

# Summary of Top Clinical Papers



**PERFORMANCE**  
through innovation

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## Reinforcement Overview

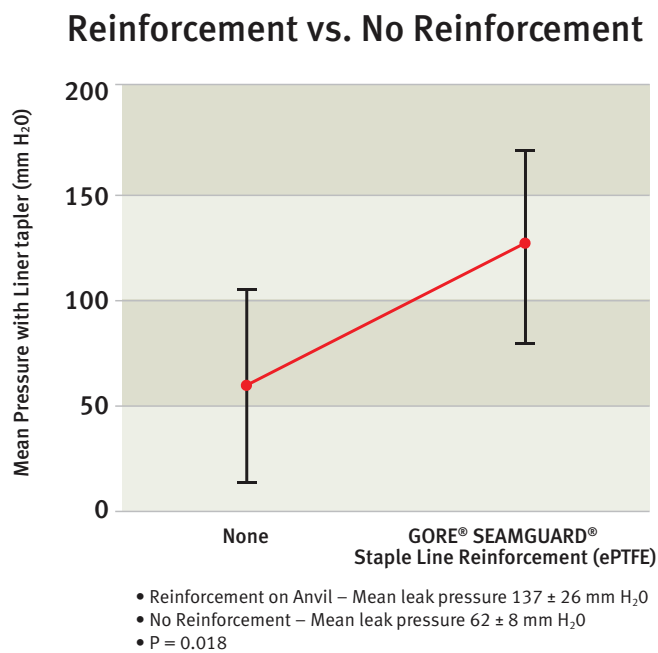
### ▶ Dr. Baker: Science of Stapling and Leaks (RP1154)

#### Overview:

A model was designed to make small gastric pouches forced to the point of leaking.

#### Summary:

- Oversewing of staple lines significantly weakened all staple lines ( $p=0.015$ ).
- Buttress material significantly increased the pressure required to cause staple line leakage ( $p=0.002$ ).
- Authors concluded buttress should be considered in an attempt to decrease leaks.



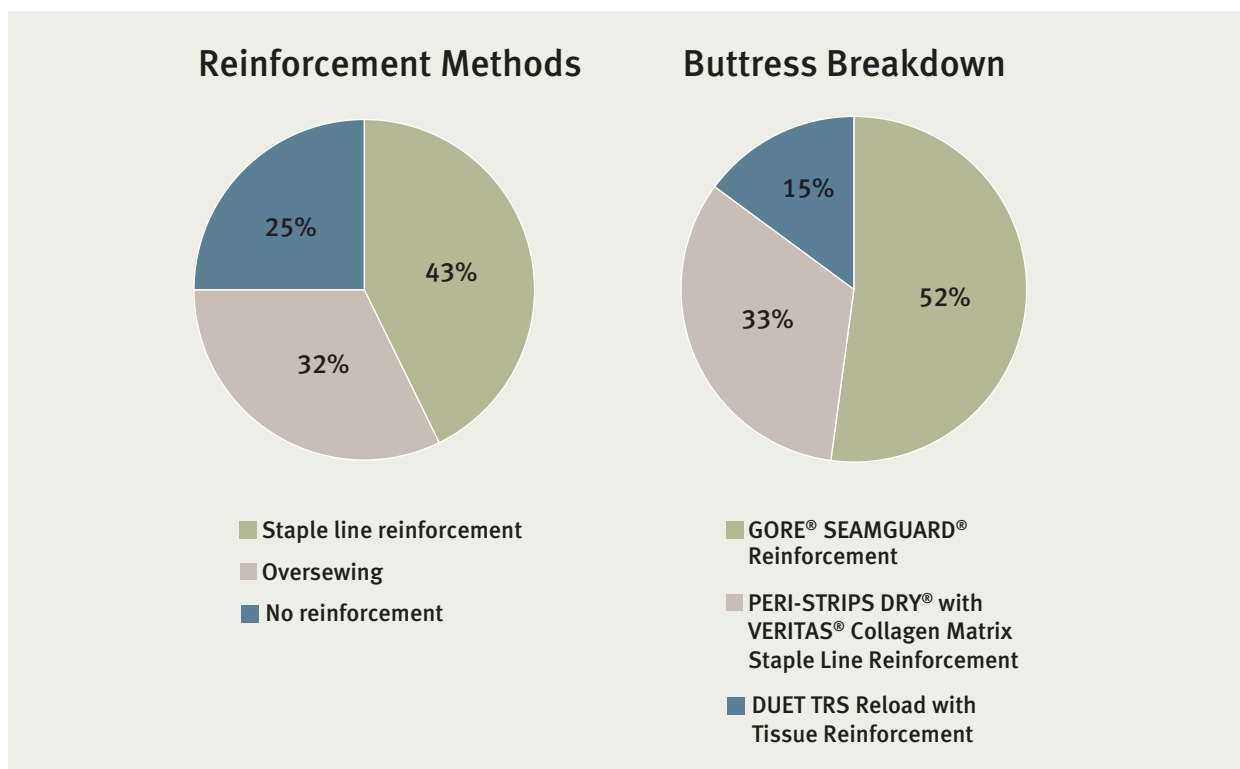
Reference: Baker RS, Foote J, Kemmeter P, Brady R, Vroegop T, Serveld M. The science of stapling and leaks. *Obesity Surgery* 2004;14(10):1290-1298.

