

Glycolide Copolymer Staple-Line Reinforcement Reduces Staple Site Bleeding During Laparoscopic Gastric Bypass

A Prospective Randomized Trial

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Hypothesis: The use of staple-line reinforcement sleeves during laparoscopic gastric bypass reduces staple-line bleeding, which may translate into a reduction in the rate of gastrointestinal hemorrhage.

Design: Prospective randomized trial.

Setting: University hospital

Patients and Interventions: Thirty-four patients undergoing laparoscopic gastric bypass were randomly assigned to receive either no reinforcement (control group, n=17) or reinforcement of the staple line with glycolic copolymer sleeves (treatment group, n=17).

Main Outcome Measures: Demographic data, the number of stapler loads used, the number of staple-line bleeding sites, the amount of blood loss, the length of time required to obtain hemostasis of the staple lines, operative time, intraoperative and postoperative complications, and serial hemoglobin levels.

Results: The mean number of stapler loads used was similar between groups. The mean number of staple-line bleed-

ing sites was significantly fewer in the treatment group for division of gastric tissue (0.4 vs 2.5 bleeding sites), jejunal tissue (0.1 vs 0.6 bleeding site), and mesenteric tissue (0 vs 0.8 bleeding site). The mean blood loss was lower in the treatment group (84 vs 129 mL). Staple misfire occurred in 1 (0.7%) of 143 stapler loads used in the treatment group compared with 0 (0%) of 138 stapler loads used in the control group. The time to obtain staple-line hemostasis was shorter in the treatment group (1.2 vs 10.1 minutes). The total operative time was similar between groups. There was no mortality or postoperative leaks. One patient in the control group had postoperative gastrointestinal hemorrhage requiring blood transfusion and reoperation. There was no significant difference in the mean hemoglobin level between groups on the first postoperative day.

Conclusions: 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.

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LAPAROSCOPIC GASTRIC BYPASS (GBP) is gaining acceptance as the preferred surgical treatment of morbid obesity. With the growing number of bariatric procedures being performed in the United States, it is important for surgeons to continue to evaluate methods to improve the outcome of laparoscopic GBP including the complication of postoperative gastrointestinal (GI) hemorrhage. The incidence of intra-abdominal and GI hemorrhage after laparoscopic GBP ranges from as low as 0.8% to as high as 9.4%, and we previously reported a 3.2% incidence of GI bleeding after laparoscopic GBP.¹⁻⁵ The most common cause for GI hemorrhage after

laparoscopic GBP is bleeding at the staple lines. The 4 potential sites for hemorrhage are the staple lines at the gastrojejunostomy, the gastric pouch, the jejunojejunostomy, and the gastric remnant.⁶ A variety of intraoperative methods have been implemented to prevent staple-line bleeding during laparoscopic GBP including the use of linear staplers with shorter staple height and oversewing of the staple lines. For example, we use the blue stapler loads (3.5-mm staple height) for construction of the gastric pouch instead of the green stapler loads (4.8-mm staple height). The shorter staple height of the stapler load provides more compression on the transected tissues.

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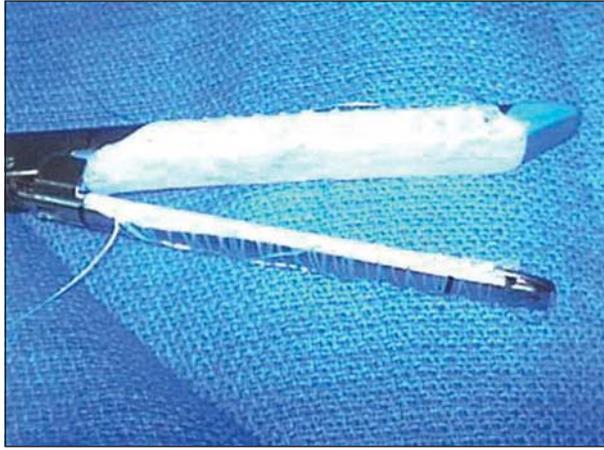


Figure 1. Glycolide copolymer staple-line reinforcement sleeves fit on the linear stapler.

