

Update on Sleeve Gastrectomy Leak Rate with the Use of Reinforcement

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Dear Editors,

I read the recent publication “Clinical Benefit of Gastric Staple Line Reinforcement (SLR) in Gastrointestinal Surgery: a Meta-analysis” with great interest [1]. A key finding in this paper is that bovine pericardium reinforcement is the most effective method of reducing leaks and bleeding in bariatric surgery. However, this finding may be questioned for a number of reasons.

In Dr. Shikora’s publication, he describes his paper as more accurate than similar studies as the data in this publication is more up to date. However, performing a literature search on all of the sleeve gastrectomy papers published on SEAMGUARD over the 2-year gap from the original analysis I did in 2012 [2] and his paper, there are only 11 new publications. Out of these 11 publications, there are a total of 1978 patients with only 7 patients having a leak. Using a weighted analysis, this equals a leak rate of 0.36 %. When combining this data with the original data included in my publication, the overall leak rate when SEAMGUARD is used for sleeve gastrectomies is 0.67 % (this included 3439 patients). Despite what was stated in Dr. Shikora’s paper, both

this leak rate and the one included in my original paper were calculated using a weighted average as a way to account for the size of the study and provide the most accurate results.

Based on this analysis, one must question how this paper found the leak rate for SEAMGUARD to be 3.25 %, which is drastically higher than what the data shows. In fact, out of all of the papers published on SEAMGUARD and sleeve gastrectomy, there are only 4 papers published with a leak rate above 3 % and 29 papers with a leak rate below 3 % (21 of which have a 0 leak rate). In Dr. Shikora’s paper, he discusses that both abstracts and full peer-reviewed publications were included. However, as abstracts often undergo a limited peer process, including abstracts in a meta-analysis is always controversial. Finally, because the papers that were used in this analysis were not all referenced, it is not possible to check on the math, whereas the paper I published includes all of the papers analyzed in the references to allow all readers to review the data. In addition, in Table 1 of this letter, I have included all of the SEAMGUARD studies I am referring to here with corresponding references (Table 2).

Finally, I must question the work around the leaks associated with the different reinforcement methods in the gastric bypass procedure. This study does not go into detail as to where the reinforcement was used and where the leak rate occurred. It is well known that roughly 90 % of leaks result from the gastrojejunal anastomosis [3], which is frequently unreinforced. Therefore, I question what correlations can be made from the use of a reinforcement and leak rates without this additional information. I faced this same challenge when researching my publication and accordingly decided not to focus on gastric bypass procedures.

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Table 1 SEAMGUARD studies with corresponding references

Paper	No. of patients without leaks	No. of patients with leaks	Leak rate (%)
Consten, 2004 ¹	10	0	0.00
Moy, 2008 ²	133	2	1.48
Saber, 2008 ³	7	0	0.00
Lewis, 2009 ⁴	42	0	0.00
Saber, 2009 ⁵	6	0	0.00
Kockerling, 2009 ⁶	38	0	0.00
Gentileschi, 2010 ⁷	8	0	0.00
Chowbey, 2010 ⁸	75	0	0.00
Diamantis, 2010 ⁹	25	0	0.00
Jacobs, 2010 ¹⁰	155	2	1.27
Dapri, 2010 ¹¹	23	2	8.00
Nath, 2010 ¹²	99	1	1.00
Simon, 2011 ¹³	57	2	3.39
Ayloo, 2011 ¹⁴	69	0	0.00
Gluck, 2011 ¹⁵	204	0	0.00
Diamantis, 2011 ¹⁶	19	0	0.00
Zhang, 2011 ¹⁷	45	0	0.00
Slater, 2011 ¹⁸	164	1	0.61
Nguyen, 2012 ¹⁹	50	0	0.00
Chopra, 2012 ²⁰	170	4	2.30
Albanopoulos, 2012 ²¹	46	2	4.17
Below papers have been published since the Gagner 2014 SOARD publication			
Gentileschi, 2012 ²²	40	0	0.00
Dey, 2013 ²³	50	0	0.00
Eisenberg, 2013 ²⁴	70	1	1.41
Durmush, 2014 ²⁵	332	0	0.00
D'Ugo, 2014 ²⁶	61	2	3.17
Pham, 2014 ²⁷	23	0	0.00
Noel, 2014 ²⁸	10	0	0.00
Elli, 2014 ²⁹	408	1	0.24
Gomberawalla, 2014 ³⁰	72	0	0.00
Schraibman, 2014 ³¹	48	0	0.00
Barreto, 2015 ³²	857	3	0.35
Total	3416	23	0.67

¹ 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. *Obes Surg.* 2004;14:1360–6.

² Moy J, Pomp A, Dakin G, Parikh M, Gagner M. How I do it. Laparoscopic sleeve gastrectomy for morbid obesity. *Am J Surg.* 2008;196:e56–9.

³ Saber A, Elgamal M, Itawi E, Rao A. Single incision laparoscopic sleeve gastrectomy (SILS): a novel technique. *Obes Surg.* 2008;18:1338–42.

⁴ Lewis CE, Dhanasopon A, Dutson EP, Mehran A. Early experience with laparoscopic sleeve gastrectomy as a single-stage bariatric procedure. *Am Surg.* 2009;75:945–9.

⁵ Saber AA, El-Ghazaly TH, Eliam A. Single-incision transumbilical laparoscopic sleeve gastrectomy. *J Laparoendosc Adv Surg Tech A.* 2009;19:755–9.

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Table 2 All papers that referenced leak rates in sleeve gastrectomy procedures and the use of GORE® SEAMGUARD® reinforcement

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Compliance with Ethical Standards Ethical approval and informed consent do not apply to this article.

Conflict of Interest Dr. Michel Gagner has received honoraria for speaking engagements from W.L. Gore & Associates, and Dr. Melissa Brown is a Product Specialist from the Medical Products Division of W.L. Gore & Associates.

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