Medical Devices: Evidence and Research

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ORIGINAL RESEARCH

A Novel, Easy-to-Use Staple Line Reinforcement for Surgical Staplers

This article was published in the following Dove Press journal:
Medical Devices: Evidence and Research

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Background: Staple line reinforcement (SLR) is a popular tool used by surgeons to increase staple line strength and improve peri-operative hemostasis. However, currently marketed buttress materials require special attention in attachment to the staple anvil and cartridge and may come loose during typical maneuvering of stapling procedures. We have evaluated a new SLR that has an attachment material that affixes buttress across the entire anvil and cartridge face to prevent slipping, twisting, sliding and/or bunching.

Methods: In benchtop and preclinical testing, the new buttress material (ECHELON ENDOPATH™ Staple Line Reinforcement) was compared to a commercially available SLR for physical characteristics, including strength, absorption, security on the anvil and cartridge during stapler manipulation, impact on the tissue healing response and tissue abrasion. The two SLR's were also compared to a staple line without buttress for hemostasis.

Results: The new SLR was 180% stronger initially and maintained a greater strength for up to 14 days of exposure to an in vitro solution ($p \leq 0.001$), even though it was lighter and exhibited a faster rate of degradation. The new buttress material maintained complete adherence to the anvil and cartridge throughout tissue manipulation, whereas the commercial product lost substantial coverage in 72% of samples. Both SLR's provided superior hemostasis to the non-buttress control, with minimal impact on tissue healing or abrasion.

Conclusion: Because the new buttress material comes with attachment material affixed across the entire anvil and cartridge face of the stapler and maintains coverage during manipulations, it should be much easier to use. The physical characteristics of the new SLR were as good as or better than current product that requires the buttress to be applied to the cartridge and anvil. In addition, the new SLR is similar in hemostasis to standard products and superior to stapling without the use of buttress. Further research is needed to determine whether these preclinical benefits carry over into a clinical setting.

Keywords: stapler, buttress, staple line reinforcement, hemostasis, anastomosis

Introduction

Stapling devices are commonly used in open and laparoscopic surgery as they allow for quick division, little tissue manipulation and closure of tissue.[1] After stapling, the tissue integrity prevents the staples from tearing through the tissue.[2] The staples do not elicit much cellular response; however, an inflammatory response may reduce tissue strength due to decreased amounts of collagen associated with the normal healing response.[3–5] In addition, edema may form due to surgical trauma, tissue manipulation or disease and affect healing. Decreased tissue strength combined with manipulations may result in the staples tearing through the tissues.[6,7]

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http://doi.org/10.2147/MDER.S234156

Staple line buttressing was developed to improve staple line strength. Application of buttress material in the staple line is thought to distribute tension throughout the staple line, seal off the staple holes and narrow the spaces between each staple, thus reducing tearing at the staple line. In addition, the buttress provides a broader pressure profile around each individual staple across the staple line, leading to potentially improved hemostasis.

Currently available absorbable buttress is provided in the form of rectangular flat strips and sleeves which are manually attached to the surgical stapler anvil and cartridge. Some reinforcement materials are attached with a gel adhesive, adding another step to the buttressing process.[8] During stapler positioning and firing, the buttress material can slip, twist, slide or bunch on the stapler anvil and cartridge.[9] If the buttress moves unintentionally, the surgeon must watch for and ensure that the buttress was fully captured by all individual staples and remove migratory staples.[10]

A novel buttress made from the same synthetic absorbable materials used in VICRYL & PDS sutures brands (polyglactin 910 & polydioxanone) buttress was recently developed in a form that comes in a simple click-and-go applicator for fast easy buttress application that attaches to the staple anvil and cartridge. This buttress was designed to provide an easy-to-use staple line reinforcement with high tensile strength and rapid absorption.

The present study compared the novel buttress to the most commonly used commercially available staple line reinforcement. Key characteristics examined included strength, absorption, security on the anvil and cartridge during tissue manipulation, abrasion, hemostasis and tissue healing.

Methods

All in vivo procedures were reviewed and animals approved for use in the studies by the Ethicon Institutional Animal Care and Use Committee in compliance with the US Animal Welfare Act Regulations (9CFR, Parts 1, 2, and 3) and the Guide for the Care and Use of Laboratory Animals of the Association for Assessment and Accreditation of Laboratory Animal Care, International. Biocompatibility testing was conducted based on International Organization for Standardization 10993: Biological evaluation of medical devices, Part 6: Tests for local effects after implantation. The tissue response to the buttress and the tissue healing response at staple line firings were evaluated using standard pathology methods.

