Use of Mesh During Repair of Hiatal Hernias

Safe, Valuable and Indicated Adjunct for Surgical Repair

Erik Peltz, D.O.

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University of Colorado Denver

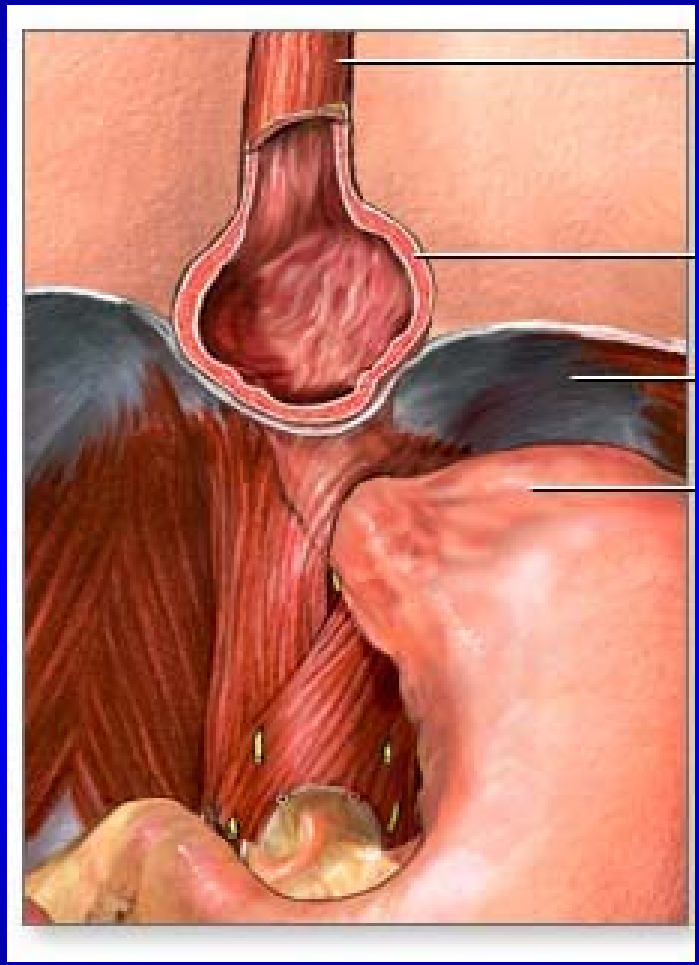
Department of Surgery

Overview

- Anatomy / Physiology
- Where is the controversy? What's this really about?
- "Evidence" that mesh is dangerous
- Evidence clearly demonstrating safety and efficacy of mesh during surgical intervention.
- Conclusions

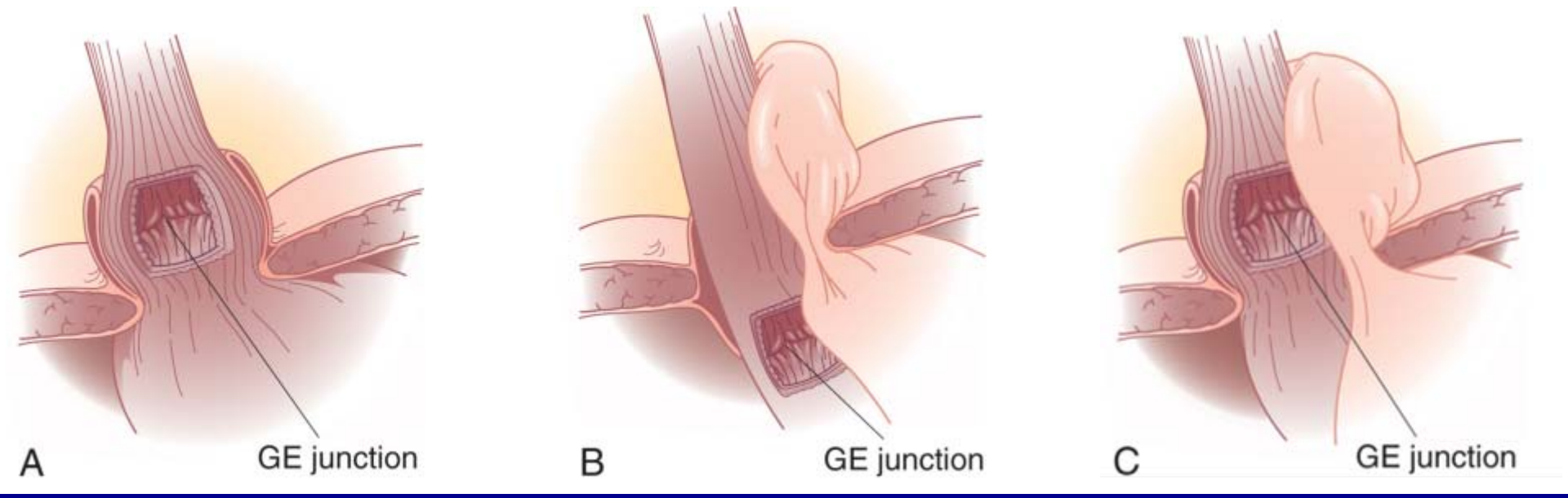
Functional Anatomy / Physiology

- Crural Sling at the GE junction
- Angle of His
  - Loss of acute angle predisposes to reflux
- Intra-abd esophagus, 2 – 2.5cm
- Lower esophageal sphincter (LOS)
- LOS function + Crural Sling + Intra – abd esoph + Angle of His