## Reinforcement Overview

### Dr. Gagner: Survey on Laparoscopic Sleeve Gastrectomy (LSG) at the Fourth International Consensus Summit on Sleeve Gastrectomy (OP622)

#### Overview:

Survey of the Sleeve Gastrectomy Summit Attendees on Various LS



Reference: Gagner M, Detel M, Erickson A, Crosby R. Survey on laparoscopic sleeve gastrectomy (LSG) at the Fourth International Consensus Summit on Sleeve Gastrectomy. *Obesity Surgery* 2013;23(12):2013-2017.

## Sleeve Gastrectomy – Reduced bleeding

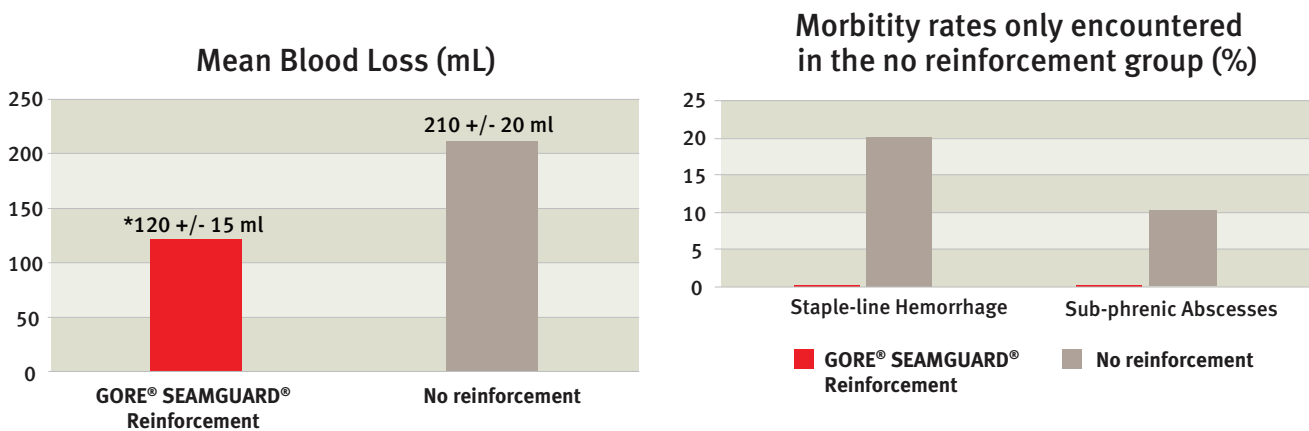
### ▶ Dr. Rosenthal: International Sleeve Gastrectomy Expert Panel Consensus Statement: Best Practice Guidelines Based on Experience of >12,000 Cases (RP1550)

#### Summary:

- 100% consensus on: “Staple line reinforcement will reduce bleeding along staple line.”
- 58% consensus on: “The use of reinforcement will reduce the leak rate, provided the green or greater load is used.”
- In addition, with regard to leaks, the experts reported an average leak rate of 1.03% with a range of 0–3.9%.