The buttress materials evaluated in this study were ECHELON ENDOPATH™ Staple Line Reinforcement ECH60R (EER, Ethicon, Inc., Cincinnati OH) and GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement 12BSGEC60A (GSG, W.L. Gore & Associates, Flagstaff AZ). EER consists of polyglactin 910 (the same material used in Vicryl suture) and two layers of polydioxanone (the same material used in PDS suture) film, attached to the anvil and cartridge with a water soluble alkylene oxide copolymer (AOC) blend. GSG comes in a sleeve configuration and is made from a synthetic copolymer, polyglycolic acid:trimethylene carbonate (PGA:TMC), having an open, interconnected pore structure, that is specified to be absorbed within 6–7 months. GSG buttress was applied to the stapler cartridge according to the Instructions for Use (IFU). The staplers used were the Echelon Flex Powered Plus 60 mm Articulating Endoscopic Stapler (PSEE60A) with staple reloads of Endopath Echelon GST60G or GST60B.

Maximum load tensile strength was measured using an Instron Testing System 5500 (Instron, Norwood, MA) with a 445 N load cell operated at a rate of 5 mm/s. The thickness was measured with a calibrated Mahr Federal Gage (Mahr Inc, Erlanger, KY) to a precision of 2.5 µm. Surface area was determined via a 3D CAD model using Solidworks 2016 (Dassault Systèmes SolidWorks Corporation, Waltham, MA) for both the cartridge and anvils sides, and the total was reported.

Staple pull through force was evaluated using a Zwick Roell Z005 load frame with a Zwick Roell 200 N load cell (Zwick Roell GmbH & Co., Ulm, Germany). Pull-through force was measured before exposure and after 7 and 14 days of exposure to an in vitro solution of a pH 7.25 phosphate buffer maintained at 37°C.

Buttress coverage after manipulation was assessed by determining the ability of buttress material to stay attached to the stapler on both the anvil and cartridge side during simulated manipulation of tissue. Manipulation was performed in a humidified environmental chamber at 43°C, using porcine stomach of thickness 3.5 ± 0.2 mm (determined with a tissue measuring device at a compression of 8 g/mm^2) with a pre-installed staple line. Seven steps were performed to assess buttress coverage after manipulation: 1. passing the closed device through a trocar into the chamber, 2. opening the jaws and articulating the jaws while pressing the side of the end effector against tissue, 3. sliding onto and grasping tissue for 5 s by partially clamping, 4. sliding onto and grasping a staple line in tissue for 5 s, 5. removing and re-inserting the device through a trocar, 6. sliding onto and grasping tissue for

5 s by fully clamping, and 7. partially opening the jaws and sliding laterally 2 cm. After the manipulations, the device was fired onto silicone, the staple line was inspected and graded as acceptable or unacceptable depending upon buttress essentially covering the staple line.

The macroscopic level of thoracic wall abrasion caused by the placement and firing of the stapler with buttress was compared between EER and GSG. The applications were intended to create a pneumostatic seal in lung resections. In each of eight hound dogs, the hemithorax was accessed using a video-assisted thoracic surgery (VATS) procedure. In the left and right lungs, five staple line sites were created on each side. At 7 ± 1 days following surgery, all animals were euthanized, and the abrasive interactions and local tissue responses of lungs and thoracic walls were macroscopically examined. Abrasions were graded on a 5-point scoring system of 0: no abrasions, 1: minimal, 2: mild, 3: moderate, or 4: marked abrasions. A non-inferiority test of EER vs GSG was performed.

For hemostasis comparisons, five Yorkshire cross domestic pigs underwent longitudinal transection of the jejunum-ileum targeting a compressed tissue thickness of 1.5 mm to 2.25 mm and a target mean arterial pressure of 85−100 mm Hg. A total of 37 sites were achieved for each article by stapling at 18–24 sites in each of the five animals. Device applications were blocked (groups of three: EER/GST60G, GSG/GST60G, and no buttress control/GST60G). Following each firing, hemostasis of the firing line was evaluated using a 5-point Likert scale at 180 s after firing.[11] The Likert scale values were converted to a binary output, ie, no Intervention needed (1–3) and intervention needed (4–5), for comparison purposes.