Staple-line reinforcement has been recognized as an effective adjunct for decreasing the occurrence of air leaks following pulmonary wedge resection.⁷⁻⁹ Recently, the concept of buttressing of the staple line was applied to patients undergoing laparoscopic GBP in an effort to improve the integrity of the staple lines and possibly reduce staple-line bleeding.^{10,11} We hypothesized that the buttressing material evenly redistributes the staple pressure exerted on the tissue over a wider surface area and thereby reduces staple-line bleeding. In this randomized clinical trial, we sought to evaluate the safety and efficacy of staple-line reinforcement sleeves in prevention of intraoperative staple-line bleeding and postoperative GI hemorrhage.

METHODS

All patients being evaluated for surgical treatment of morbid obesity were considered for enrollment in this trial. Patients were considered eligible for enrollment if their body mass index (BMI [calculated as weight in kilograms divided by the square of height in meters]) was 40 to 60 and they were 18 to 60 years of age. Exclusion criteria were previous obesity surgery, large abdominal ventral hernia, or the presence of a large hiatal hernia. Written informed consent was obtained from all patients who agreed to undergo randomization. After providing study consent, the patients were randomly assigned by the use of sealed envelopes either to the treatment group (ie, those who received the staple-line reinforcement sleeves) or the control group (ie, those who received staples only). Patients were informed of their treatment group during the preoperative clinic visit. The maximal allowable difference in the number of patients assigned to the 2 treatment groups was 6. This study was performed with approval of the Institutional Review Board of the University of California Irvine Medical Center.

PROCEDURE

Thigh-length antiembolic stockings and sequential compression devices were placed on both lower extremities before induction of anesthesia for prophylaxis against venous thromboembolism. Laparoscopic GBP procedure was performed through 5 abdominal trocars. A 15- to 20-mL transected gastric pouch was created; a 75-cm Roux limb was constructed for patients with a BMI of 40 to 49 and a 150-cm Roux limb was constructed for patients with BMI of 50 to 60. The gastrojejunostomy was per-

formed with a circular stapler. For patients randomized to the treatment group, the glycolide copolymer staple-line reinforcement sleeves (Bioabsorbable SeamGuard; W. L. Gore & Associates, Inc, Flagstaff, Ariz) were applied onto the linear stapler (United States Surgical Corporation, Norwalk, Conn) during construction of the gastric cardia and division of the jejunum and jejunal mesentery. The staple-line reinforcement sleeves were not utilized during creation of the jejunojejunostomy or gastrojejunostomy. The staple-line reinforcement sleeves are supplied in pairs. One sleeve fits on the cartridge jaw of the stapler and the other sleeve fits on the anvil jaw of the stapler (**Figure 1**). Once the linear stapler is passed through the trocar and positioned onto the tissue, the suture attached to the staple-line reinforcement sleeves is removed prior to firing. The stapler is released after firing, leaving the bioabsorbable reinforcement material along the staple line on both sides. We used the blue stapler loads (3.5-mm staple height) during the creation of the gastric pouch, the white stapler loads (2.5-mm staple height) during the division of the jejunum, and the gray stapler loads (2.0-mm staple height) during the division of the jejunal mesentery. For patients randomized to the control group, no staple-line reinforcement sleeves were used.