Gordon et al., The role of the hiatus hernia in GERD. Aliment Pharm 2004

- Type 1 (A) : Upward migration of GE junction through the esophageal hiatus (most common)
- Type 2 (B) : Stomach herniated along the esophagous an intra-abdominal GE junction (Rare, 5 - 15%)
- Type 3 (C) : GE junction migration is accompanied by PEH



Townsend: Sabistons Textbook of Surgery, 18th Edition
Koch, Grandernath et al. Surg Endosc Aug 2010

- 1853 – Bowditch first published description of HH
- 1919 – Soresi, HH reduction / crural approximation
- 1956 – Nissen fundoplicaiton
- 1957 – Collis transthoracic gastroplasty

- Open repair as the "Gold Standard" for refractory GERD, Hiatal Hernias
  - Recurrence 2 – 15%

- 1990's – Laparoscopic Antireflux Surgery (LARS) emerges
- 2000's – LARS becomes standard operative approach for GERD and hiatal hernia repair. Reported "80 – 90%" success rate by many authors.

Mitiek M., Andrade S., Ann Thorac Surg 2010; Granderath et al., Arch Surg 2005

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Where is the Controversy? Recurrence

- Laparoscopic Repair of Large Type III Hiatal Hernia: Objective Follow-up Reveals High Recurrence Rate
  - Hashemi, DeMeester et al., JACS 2000

  - Retrospective Review 54 pts 1985 – 1998
  - Recurrence assessed by video esophogram
    - 74% (20 / 27pts) Follow-up open, median 35 mo
    - 77% (21 / 27pts) Follow-up laparoscopic, median 17 mo

  - Recurrence:
    - Open (Abd , Thoracotomy) 3 / 20 (15%)
    - Laparoscopic primary repair **9 / 21 (42%)**

      $p < 0.001$
    - Independent of age, gender, pre-op sx, manometry, 24 hour pH monitor or hernia size.

Where is the Controversy?

- High recurrence rate
- Solution: Essential components for surgical repair
  - Complete excision of hernia sac
  - Restoration of intra-abdominal esophageal length
  - Crural approximation
  - Anti-reflux procedure

Gouvas et al. Dis Esoph 2010; Soricelli et al. Surg Endosc 2009

Where is the Controversy?

- High recurrence rate
- Solution:
  - **Strict Adherence to Basic Surgical Tenets!**
    - Tension free approximation of tissues!
    - Crura: soft, parallel muscle fibers with little or no tendonous reinforcement
    - Unlike other hernias the hiatus is in constant motion with respiration, esophageal peristalsis, cardiac activity, body position alterations and subjected to increased abdominal pressures with cough / vomitting / valsalva / strain etc…

Gouvas et al. Dis Esoph 2010; Soricelli et al. Surg Endosc 2009, Stadlhuber et al. Surg Endosc 2009

Mesh Repair

- Questions:
  - Is it effective?
  - Is it safe?
  - Mesh Opponents:
    - **erosion into adjacent structures (esophagous / stomach)**
    - **adhesions / fibrosis, stenosis / dysphagia**
    - **foreign body infection, etc.**

Overview

- Anatomy / Physiology: Anatomic disruption of inherent anti-reflux mechanisms
- Where is the controversy? What's this really about?
  - 1) Mesh employed to reduce recurrence
  - 2) Mesh dangerous? Complications?
- "Evidence" that mesh is dangerous
- Evidence clearly demonstrating safety and efficacy of mesh during surgical intervention.
- Conclusions

"Mesh is Dangerous!!!"

Mesh complications after prosthetic reinforcement of hiatal closure: a 28-case series

Rudolf J. Stadlhuber · Amr El Sherif · Sumeet K. Mittal · Robert J. Fitzgibbons Jr · L. Michael Brunt · John G. Hunter · Tom R. DeMeester · Lee L. Swanstrom · C. Daniel Smith · Charles J. Filipi

- Stadlhuber et al. Surg Endosc 2009

- 28 Case Series (ie. compilation of case reports)
- Methods:
  - Pubmed search + Direct contact to other contributing authors.

- 14 reported cases identified in publication.
- 14 additional cases

- 26 laparoscopic, 2 open procedures

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- 28 patients
  - Polypropylene n = 8
  - PTFE n = 12
  - Biological n = 7
  - Dual Mesh n = 1

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- Stadlhuber et al. Surg Endosc 2009

- 28 patients
  - Symptoms
    - Dysphagia (22)
    - Heartburn (10)
    - Chest pain (14)
    - Fever (1)
    - Epigastric pain (2)
    - Weight loss (4)
  - Complication
    - Erosion (17)
    - Hiatal Stenosis (6)
    - Dense Fibrosis (5)

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- 28 patients
  - Outcomes:
    - 23 mesh removals ("open and lap")
    - 6 esophagectomies (+ 1 in "future")
    - 2 partial gastrectomy, 1 total gastrectomy
    - 2 pts died 3 mo postop
    - 5 pts dependent on tube feeding

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- Conclusions:
  - "Mesh reinforcement is not without complication"
  - "Incidence of complications may be greater than previously reported"
  - **What's the denominator?**

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- Stadlhuber et al. Surg Endosc 2009

- The Forest or the Trees?

This publication presents several catastrophic outcomes and complications in a minority of highly selected patients without complete context to assess contributing patient and operative factors.

So how do the majority of patients do?