The tissue healing response at staple line firings was evaluated in gastric and pulmonary tissues using EER, GSG and stapled sites with no buttress applied. Twenty-four purpose-bred hound mix dogs had 6 article application sites (3 full-thickness gastric with GST60G with or without EER/GSG and 3 thoracic sites with GST60B with or without EER/GSG per animal). At 10, 30, and 120 ± 1 days, eight dogs were euthanized and a necropsy performed. The staple lines were collected and placed in 10% neutral buffered formalin. Routine histopathology was performed to document staple line healing response at each study interval.

Results

EER sustained a maximum load 2.8 times greater than GSG, although it was 16% thinner (Table 1). EER had significantly greater staple pull-through force initially and after 7 and 14 days in an in vitro solution. The initial pull-through force for EER was 93% greater than for GSG. Pull-through force for both products decreased exponentially; the half-life of the degradation was approximately 42% faster for EER (Figure 1). Coverage of the buttress after simulated manipulation was 100% for EER, but only 28% for GSG.

Abrasion scores on the thoracic wall for EER were non-inferior to GSG ($p<0.05$, Table 2, Figure 2). For both products, there were no abrasion scores of 4 (marked abrasions). For EER, 92% of scores were less than or equal 2 (mild abrasions), compared to 76% for GSG. Hemostasis (proportion of applications needing intervention) for EER was not significantly inferior to GSG with a non-inferiority margin of 20% using a bootstrap method ($p<0.001$). EER had significantly fewer observations of requiring intervention than the no buttress control ($p<0.001$, Figure 3).

Tissue Healing Response: All animals survived through study completion with no clinical findings outside of an expected range for this type of procedure. Microscopically,

Table 1 Comparisons of EER and GSG Physical Characteristics

Measure	EER	GSG	Statistical Test	p-value
Maximum Load	38.9 ± 5.1 N	10.2 ± 1.6 N	Student's *t*-test	<0.001
Area	26.97 cm^2	49.21 cm^2	–	–
Thickness	163 ± 3 μm	194 ± 23 μm	Student's *t*-test	<0.001
Staple pull-through force				
Day 0	97.9 ± 14.9 N	32.6 ± 7.6 N	Student's *t*-test	<0.001
Day 7	47.4 ± 6.1 N	24.6 ± 5.8 N	Student's *t*-test	<0.001
Day 14	13.1 ± 2.3 N	10.5 ± 3.3 N	Student's *t*-test	0.001
Force dgradation half-life	4.8 days	8.4 days	NA	NA
Absorption time	17 weeks	24–48 weeks	NA	NA
Coverage after manipulation	40/40 (100%)	11/40 (28%)	Fisher's exact test	p<0.001

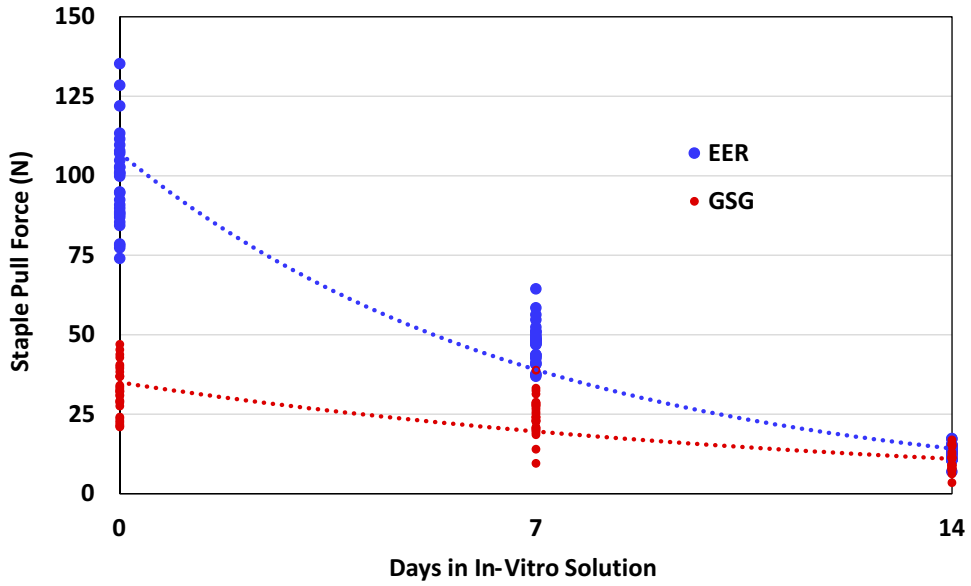

Figure 1 Staple pull-through force for EER and GSG after 0, 7 and 14 days in an in vitro solution with exponentially decreasing trendlines.

the EER tissue healing response at the gastric and pulmonary staple lines was considered acceptable at 10, 30, and 120 days and was comparable to the tissue healing response observed at staple lines for GSG and no buttress control. Tissue healing at the staple line was similar for EER, GSG and the no buttress control. The overall tissue response to EER was closer to the tissue response observed for GSG than to the tissue response observed with the no buttress control as expected due to the additional response directed towards the bioabsorbable buttress material.