OUTCOME MEASURES AND STATISTICAL ANALYSES

Demographic data and BMI were collected and recorded prospectively on a computerized data form. The primary outcome measures were the number of stapler loads used during construction of the gastric pouch and the division of jejunum and jejunal mesentery; the number of bleeding sites at the transected edge of the gastric pouch, jejunum, and jejunal mesentery; and operative time required to obtain hemostasis of the staple-line bleeding sites. A bleeding site was defined as bleeding at the staple-line edge requiring operative intervention such as clipping, electrocautery, or oversewing of the staple lines to achieve hemostasis. Secondary outcome measures include total operative time, amount of blood loss, length of hospital stay, intraoperative and postoperative complications, blood transfusion requirement, serial hemoglobin levels, and cost. Intraoperative blood loss was calculated by subtracting the amount of irrigation fluid administered from the amount of fluid suctioned from the abdominal cavity. Postoperative GI hemorrhage was defined as a decrease in hematocrit reading of 10 points or the need for a blood transfusion and signs of upper or lower GI hemorrhage (hematemesis or bright red blood per rectum). A research assistant (A.S.) attended all operations for collection of intraoperative data and recording on a preconstructed data form. Costs for the control and treatment groups were derived from the University of California Irvine Medical Center's decision support system database. Costs are reported in US dollars. Operative service costs included operative time, operative supplies, and postanesthesia care. Hospital service costs included nursing, pharmaceutical, diagnostic, therapeutic, and other services. The total cost represents the operative and hospital service costs. Continuous data are expressed as mean \pm SD. Analyses of differences between groups for demographic and operative data were performed using 2-sample *t* tests or Fisher exact tests for categorical data. Statistical evaluations were performed using SPSS statistical software, version 12.0 (SPSS Inc, Chicago, Ill). *P* < .05 was considered significant.

RESULTS

Thirty-four patients undergoing laparoscopic GBP were randomly assigned to either the treatment group (ie, those

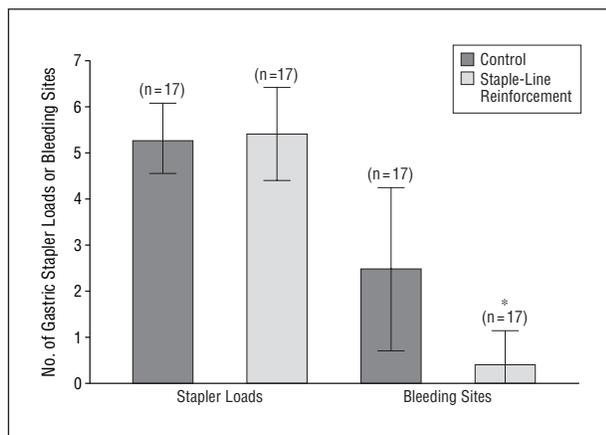


Figure 2. The number of stapler loads used compared with the number of staple-line bleeding sites during the construction of the gastric pouch for laparoscopic gastric bypass. Asterisk indicates $P < .05$, *t* test.

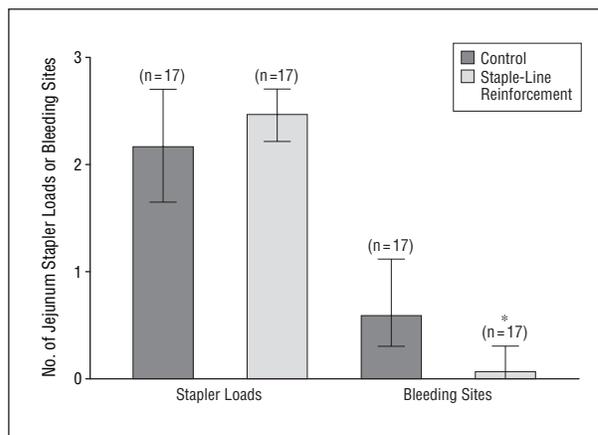


Figure 3. The number of stapler loads used compared with the number of staple-line bleeding sites during the division of jejunum for laparoscopic gastric bypass. Asterisk indicates $P < .05$, *t* test.

who received the staple-line reinforcement sleeves, $n = 17$) or the control group (ie, those who received staples only, $n = 17$). The 2 groups were similar in BMI and sex ratio. There was a total of 30 women and 4 men with a mean BMI of 46 ± 5 . The mean age was higher in the treatment group (47 ± 11 vs 40 ± 9 years, $P < .01$).

The mean number of stapler loads used during construction of the gastric pouch was 5.3 ± 0.8 for the control group and 5.4 ± 1.0 for the treatment group (**Figure 2**). The mean number of bleeding sites requiring intervention during construction of the gastric pouch was higher in the control group (2.5 ± 1.8 vs 0.4 ± 0.7 bleeding site, $P < .01$). The mean number of stapler loads used during the division of the jejunum and its mesentery was 2.2 ± 0.5 for the control group and 2.5 ± 0.5 for the treatment group (**Figure 3**). The mean number of bleeding sites requiring intervention during division of the jejunum was higher in the control group (0.6 ± 0.2 vs 0.1 ± 0.2 bleeding site, $P < .01$). The mean number of stapler loads used during division of the jejunal mesentery was 1.2 ± 0.3 for the control group and 1.3 ± 0.3 for the treatment group (**Figure 4**). The mean number of bleeding site requiring intervention during division of the jejunal mesentery was higher in the control group (0.8 ± 0.3 vs 0 bleeding sites, $P < .01$).