Overview

- Anatomy / Physiology: Anatomic disruption of inherent anti-reflux mechanisms
- Where is the controversy? What's this really about?
  - 1) Mesh employed to reduce recurrence
  - 2) Mesh dangerous? Complications?
- "Evidence" that mesh is dangerous
  - **AKA: How do the minority of patients do?**
- Evidence clearly demonstrating safety and efficacy of mesh during surgical intervention.
- Conclusions

Mesh: Safe and Invaluable

- LARS With Routine Mesh-Hiatoplasty in the Treatment of GERD
  - Granderath et al. J Gastrointest Surg, 2002
    - Prospectively collected data
    - 361 pts 1993 – 1998 Laparoscopic primary repair + Fundoplication
    - 170 pts after 1998 posterior onlay of 1 x 3 cm polypropylene mesh + Fundoplication
  - Preop
    - GERD sx (mean 8 yrs)
    - PPI
    - EGD with bx
    - Esophageal Manometry
    - 24 hour pH monitoring

Mesh: Safe and Invaluable

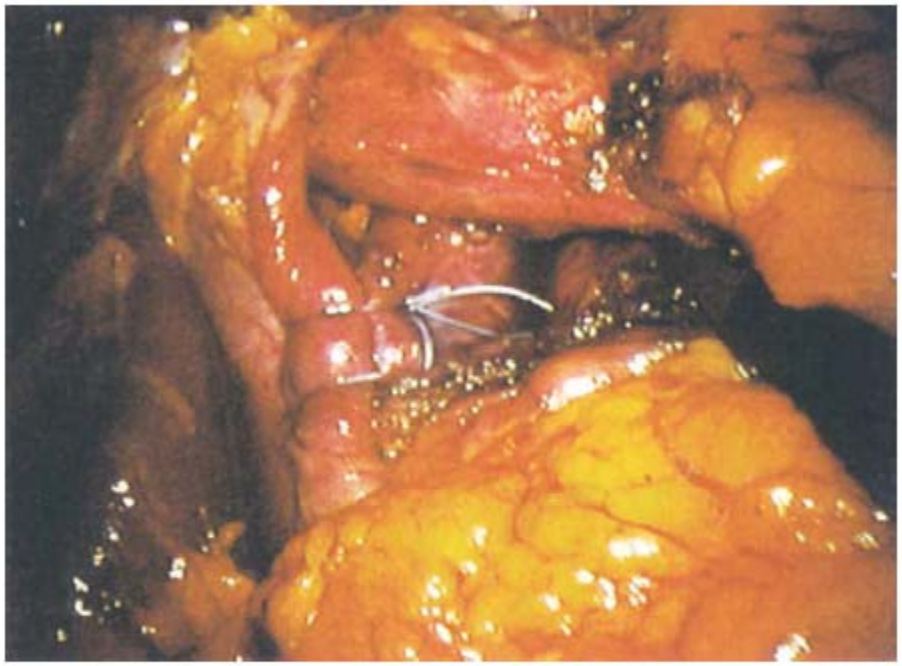

Fig. 1. Intraoperative situs after hiatal closure using two single sutures without mesh as performed in the first group of 361 patients. After suturing of the crura, the esophagus is laying loose in the hiatus.

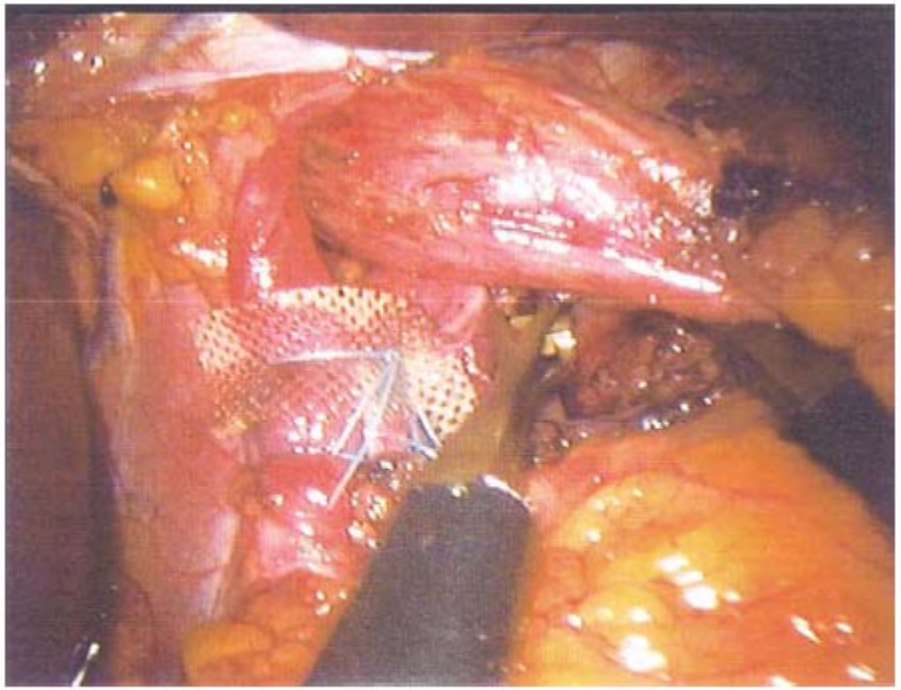

Fig. 3. Completed mesh-hiatoplasty before creation of the Nissen fundoplication.

- 6wks – EGD
- 3mo / 1 yr – Sx evaluation, Manometry, 24 hr pH
- Barium swallow / EGD for symptomatic pt's and to confirm recurrence.