Table 2 Abrasion Scores, Hemostasis for EER, GSG and No Buttress Control

Measure	EER	GSG	No Buttress
Abrasion score			
Mean ± St Dev (n)	1.72 ± 0.68 (25)	2.04 ± 0.68 (25)	–
Median	2.0	2.0	
Hemostasis			
Mean ± St Dev (n)	2.19 ± 0.40 (37)	2.14 ± 0.63 (37)	3.08 ± 0.80 (37)
Median	2.0	2.0	3.0
Hemostasis Likert scores			
1	0	3	0
2	30	28	10
3	7	4	14
4	0	2	13
5	0	0	0
Proportion requiring hemostasis intervention	0.0%	5.5%	35.1%

At 10 days, there were small amounts of acute inflammation and hemorrhage and/or edema (an expected result of surgical trauma) adjacent to the staple line that often overlapped with or extended within all treatments. The tissue response to the no buttress control was limited to the staple line itself (ie, the area of compressed/crushed and cut tissues). At 30 days, most of the tissue response with EER and GSG was oriented towards the buttress, and in the no buttress control, the tissue response was limited to the staple line itself, similar to what was noted at 10 days. At 120 days, tissue healing progressed towards remodeling at the staple lines of all articles in the stomach and lungs. In the stomach, the wall cut edges stretched out and flattened and were bridged by fibrous tissue; the mucosal epithelium was fully regenerated. In the lungs, the compressed tissue was partially replaced and infiltrated by fibrous tissue and the staple line on the pleural aspect was covered by a thin fibrous layer. EER was considered essentially absorbed at 120 days with <10% of the article remaining extracellular in location. The bundles of filaments component (Vicryl) of the EER buttress were completely absorbed and only a few to multiple film fragments remained extracellular in location. GSG absorption varied at 120 days and was considered not essentially absorbed in most sites with estimated greater than 10% of the article remaining extracellular in location.

Discussion

The use of currently marketed staple line reinforcement needs the buttress material to be applied to the stapler