There was no conversion to open laparotomy in either group. Staple misfire occurred in 1 (0.7%) of 143 total number of stapler loads used in the treatment group compared with 0 of 138 total number of stapler loads used in the control group. The mean amount of blood loss was lower in the treatment group (84 ± 50 vs 129 ± 63 mL). The operative time to obtain hemostasis of the staple lines was lower in the treatment group (1.2 ± 0.8 vs 10.1 ± 6.4 minutes). The mean operative time was similar between groups (135 ± 16 vs 138 ± 26 minutes). There was no significant difference in the mean hemoglobin level between groups preoperatively (39.9 ± 3.5 vs 41.5 ± 3.6 g/dL) and on the first postoperative day (36.4 ± 4.0 vs 37.9 ± 3.8 g/dL). There was no mortality. The mean length of stay was not significantly different between groups (2.9 ± 1.0 days for the control group vs 2.8 ± 0.7 days for the treatment group). There was no postoperative leak or intra-

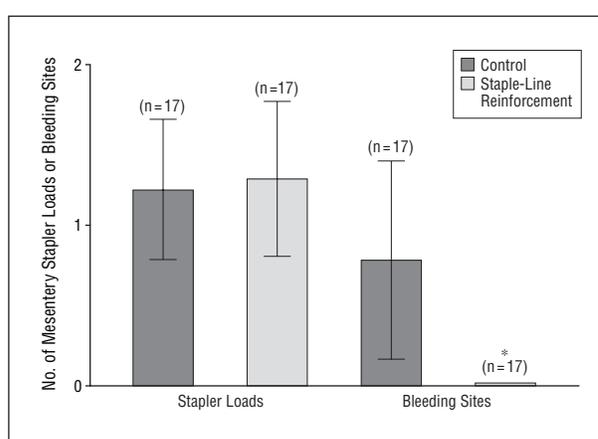


Figure 4. The number of stapler loads used compared with the number of staple-line bleeding sites during the division of jejunal mesenteric tissue for laparoscopic gastric bypass. Asterisk indicates $P < .05$, *t* test.

abdominal abscess in either group. One patient in the control group had postoperative GI hemorrhage requiring a blood transfusion and reoperation. This patient developed mild hypotension and tachycardia and had bright red blood per rectum at 4 hours postoperatively. The patient underwent a laparoscopic reexploration procedure and was found to have no evidence of intra-abdominal bleeding but a distended gastric remnant. A gastrotomy was created in the gastric remnant with removal of 800 mL of blood clots. On decompression of the gastric remnant, the staple lines at the gastric remnant were oversewn with continuous sutures. Anastomotic stricture occurred in 1 patient in each of the control and treatment group. There was no gastrogastric fistula in either group.

The mean operative service cost was significantly higher in the treatment group ($\$6766 \pm \1712 vs $\$5177 \pm \1502 , $P = .01$). There were no significant differences in the mean hospital service cost ($\$5445 \pm \1558 for the control group vs $\$4977 \pm \754 for the treatment group, $P = .3$) and the mean total hospitalization cost ($\$10\,623 \pm \2294 for the control group vs $\$11\,744 \pm \1962 for the treatment group, $P = .2$) between groups.