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- LARS With Routine Mesh-Hiatoplasty in the Treatment of GERD
  - Granderath et al. J Gastrointest Surg, 2002

  - Results:
    - Intrathoracic Wrap Herniation – 1 yr follow-up

      - Primary repair: **6.1%** (22 / 361) reherniation
        4.7 (17 / 361)% re – op

      - Mesh: **0.6%** (1 / 170) reherniation
        0.6% (1 / 170) re – op

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	GERD symptoms								
	Before surgery			3 mo postoperatively			1 yr postoperatively		
	None	Mild to moderate	Severe	None	Mild to moderate	Severe	None	Mild to moderate	Severe
Heartburn									
Group 1	14.1%	11.7%	74.2%	99.2%	0.8%	0%	99.4%	0.6%	0%
Group 2	12.9%	11.2%	75.9%	98.8%	1.2%	0%	99.4%	0.6%	0%
Regurgitation									
Group 1	33.0%	23.2%	43.8%	98.6%	0.8%	0.6%	99.7%	0.3%	0%
Group 2	32.4%	20.0%	47.6%	98.2%	1.2%	0.6%	100%	0%	0%
Chest pain									
Group 1	47.1%	21.3%	31.6%	88.8%	9.5%	1.7%	89.4%	10.6%	0%
Group 2	45.9%	19.4%	34.7%	89.2%	8.4%	2.4%	88.0%	11.4%	0.6%
Dysphagia									
Group 1	95.0%	4.4%	0.5%	80.2%	18.7%	1.1%	95.1%	4.9%	0%
Group 2	95.9%	2.9%	1.2%	64.7%	34.1%	1.2%	95.6%	4.4%	0%

- Dysphagia at 3 mo. $p < 0.05$. No difference at 1 yr.

Mesh: Safe and Invaluable

- LARS With Routine Mesh-Hiatoplasty in the Treatment of GERD
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  - Results:

    - Recurrence Mesh 0.6 vs Primary 6.1%
    - Dysphagia Mesh 19.8% vs Primary 45.3%, p = 0.05
    - Symptom free at 1 yr Mesh, Primary > 90%
    - Reoperation Mesh 0.6 vs Primary 4.7%

Mesh: Safe and Invaluable

- LARS With Routine Mesh-Hiatoplasty in the Treatment of GERD
  - Granderath et al. J Gastrointest Surg, 2002
  - Results:
    - 0 / 170 erosion in 170 pts with mesh at 1 yr
  - Conclusion:
    - Mesh safe and effective in preventing recurrence 1 yr

Mesh: Safe and Invaluable

- Prospective, Randomized Trial of Lap PTFE Patch Repair vs Simple Cruroplasty for Large Hiatal Hernia.
  - Frantzides et al. Arch Surg, 2002

  - 72 pts symptomatic reflux / Hernia > 8cm 1991 – 2000
  - 36 pts – primary cruroplasty + fundoplication
  - 36 pts – suture approximation + PTFE "keyhole" + fundoplication

  - Preop: Esophagogram, EGD, Manometry, Sx eval

  - Follow-up: 1wk, 2wk, 1mo, 3mo, yearly
    - EGD / esophagogram 3 mo, Q 6 mo.

Mesh: Safe and Invaluable

- Prospective, Randomized Trial of Lap PTFE Patch Repair vs Simple Cruroplasty for Large Hiatal Hernia.
  - Frantzides et al. Arch Surg, 2002
  - Results: Mean follow up 3.3 yrs (6 mo to 6 yrs)

○ Recurrence:	Mesh	0% (0 / 36)	**p < 0.006**
	Suture	22% (8 / 36)	
○ Reoperation	Mesh	0% (0 / 36)	
	Suture	13% (5 / 36)	

- ○ No erosions / strictures / infectious complications of mesh (36 pts from 6 mo to 6 yrs follow-up)

Mesh: Safe and Invaluable

- Prospective, Randomized Trial of Lap PTFE Patch Repair vs Simple Cruroplasty for Large Hiatal Hernia.
  - Frantzides et al. Arch Surg, 2002

  - Conclusion:
    - Mesh reduces recurrence with large (> 8cm) hiatal hernia repair. (0% vs 22%)
    - Reduced reoperative rate with mesh placement
    - Cost slightly increased $960 ± $70 due to longer operative time and PTFE cost.

Mesh: Safe and Invaluable

- Laparoscopic Nissen Fundoplication with Prosthetic Hiatal Closure Reduces Postoperative Intrathoracic Wrap Herniation.
  -Granderath et al. Arch Surg, 2005

  - Prospective Randomized Trial: 100 pts 2001 – 2002
  - 50 pts Lap Nissen + simple suture cruroplasty
  - 50 pts Lap Nissen + suture approximation + posterior polypropylene mesh onlay

Mesh: Safe and Invaluable

- Laparoscopic Nissen Fundoplication with Prosthetic Hiatal Closure Reduces Postoperative Intrathoracic Wrap Herniation.
  -Granderath et al. Arch Surg, 2005

  - Results: Post-op
    - Heartburn
    - Reflux
    - Dysphagia
    - LES pressure
    - DeMeester Score
    - Esophagogram