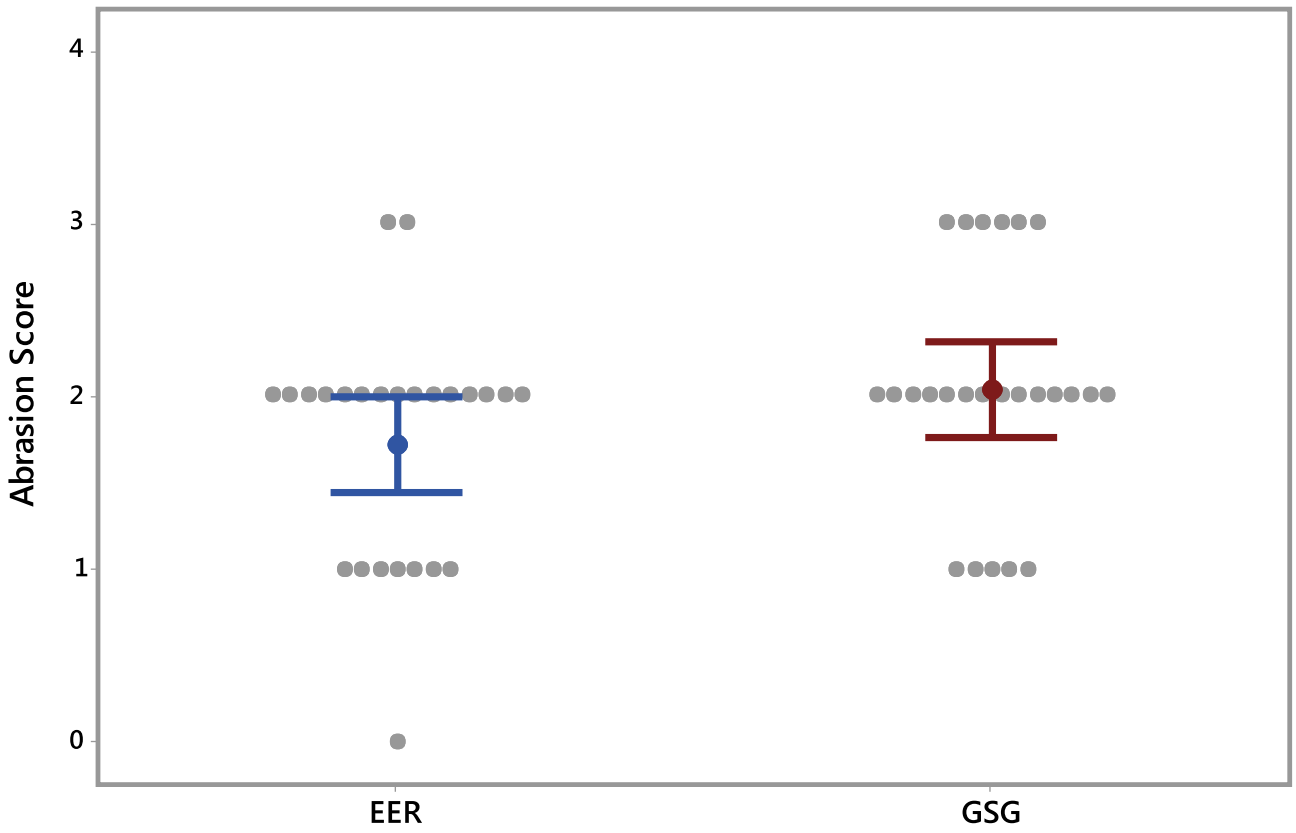

Figure 2 Abrasion scores for EER and GSG, with mean and 95% confidence interval.

cartridge and anvil and may also need an adhesive applied. If an adhesive is not used, as with GSG, there is an elevated risk of the buttress material slipping, twisting, sliding or bunching up on the anvil and cartridge.[9]

The new ECHELON ENDOPATH Staple Line Reinforcement comes in a pre-installed applicator with pre-applied buttress attachment material that can be easily applied to the stapler on the anvil and staple cartridge, designed to make buttress application simple and keep (prevent) the buttress material from moving or detaching from the anvil and/or cartridge. In this study, the EER buttress material has been shown to be significantly stronger than GSG, even though EER is thinner. The greater strength of EER continued through 14 days of in vitro submersion while the absorption rate of EER was faster than GSG, with similar tissue healing profiles.

The interaction between device and tissue is considered essential in forming a staple line of high integrity,[12] and one of the keys to a well-formed staple line is having a staple height appropriate for the tissues being apposed. If buttress material is displaced or bunches, the compression can be uneven. Perhaps the most salient difference between the two staple line reinforcements evaluated here is in the performance during simulated tissue manipulation. After seven maneuvers commonly executed during a surgical procedure, all the EER devices maintained complete coverage of the cartridge by the buttress material while over 70% of the GSG devices lost substantial amounts of coverage.

Complications related to stapling may include bleeding and anastomotic failure, such as stricture or leak.[13] Numerous studies have shown that buttress can be an effective tool in the mitigation of bleeding at the staple line.[14–17] In the current study, hemostasis outcomes were significantly improved by the buttresses compared to no buttress (bare staples); however, there was no difference between the two staple line reinforcements.

The design of the EER incorporates several features that make the material easier to use and functionally superior. GSG buttress comes in a tube form with suture lacing, and is attached by sliding over the cartridge/anvil. This lacing may become un-zipped by pulling suture prior to firing while the EER buttress material comes in a pre-installed applicator with pre-applied buttress attachment material that can be simply applied to the stapler on the anvil and staple cartridge simultaneously. The GSG has

