baseline	POD#30	1-year	2-year
GERD HQRL	x	x	x	x
Additional Foregut Q&A	x	x	x	x
EQ5D	x	x	x	x
VAS	x	x	x	x
Decision Regret		x	x	x
Imaging (CT, UGI, MRI)			x	x

Progress To-Date

First consent - 9/11/2023

First randomization - 10/18/2023

88 patients consented

77/164 patients randomized

3 next week!

Cleveland Clinic

Every life deserves world class care.