Heartburn

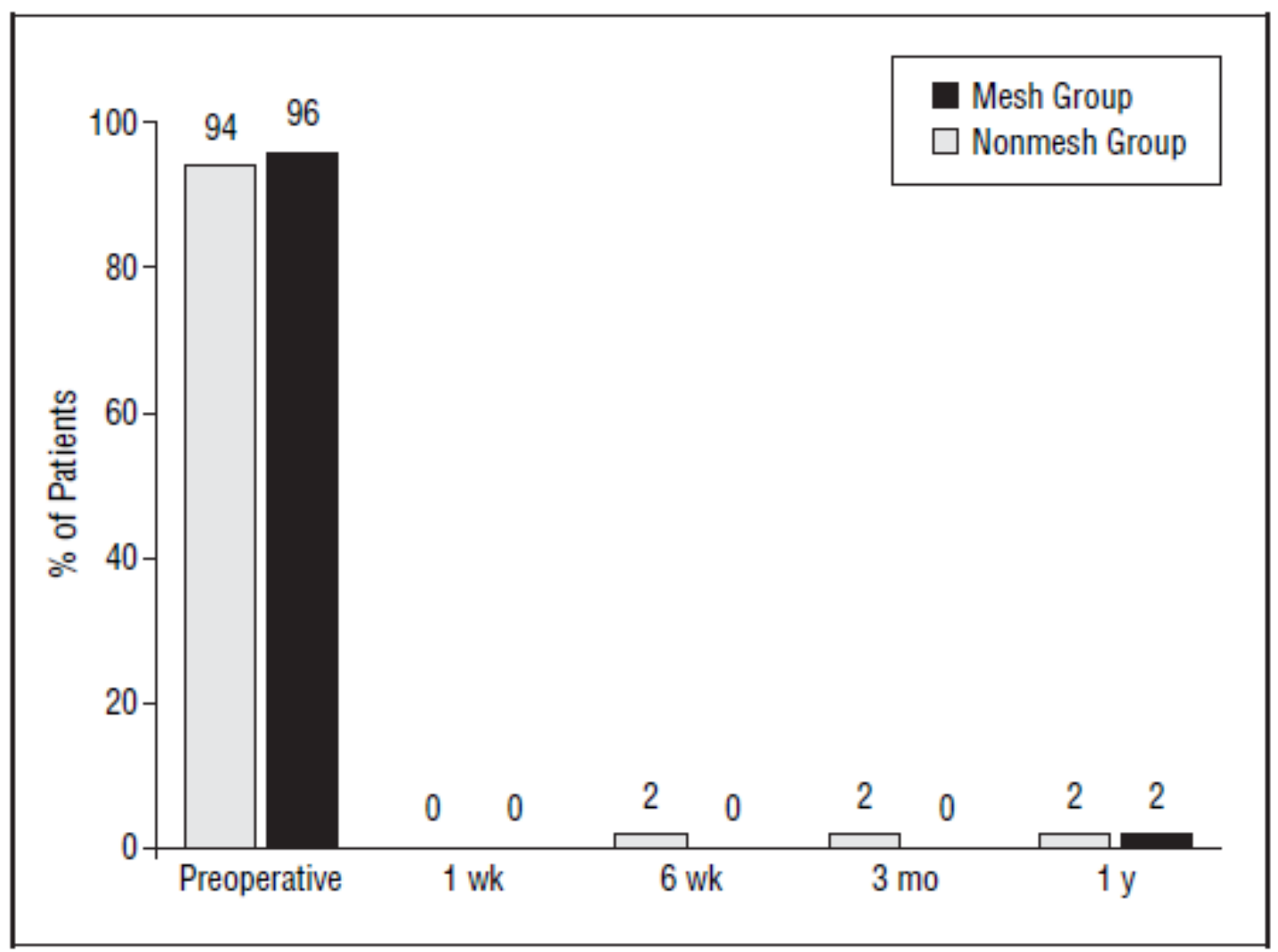

Figure 15. Incidence of heartburn.