Reference: Consten, ECJ, Gagner M, Pomp A, Inabnet WB. Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane. *Obesity Surgery* 2004;14(10):1360-1366.

### ▶ Dr. Consten: Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane (RP1155)



“Early results may show that [GORE® SEAMGUARD® Reinforcement] reduces staple line hemorrhage and leakage. This may have contributed to a shorter hospital stay, decreased costs and lower morbidity after laparoscopic bariatric surgery.”

Reference: Consten, ECJ, Gagner M, Pomp A, Inabnet WB. Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane. *Obesity Surgery* 2004;14(10):1360-1366.

## Sleeve Gastrectomy – Reduced Leaks, Systematic Review of 88 Papers

### ► Dr. Gagner: Comparison of laparoscopic sleeve gastrectomy leak rates in four staple-line reinforcement options: a systematic review (RP1652)

#### Leak Rates by Reinforcement Method

REINFORCEMENT METHOD	LEAKS	# OF PATIENTS WITHOUT LEAKS	% LEAKS	P-VALUE COMPARED TO APM <sup>A</sup>
Absorbable membrane	16	1,446	1.09	–
Oversewing (suture)	86	4,128	2.04	0.02
No Reinforcement	67	2,512	2.60	0.001
Bovine Pericardium	22	643	3.30	0.0006
<b>Total</b>	<b>191</b>	<b>8,729</b>	<b>2.14</b>	<b>–</b>

*“This review found that [GORE® SEAMGUARD® Reinforcement] was associated with a significantly lower leak rate than oversewing, BPS reinforcement, and no reinforcement.”*

**Reference:** Gagner M, Buchwald JN. Comparison of laparoscopic sleeve gastrectomy leak rates in four staple-line reinforcement options: a systematic review. *Surgery for Obesity & Related Diseases* 2014;10(4):713-723.

## Sleeve Gastrectomy – Meta-Analysis

### Gagner's review

- Reinforcement methods are broken down into three groups
  - Bioabsorbable
  - Bovine pericardium
  - Oversewing
- Significantly reduced leaks found with the use of bioabsorbable reinforcement

### Other reviews

- Reinforcement methods are all lumped into one group which includes:
  - Bioabsorbable, bovine pericardium, and oversewing
- No differences found when reinforcement is used

### *Why the difference?*

Not all reinforcements are the same and should be analyzed separately

## Sleeve Gastrectomy – Reduced Leaks

### Dr. Durmush: Short-term outcomes of sleeve gastrectomy for morbid obesity: does staple line reinforcement matter? (OP544)

#### Summary:

332 PATIENTS WITH GORE® SEAMGUARD® REINFORCEMENT	186 PATIENTS WITH SUTURE	SIGNIFICANCE
• No leaks	1.6% leaks	*p<0.05
• Reduced operating time (avg 72.2 min)	85 min	*p<0.0001

**Note:** The bougie size was significantly smaller in the EBSG group (p<0.0001), with an average bougie size of 33.5 versus 40 in the non-reinforcement group

*“Patients in whom synthetic PGA/TMC staple line reinforcement material was applied during LSG had no postoperative leaks or hemorrhages from the staple line. The differences in leak rate between the reinforcement-material group and the no-reinforcement-material group was significant (p=0.045).”*

**Reference:** Durmush EK, Ermerak G, Durmush D. Short-term outcomes of sleeve gastrectomy for morbid obesity: does staple line reinforcement matter? *Obesity Surgery* 2014;24(7):1109-1116.