Intraoperative staple-line bleeding and postoperative GI hemorrhage are well-known complications of laparoscopic GBP.¹⁻⁴ Intraoperative staple-line hemorrhage is a common occurrence during laparoscopic GBP, whereas the incidence of postoperative GI hemorrhage after laparoscopic GBP is less common, ranging from 0.8% to 9.4%.¹⁻⁵ In our series of 155 patients who underwent laparoscopic GBP, the incidence of GI hemorrhage was 3.2%.⁴ Although uncommon, GI hemorrhage in the early postoperative period must be detected early and managed expeditiously because it can be life-threatening. Intraoperative staple-line bleeding can be a nuisance with the need to control bleeding sites by oversewing of the staple-line edges or the use of clips and/or electrocautery. Champion and Williams¹² reported that the mean number of clips applied to staple lines during laparoscopic GBP for control of staple-line bleeding ranged from 21 to 30. Staple-line bleeding can be a reflection for potential intraluminal bleeding. In this study, we examined the efficacy of staple-line reinforcement sleeves in reducing intraoperative staple-line bleeding and GI hemorrhage. Our results demonstrated that patients receiving staple-line reinforcement sleeves had fewer staple-line bleeding sites, a decreased amount of blood loss, and reduced time required to obtain hemostasis of the staple lines. The rate of GI hemorrhage in this small trial was 5.9% for the control group and 0% for the treatment group. A single patient in the control group developed postoperative GI hemorrhage requiring blood transfusions and operative intervention for control of the hemorrhage.

Postoperative GI hemorrhage after laparoscopic GBP occurs as a result of intraluminal bleeding at the staple lines of the gastrojejunostomy, jejunojejunostomy, gastric pouch, or gastric remnant.^{1,2} Podnos et al¹³ reported that the incidence of GI hemorrhage is higher after laparoscopic GBP compared with open GBP (1.9% vs 0.6%, respectively). One of the reasons for this difference is related to frequent oversewing of the staple lines during open GBP. Oversewing of the staple lines during laparoscopic GBP can be challenging and time-consuming. Staple-line reinforcement sleeves had been used as a buttress material in an effort to eliminate the need for oversewing of staple lines during laparoscopic GBP.^{10,11} Although this study did not conclusively demonstrate that the use of staple-line reinforcement sleeves lowers the rate of GI hemorrhage, we found that intraoperative staple-line bleeding was significantly reduced. In this trial, we noted an 84% reduction in staple-line bleeding sites at gastric tissue, an 83% reduction in staple-line bleeding sites at jejunal tissue, and a 100% reduction in staple-line bleeding sites at mesenteric tissue with the use of the staple-line reinforcement sleeves. We hypothesize that the reduction in intraoperative staple-line hemorrhage will result in a lower rate of postoperative GI hemorrhage. The mechanism for reduction in staple-line hemorrhage is the compressive effect of the staple-line reinforcement material on the transected tissue. The reduction in staple-line bleeding reduces the need for oversewing of the staple-line edges and reduces the time required to

obtain hemostasis of the staple lines. We did not observe a reduction in the overall operative time, however, probably because any reduction in the operative time for obtaining hemostasis of the staple lines (approximately 9 minutes) was offset by the time required to place the reinforcement sleeves onto the linear stapler by the surgical technician.

The safety of staple-line reinforcement sleeves is related to the risk for staple misfire and staple malformation because of the added thickness of the biomaterial. The use of staples with insufficient length may lead to disruption of the staple line owing to inadequate staple closure. Specifically, the glycolide copolymer sleeves increase the thickness of the tissue to be stapled by 0.5 mm. In this study, we did not adjust the staple height of the stapler cartridges in patients receiving the staple-line reinforcement sleeves. We continue to use the blue loads for gastric tissue, the white loads for jejunal tissue, and the gray loads for jejunal mesenteric tissue despite the presence of the glycolide copolymer sleeves. There was only a single staple misfire (0.7%) in the group receiving staple-line reinforcement. In addition, we have not experienced any problem in stapling across staple line with previously placed reinforcement sleeves. Another safety issue with the use of staple-line reinforcement sleeves is the biocompatibility of the material, particularly when placed adjacent to the GI tract. The use of nonabsorbable staple-line reinforcement material (expanded polytetrafluoroethylene [ePTFE] or bovine pericardium) in the GI tract can possibly lead to indolent infection, fistula formation, and erosion.¹⁴ An advantage of the glycolide copolymer sleeves is its bioabsorbable characteristic; they should be completely absorbed within 6 months.