Regurgitation

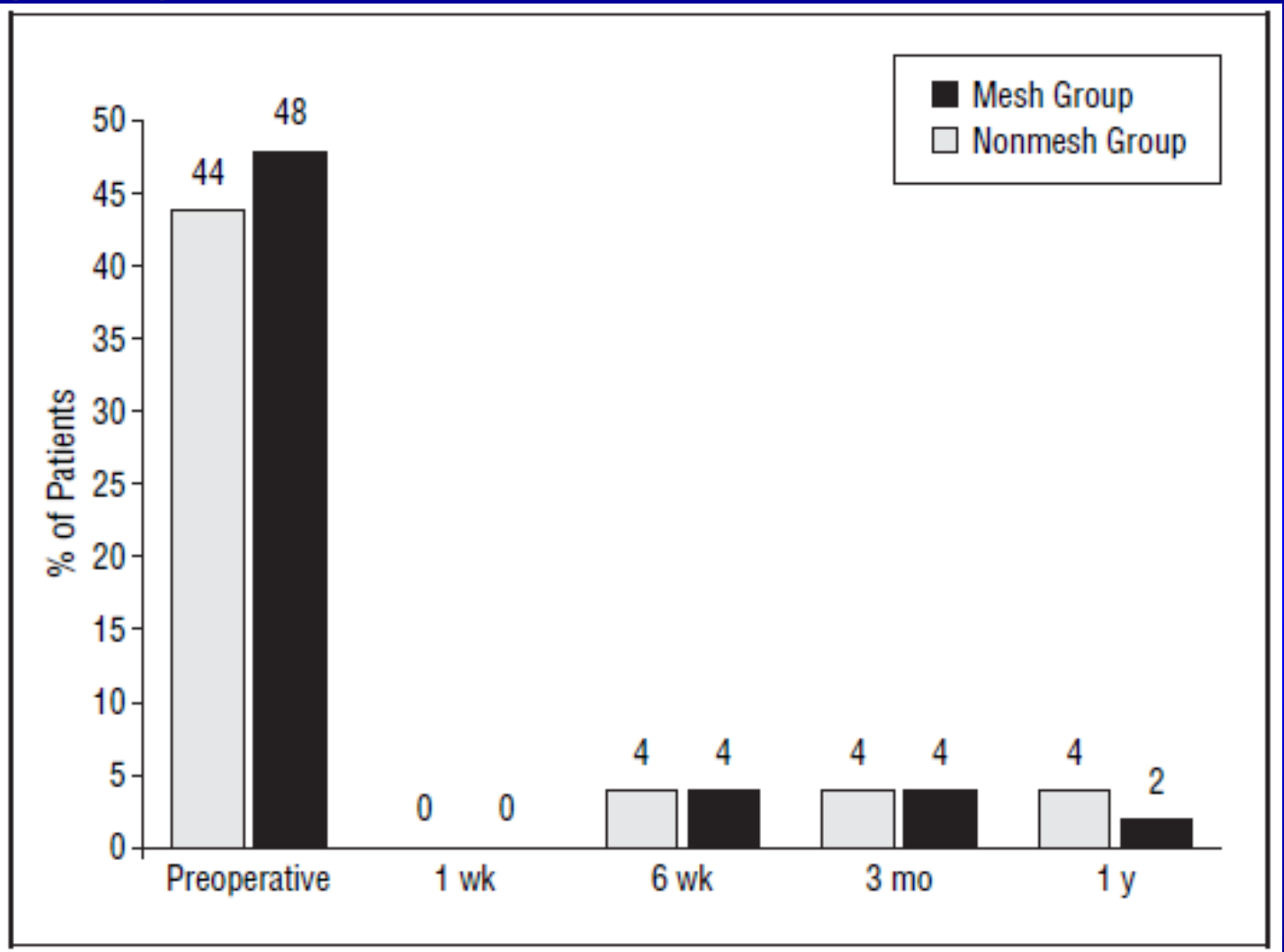

Figure 16. Incidence of regurgitation.

Manometry – LES sphincter

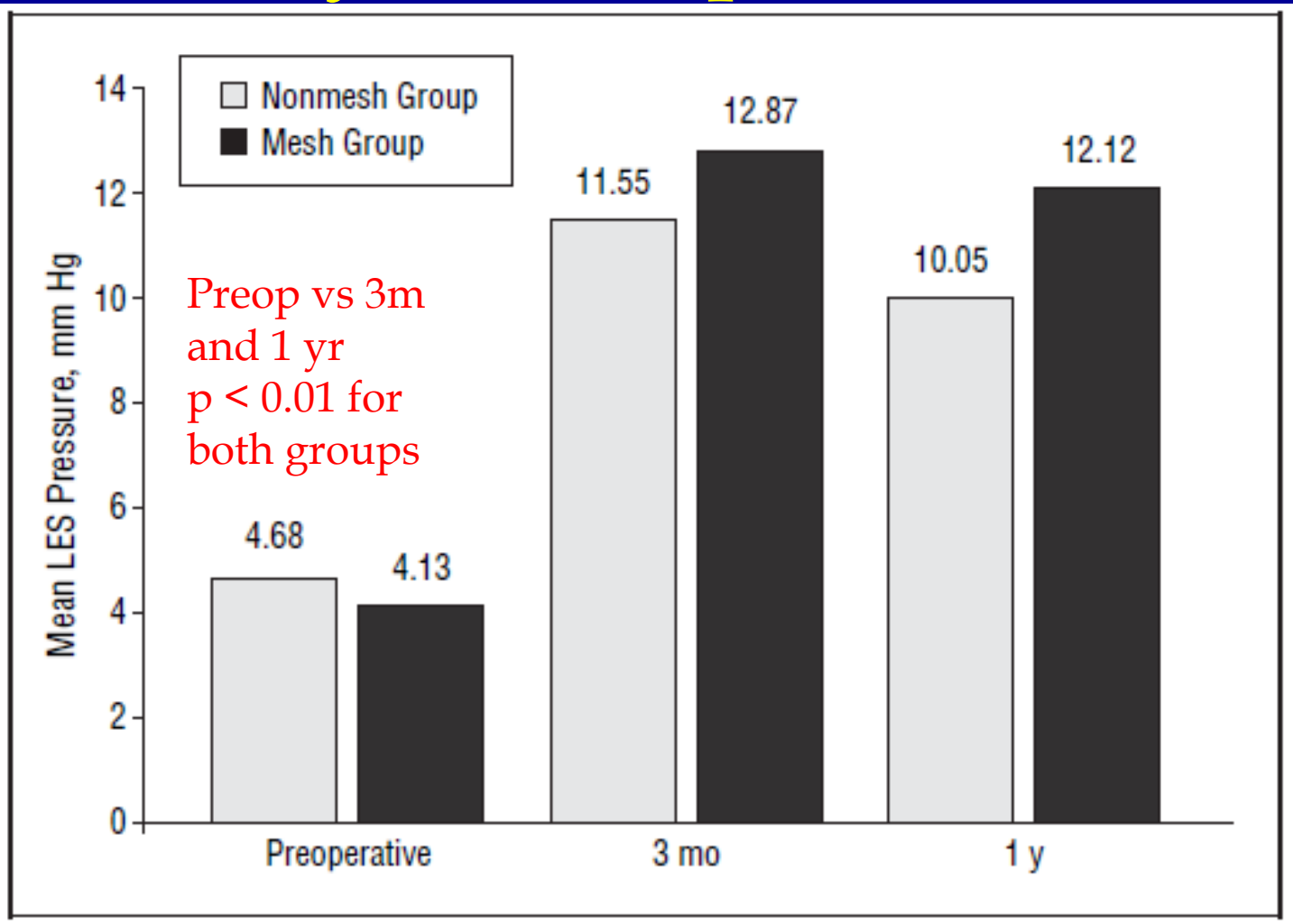

Figure 18. Results of esophageal manometry. LES indicates lower esophageal sphincter.