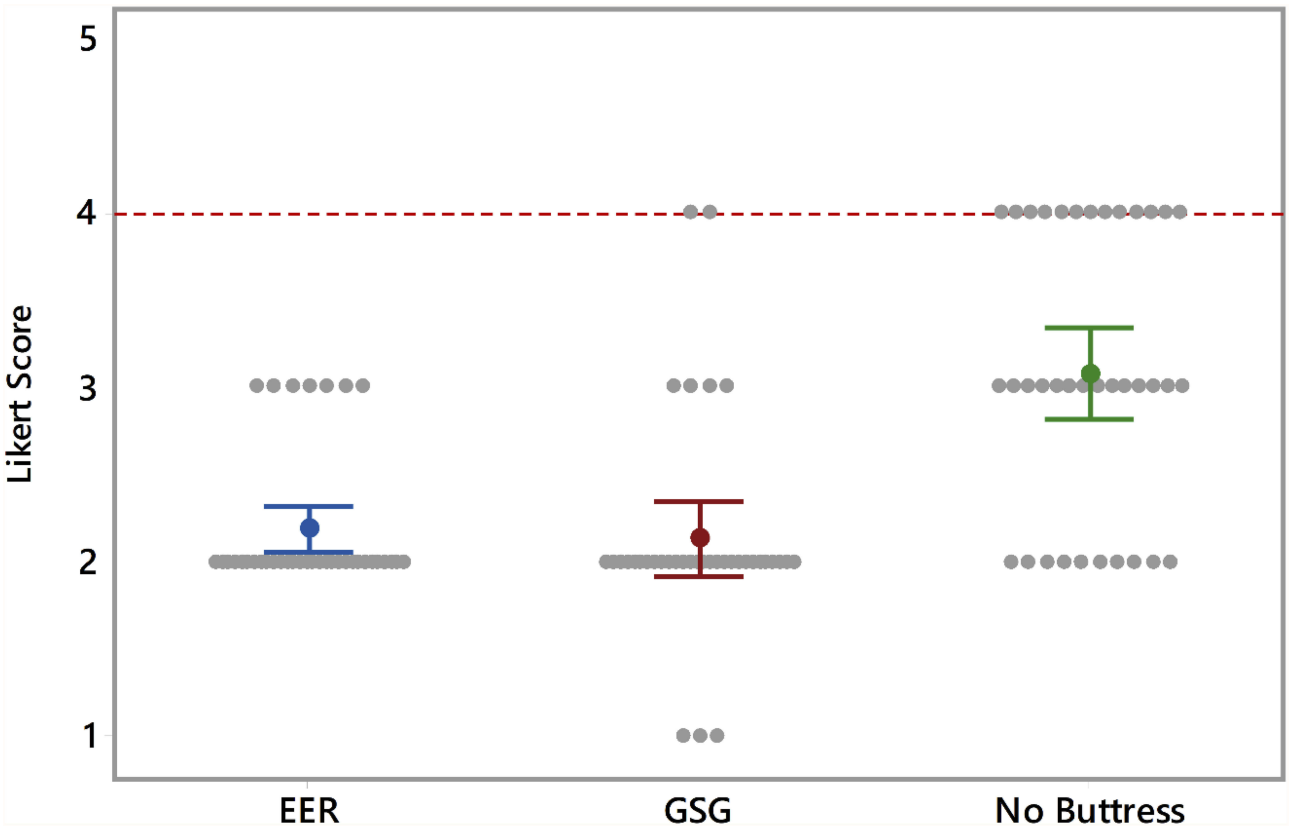

Figure 3 Hemostasis Likert scores for EER/GST60G, GSG/GST60G and No Buttress/GST60G, with mean and 95% confidence interval. Likert scores of 4 and above were considered to be requiring intervention.

a melt-blown, non-woven architecture, the EER buttress is a laminated knit mesh structure. The knit direction is designed at an optimized angle to increase strength and reduce stretching during the manipulation and firing of the stapler.

A potential concern with the use of buttress is the risk of tissue abrasion resulting from the interaction of a buttress surface with the tissue and the cyclical movement of tissues against each other. Issues with abrasion and concomitant bleeding complications have been reported when using staple line reinforcements.[18,19] In this study, we examined the potential for abrasion and compared the novel buttress to a commercially available product without a history of increased abrasion or bleeding. EER was found to be non-inferior to GSG, with no evidence of marked abrasion and a lower rate of moderate abrasion.

To our knowledge, this is the first time that buttress coverage after simulated tissue manipulation has been evaluated. No difference was observed in hemostasis performance between EER and GSG, however, little tissue manipulation was performed during this preclinical test. It is possible that if tissue manipulation were to be performed prior to the hemostasis test, a difference in bleeding might have been observed. While the tissue healing was comparable between EER and GSG, the EER did absorb faster than the GSG.

Clinically buttressing material is commonly used as a way to lower intraoperative as well as postoperative complications,[20,21] in addition, buttressing is associated with lower complication rate in early surgeon experience.[22] ECHELON ENDOPATH Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed, and can be used for reinforcement of staple lines during lung resection, bariatric, gastric, small bowel and colorectal procedures. Further clinical testing of this novel staple line reinforcement is needed to evaluate its effectiveness in a clinical setting.

Disclosure

All authors are employees of Ethicon, Inc which produced ECHELON ENDOPATH Staple Line Reinforcement. The authors report no other conflicts of interest in this work.

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