Other possible benefit for the use of staple-line reinforcement sleeves during laparoscopic GBP is the reduction in staple-line leaks. Shikora et al¹⁰ reported no staple-line leaks in 250 consecutive patients who underwent laparoscopic GBP with the use of bovine pericardial staple-line reinforcement strips. One of the reasons for development of a staple-line leak after laparoscopic GBP is a scenario of a distal bowel obstruction resulting in dilation of the Roux limb and gastric remnant. The increased intraluminal pressure acting on the gastric pouch, gastrojejunostomy, and gastric remnant staple lines may lead to staple-line disruption. In a swine study comparing seam burst pressure, Arnold and Shikora¹⁵ reported that staple lines buttressed with bovine pericardial staple-line reinforcement strips sustained significantly higher mean burst pressures than nonbuttressed staple lines. Their study demonstrated that a buttressed staple line can maintain seam integrity at a significantly higher intraluminal pressure compared with a nonbuttressed staple line.

The cost for the staple-line reinforcement sleeves must be considered in any trial examining its cost-effectiveness. The cost for a pair of glycolide copolymer sleeves is \$120. The mean number of staple-line reinforcement sleeves used in the treatment group was 8.4, which represents an additional \$1009 in cost for the procedure. In our study, the actual operative service cost was higher in the treatment group than in the control group by \$1589. However, this cost was partially negated by any reopera-

tion or transfusion for GI hemorrhage. In this study, the total hospitalization cost was not different between the 2 groups.

CONCLUSIONS

Surgeons performing laparoscopic GBP may wish to consider the use of staple-line reinforcement material as an adjunct in the prevention of intraoperative staple-line bleeding and GI hemorrhage. We found the use of glycolide copolymer staple-line reinforcement sleeves to be safe and effective in reducing intraoperative staple-line bleeding. Glycolide copolymer staple-line reinforcement sleeves may also reduce the rate of GI hemorrhage in patients undergoing laparoscopic GBP; however, a larger study is needed to confirm our clinical finding.

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REFERENCES

1. Mehran A, Szomstein S, Zundel N, Rosenthal R. Management of acute bleeding after laparoscopic Roux-en-Y gastric bypass. *Obes Surg.* 2003;13:842-846.
2. Higa KD, Ho T, Boone KB. Laparoscopic Roux-en-Y gastric bypass: technique and 3-year follow-up. *J Laparoendosc Adv Surg Tech A.* 2001;11:377-382.
3. Schauer PR, Ikramuddin S, Gourash W, et al. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. *Ann Surg.* 2000;232:515-529.
4. Nguyen NT, Rivers R, Wolfe BM. Early gastrointestinal hemorrhage after laparoscopic gastric bypass. *Obes Surg.* 2003;13:62-65.
5. Lujan JA, Frutos D, Hernandez Q, et al. Laparoscopic versus open gastric bypass in the treatment of morbid obesity: a randomized prospective study *Ann Surg.* 2004;239:433-437.
6. Nguyen NT, Longoria M, Chalifoux S, Wilson SE. Early gastrointestinal hemorrhage after laparoscopic gastric bypass. *Obes Surg.* 2004;14:1308-1312.
7. Murray KD, Ho CH, Hsia JY, Little AG. The influence of pulmonary staple line reinforcement on air leaks. *Chest.* 2002;122:2146-2149.
8. Vaughn CC, Wolner E, Dahan M, et al. Prevention of air leaks after pulmonary wedge resection. *Ann Thorac Surg.* 1997;63:864-866.
9. Miller JI, Landreneau RJ, Wright CE, Santucci TS, Sammons BH. A comparative study of buttressed versus nonbuttressed staple line in pulmonary resections. *Ann Thorac Surg.* 2001;71:319-323.
10. Shikora SA, Kim JJ, Tarnoff ME. Reinforcing gastric staple-lines with bovine pericardial strips may decrease the likelihood of gastric leak after laparoscopic Roux-en-Y gastric bypass. *Obes Surg.* 2003;13:37-44.
11. Consten EC, 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;14:1360-1366.
12. Champion JK, Williams MD. Prospective randomized comparison of linear staplers during laparoscopic Roux-en-Y gastric bypass. *Obes Surg.* 2003;13:855-860.
13. Podnos YD, Jimenez JC, Wilson SE, Stevens CM, Nguyen NT. Complications after laparoscopic gastric bypass: a review of 3464 cases. *Arch Surg.* 2003;138:957-961.
14. Consten EC, Dakin GF, Gagner M. Intraluminal migration of bovine pericardial strips used to reinforce the gastric staple line in laparoscopic bariatric surgery. *Obes Surg.* 2004;14:549-554.
15. Arnold W, Shikora SA. A comparison of burst pressure between buttressed versus non-buttressed staple lines in an animal model. *Obes Surg.* 2005;15:164-171.