24 hour pH monitoring

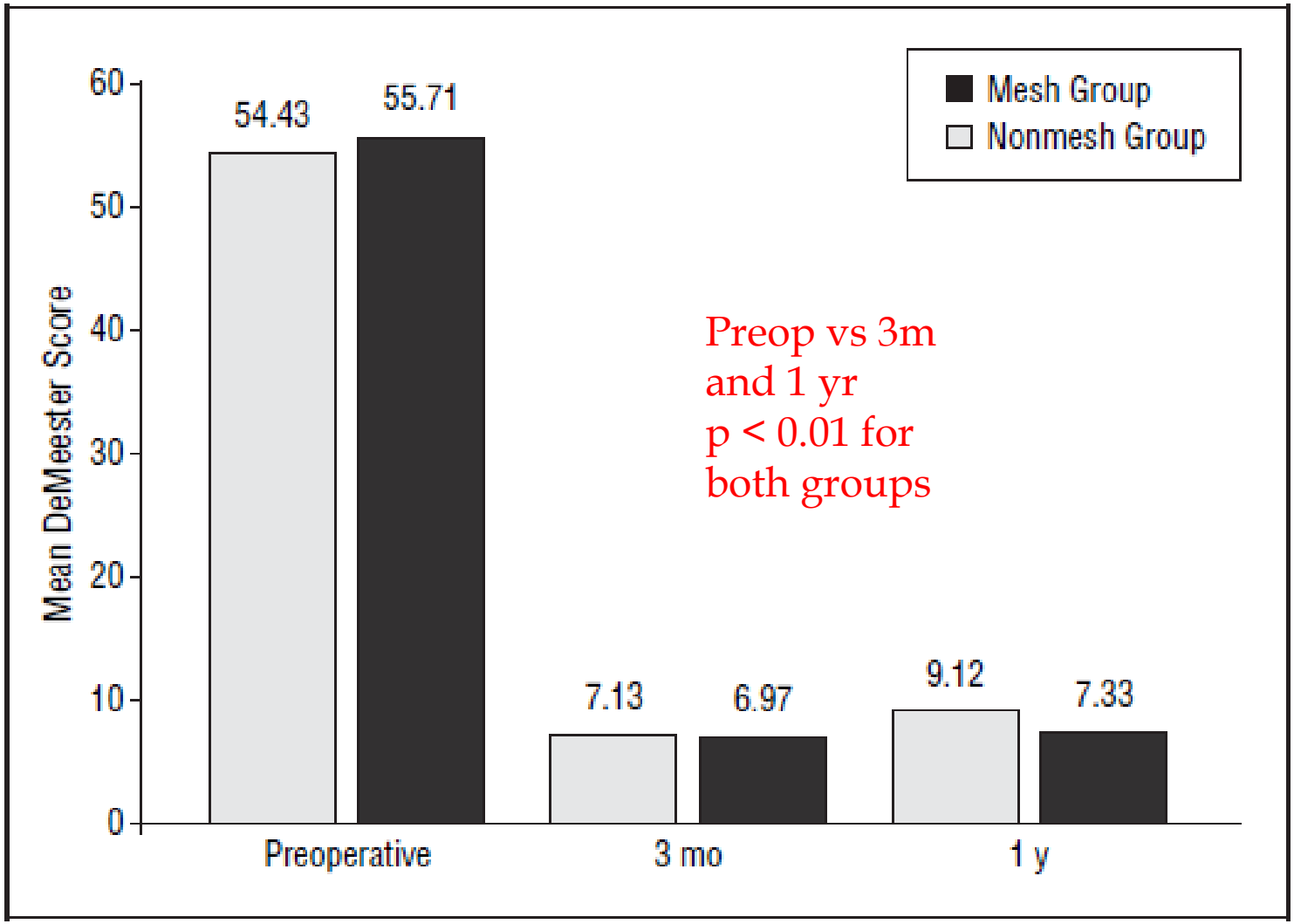

Figure 19. Results of 24-hour pH monitoring.