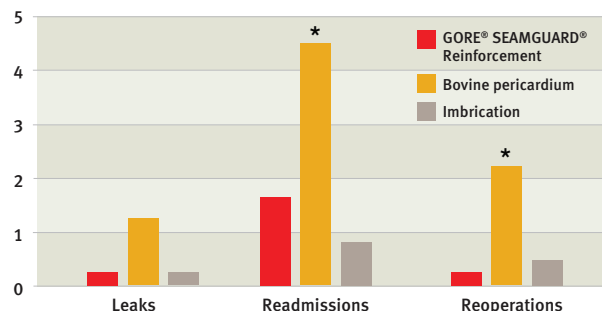
### Dr. Barreto: A comparison of a single center’s experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients. (RP1686)

#### Summary:

1,502 PATIENTS FROM THE SAME INSTITUTION WERE COMPARED
• 373 pt (24.8%) were reinforced by imbrication
• 269 pts (17.9%) were reinforced with bovine pericardium (BPS)
• 860 pts (57.3%) were reinforced with GORE® SEAMGUARD® Reinforcement (APM)

**Conclusion:** *“This study demonstrated that BPS is associated with significantly higher readmission and reoperation rates with a trend towards a higher leak rate”*

**Reference:** Barreto TW, Kemmeter PR, Paletta MP, Davis AT. A comparison of a single center’s experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients. *Obesity Surgery*. In press.



\*Significantly higher readmission and reoperation rates with BPS



## Gastric Bypass – Reduced Bleeding

### — Dr. Miller: Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial. (RP1386)

**Summary:**

24 PATIENTS WITH GORE® SEAMGUARD® REINFORCEMENT	24 PATIENTS WITH NO STAPLE LINE REINFORCEMENT	SIGNIFICANCE
No leaks	One intraoperative leak	
Fewer clips used (~2)	More clips used (~22)	*p<0.0001
Higher post-op hemoglobin	Lower post-op hemoglobin	*p<0.05
No fistulas	Three fistulas	p=0.2
Reduced operative time (~115 min)	Operative time (~150 min)	*p<0.05

**Observation:** “Intraoperative staple line bleeding was significantly reduced.” “The avoidance of a single severe complication would make its use worth it.”

**Reference:** Miller KA, Pump A. Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial. *Surgery for Obesity & Related Diseases* 2007;3(4):417-422.

### — Dr. Nguyen: Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial. (RP1232)

**Summary:**

17 PATIENTS WITH GORE® SEAMGUARD® REINFORCEMENT	17 PATIENTS WITH NO STAPLE LINE REINFORCEMENT	SIGNIFICANCE
Lower mean blood loss	Higher mean blood loss	*p<0.01
Fewer staple line bleeding sites	Higher bleeding sites	*p<0.01
Less time to staple line hemostasis	Greater time to hemostasis	*p<0.01
No transfusions	1 transfusion and reoperation	

**Observation:** “The use of glycolide copolymer staple line reinforcement sleeves in patients undergoing laparoscopic gastric bypass is safe and significantly reduces staple line bleeding sites and may reduce the incidence of gastrointestinal hemorrhage.”

**Reference:** Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE. Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial. *Archives of Surgery* 2005;140(8):773-778.

## Distal Pancreatectomies – Leak Rates

PAPER / ABSTRACT*	GORE® SEAMGUARD® REINFORCEMENT	No SLR	SIGNIFICANCE
Jimenez et al., 2007 <sup>1</sup>	13 patients – NO leaks	18 patients – 39% leaks	*p=0.025
Thaker et al., 2006 <sup>2</sup>	16 patients – NO leaks	19 patients – 26% leaks	*p=0.03
Pugliese et al., 2008 <sup>3</sup>	7 patients – NO leaks	7 patients – 57% leaks	*p=0.0349
Thaker et al., 2007 <sup>4</sup>	29 patients – 3.5% leaks	11 patients – 36% leaks	*p=0.005
Rotellar et al., 2008 <sup>5</sup>	7 patients – NO leaks	2 patients – 2 leaks	
Yamamoto et al., 2009 <sup>6</sup>	47 patients – 4% leaks	38 patients – 26% leaks	*p=0.01
Melotti et al., 2007 <sup>7</sup>	7 patients – No leaks	18 patients – 31% leaks	

**Large patient series are not needed to show the significant reduction in leaks when GORE® SEAMGUARD® Reinforcement is used on the pancreas.**

<sup>1</sup> Jimenez RE, Mavanur A, Macaulay WP. Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy. *Journal of Gastrointestinal Surgery* 2007;11(3):345-349.