DISCUSSION

James E. Goodnight, MD, Sacramento, Calif: Relative to this paper, I do not do this work, but I presume I was asked to discuss this paper from the viewpoint of someone who often must decide whether to spend money on a program and whether that program is worthwhile. A second part of my disclaimer is that it is true what my faculty at the University of California, Davis, observe, that I often cannot read the handwriting on the wall, but as the Distinguished Medicine Chair Emeritus from the University of California, San Francisco, Dr Holly Smith notes, there is a reason for it. When dealing with any of these knotty issues, or unhappy faculty, I cannot read the handwriting on the wall because they have got me with my back to the wall. So much for apologies. I am paid to distinguish feces from fine shoe polish.

Let me first compliment Dr Nguyen on his usual excellent presentation for producing a small, but clean, and well done study, carefully examining key issues. Dr Nguyen is to be admired for undertaking this study that introduced uncertainty in an operation that he and others have very nearly perfected. The risk of the glycolide copolymer reinforcement sleeves is related to their advantage, which is to increase the pressure on the tissue under the staples such that bleeding is prevented. But this does risk failure if the staples do not hold with resulting disruption of staple line and leaks. Happily this did not happen with this product in Dr Nguyen's hands.

Bariatric surgery in particular is a product line that must be accomplished with maximum efficiency, with minimum complications to whatever degree possible, and performed at the lowest possible cost. In this vein, W. L. Gore and Associates are to be complimented for applying their excellent technology, their copolymer technology, to produce a product that certainly by this study does work fairly efficiently to do what it is intended to do, and the product does not seem to cause problems.

Having said that, in skilled hands, are the results of using this product worth spending an extra \$1500 per case? From what Dr Nguyen has presented, I would say, "No." This glycolide copolymer reinforcement is a relatively expensive solution to a relative nonproblem. In reality, and as this paper attests, bleeding from the suture line in surgery is a relatively easily managed problem with clips, with sutures placed by these very skilled laparoscopists, and in their hands, postoperative bleeding, while upsetting, is relatively uncommon. The product works actually quite well, but its use does not lower cost, it does not increase efficiency, and it does not significantly improve outcomes. Good try, but that's life.

From discussion with those who do this work and from available data that Dr Nguyen cites, as well as from his own work which appears within his study, it seems as if careful mastery of the technique, particularly when coming across the mesentery, small staple height, and a tight anal sphincter in watching these patients postoperatively are the mainstays in dealing with staple line in postoperative bleeding.

To conclude, I would say that I have nothing but admiration for all involved, Dr Nguyen, his fellow bariatric surgeons, and W. L. Gore and Associates, but I am not ready to buy. I have 2 questions for Dr Nguyen. Before the almighty forces that happen to be expressing themselves today, your colleagues here and the representatives from W. L. Gore and Associates whom we thank for their many wonderful products and their support of this meeting, as well as the many other excellent industry supporters, will you incorporate this product or something very similar in your routine work? My second question is the free-association thinking of a noncombatant. Would you be interested and perhaps use a product that added \$500 or \$600, not \$1500 per case, a product that is a combined unit, perhaps

staples and buttressing combined or a copolymer-coated staple that reduces bleeding, an industry challenge, if you will?

Lawrence A. Danto, MD, Truckee, Calif: I do not really have a discussion, nor do I have experience with this; but the thought occurred to me as I was listening to the presentation: is there any experience using a product like this in splenic (or liver) salvage?