Dysphagia

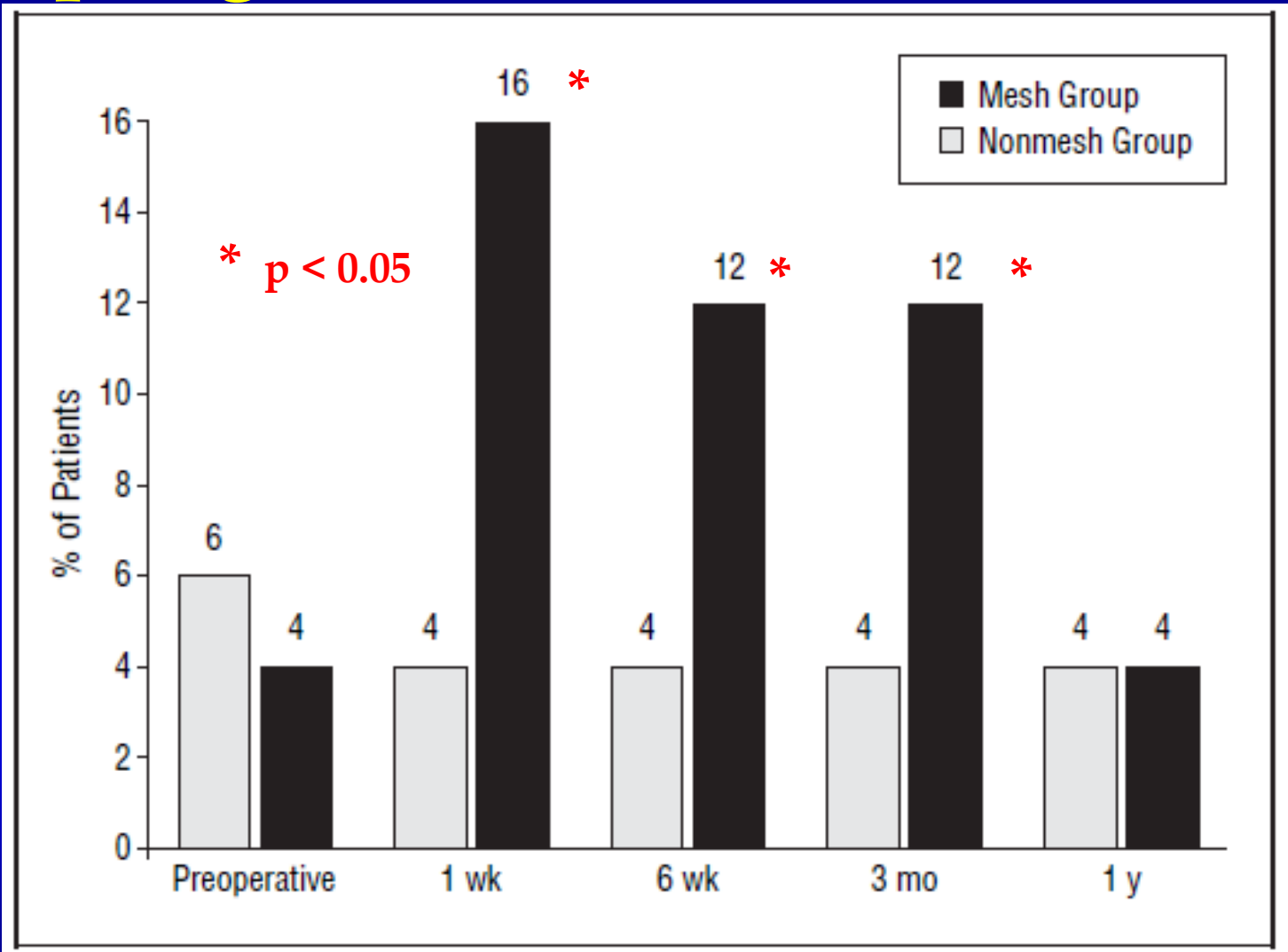

Figure 17. Incidence of dysphagia.

Mesh: Safe and Invaluable

- Laparoscopic Nissen Fundoplication with Prosthetic Hiatal Closure Reduces Postoperative Intrathoracic Wrap Herniation.
  -Granderath et al. Arch Surg, 2005

  - Results:

    - Recurrence: Mesh 8% (4 / 50) **p < 0.001**

      Suture 26% (13 / 50)

Mesh: Safe and Invaluable

- Laparoscopic Nissen Fundoplication with Prosthetic Hiatal Closure Reduces Postoperative Intrathoracic Wrap Herniation.
  -Granderath et al. Arch Surg, 2005

  - Conclusions:
    - Lower recurrence with mesh 8% vs 26% **$p < 0.001$**
    - Heartburn, regurgitation, LES function and pH exposure improve significantly in both groups (p NS)
    - Increased dysphagia at 1wk / 6wk and 3 months with Mesh. No difference at 1 year post-op.

Mesh: Safe and Invaluable

- Laparoscopic Nissen Fundoplication with Prosthetic Hiatal Closure Reduces Postoperative Intrathoracic Wrap Herniation.
  -Granderath et al. Arch Surg, 2005

  - Complications:
    - No erosions, fibrotic stenosis in 50 pts with mesh
    - Authors comment that in 300 pts with mesh placement since 1998 and a follow-up of 90% they have observed NO mesh erosion.

Mesh: Longterm Results?

- Limited follow-up from radomized trials
  - (Frantzides mean 3.3 yrs)

- Soricelli et al. Surg Endosc 2009
  - Retrospective, Mean Follow-up 95 mo
  - Recurrence:
    - 93 suture 9.6%, 113 mesh 1.8%, 91 suture + mesh 0.49%
  - No erosion

- Keidar et al. Surg Lap End 2003
  - Retrospective, Mean Follow-up 58 months
  - Recurrence:
    - Suture 4 / 23 (18%), Mesh 1 / 10 (10%)
  - 1 erosion ! Lap removal / redo – symptom free.

Conclusions

- Mesh placement is not only safe in the majority of patients but a valuable adjunct for treatment of GERD and associated hiatal hernias significantly reducing recurrence rates.

- While anecdotal case reports demonstrate that like other surgical procedures mesh placement is not FREE of complication they provide little in the estimation of true incidence of complications.

Future Directions / Considerations

- Biologic Mesh
  - Multicenter RCT Oelschlager, Swanstrom et al
    - Recurrence: suture 12 /57 (24%) vs SIS 4 / 51 (9%)
- Biomesh vs Dualmesh vs PTFE vs Polypropylene
- Evaluation / standardization of mesh configuration.
  - Keyhole vs “U-shape” vs posterior onlay
- Size criteria for application
  - All patients?
  - 5 cm?
  - 8 cm?

- “It appears that we have learned nothing from our past experience with inguinal and ventral hernia repairs and the reduction in recurrence from routinely employing mesh prostheses to reinforce weak tissue.”

  – Champion et al. Surg Endosc 2003