<sup>2</sup> Thaker RI, Matthews BD, Linehan D, Strasberg SM, Eagon JC, Hawkins WG. Staple line reinforcement with bioabsorbable mesh reduces leak rate following distal pancreatectomy. Abstract presented at the American Hepato-Pancreato-Biliary Association Meeting (AHPB); March 9-12, 2006; Miami Beach, FL. *HPB* 2006;8(Supplement 1):60.

<sup>3</sup> Pugliese R, Maggioni D, Sansonna F, et al. Laparoscopic distal pancreatectomy. A retrospective review of 14 cases. *Surgical Laparoscopy, Endoscopy & Percutaneous Techniques* 2008;18(3):254-259.

<sup>4</sup> Thaker RI, Matthews BD, Linehan DC, Strasberg SM, Eagon JC, Hawkins WG. Absorbable mesh reinforcement of a stapled pancreatic transection line reduces the leak rate with distal pancreatectomy. *Journal of Gastrointestinal Surgery* 2007;11(1):59-65.

<sup>5</sup> Rotellar F, Pardo F, Montiel C, et al. Totally laparoscopic Roux-en-Y duct-to-mucosa pancreaticojejunostomy after middle pancreatectomy. A consecutive nine-case series at a single institution. *Annals of Surgery* 2008;247(6):938-944.

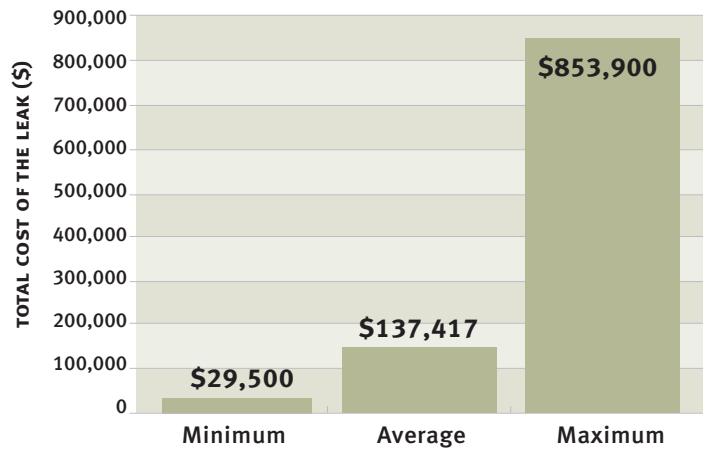
<sup>6</sup> Yamamoto M, Hayashi MS, Nguyen NT, Nguyen TD, McCloud S, Imagawa DK. Use of Seamguard to prevent pancreatic leak following distal pancreatectomy. *Archives of Surgery* 2009;144(10):894-899.

<sup>7</sup> Melotti G, Butturini G, Piccoli M, et al. Laparoscopic distal pancreatectomy results on a consecutive series of 58 patients. *Annals of Surgery* 2007;246(1):77-82.

## Reinforcement Overview

### Dr. Bour: Total Charges for Post-Operative Leak Following Laparoscopic Sleeve Gastrectomy (AS2047-EN1)

#### Cost of Treating a Leak – Post-Sleeve Gastrectomy



#### GORE® SEAMGUARD® Reinforcement

$$\begin{array}{r}
 100 \text{ Sleeve Cases} \\
 \times \quad 1\% \text{ Leak Rate} \\
 \hline
 1 \text{ leak} \\
 \times \$137,417/\text{leak} \\
 \hline
 \mathbf{\$137,417}
 \end{array}$$

#### Reinforcement with Unknown Data

$$\begin{array}{r}
 100 \text{ Sleeve Cases} \\
 \times \quad 2\% \text{ Leak Rate} \\
 \hline
 2 \text{ leaks} \\
 \times \$137,417/\text{leak} \\
 \hline
 \mathbf{\$274,834}
 \end{array}$$

**Results in \$412,251 in potential savings!!**

Reference: Boer ES, *et al.* Total Charges for Post-Operative Leak Following Laparoscopic Sleeve Gastrectomy. Presented at Obesity Week 2013; November 11-16; Atlanta, GA.



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