Myriam Curet, MD, Stanford, Calif: I have 2 questions. Do you think there is an increased incidence of bleeding with stapled anastomosis vs hand-sewn anastomosis? My second question is, do you think there is an increased incidence of bleeding with the type of deep venous thrombosis (DVT) prophylaxis you used, specifically if you continue to use it postoperatively rather than just as perioperative DVT prophylaxis?

Donald B. McConnell, MD, Portland, Ore: In our bariatric surgical program in Portland, we use endoscopic staplers both in open and laparoscopic surgery. In my open cases, postoperative bleeding has occurred only once in a patient who received anticoagulated therapy for a DVT. Bleeding from the base of the mesentery after creating a Roux-en-Y GBP is avoided by directly oversewing with a figure-of-eight silk suture. I also routinely oversee staple lines. The high cost of the staple-line glycolide copolymer sleeve may be offset by avoiding extra time to oversee bleeding sites. Do you think glycolide copolymer staple-line reinforcement will lower the leak rate and stricture rate?

Dr Nguyen: Dr Goodnight first asks whether GI hemorrhage is a significant problem or not. Although I believe that we have technically advanced this laparoscopic operation, we have not eliminated altogether the problem of GI hemorrhage. We observed a 3.2% incidence of GI hemorrhage after laparoscopic GBP, which led us to investigate methods to minimize this potentially life-threatening complication. The purpose of this study was to examine the rate of intraoperative staple-line bleeding that may affect the overall rate of postoperative GI hemorrhage. To prove the efficacy of staple-line reinforcement in reducing GI hemorrhage would require a much larger trial.

Cost is definitely a factor in the evaluation of any new technology. GI hemorrhage can be a life-threatening postoperative complication if not treated expeditiously. We have a very low threshold for operative intervention and use the "golden rule" that if a patient is seen with signs and symptoms of GI hemorrhage within the first 6 hours of the operation, we are more likely to proceed with operative intervention. Delay in treatment can lead to morbidity and even mortality. The cost of treat-

ing GI hemorrhage includes blood transfusion, possible operative or endoscopic intervention, intensive care unit care, and prolongation of the hospital stay. Although the incidence of bleeding is low, any measure that can reduce GI hemorrhage would be welcomed. To summarize, the cost for the technology would potentially be offset by the cost for management of patients with this complication.

We do not have experience with this product in splenic salvage; however, there have been some data to support the use of staple-line reinforcement products on solid organs such as the spleen and pancreas. We have experience with the use of staple-line reinforcement products during the division of large vascular pedicles. For example, during laparoscopic esophagectomy, we routinely divide the azygous vein. The use of staple-line reinforcement material essentially eliminates bleeding during this critical step. In addition, if there is bleeding at the vascular pedicle, you can use the staple-line reinforcement material as a mechanism to grasp the vein to control bleeding with a clip applicator rather than grasping the vein itself.

Dr Curet asks if there is a higher incidence of bleeding associated with hand-sewn vs a stapled anastomosis. We find that the stapled anastomosis is associated with a higher rate of GI hemorrhage. When we converted from open surgery to laparoscopic operations, the number of hand-sewn anastomoses decreased. Most surgeons use either the circular or the linear staple technique to perform the gastrojejunostomy. I know that you prefer a hand-sewn technique but not all surgeons have the dexterity to perform a hand-sewn anastomosis and complete it in a timely manner.

With regard to the role of DVT prophylaxis and GI hemorrhage, the literature suggested that there is a higher incidence of bleeding associated with the use of preoperative antithrombotics such as heparin or low-molecular-weight heparin.

Dr McConnell asked if glycolide copolymer staple-line reinforcement will lower leak rate and stricture rate. We have no clinical experience with regard to the use of staple-line reinforcement material intraluminally during construction of the jejunojejunostomy and gastrojejunostomy. We must caution that its use intraluminally may increase the rate of anastomotic stricture. With regard to the leak rate, animal studies have demonstrated that a buttressed staple line can maintain seam integrity at a significantly higher intraluminal pressure compared to a nonbuttressed staple line.