Int Surg 2018;**103:**129–138
DOI: 10.9738/INTSURG-D-15-00171.1

Prospective, Multicenter Randomized Controlled Trial Comparing Two Hemorrhoidopexy Staplers: The HEMOSTASIS Study

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The objective of this study was to compare two hemorrhoidopexy staplers (EEA versus PPH03). Stapled hemorrhoidopexy is a treatment option for patients with symptomatic internal hemorrhoids who have failed more conservative measures. However, staple line bleeding remains common. Recent improvements in stapler design have attempted to reduce intraoperative bleeding and the need for intervention. HEMOSTASIS is a prospective, multicenter, 1:1 randomized controlled trial. Twelve hospital centers in the United States enrolled participants between 18 and 85 years of age with symptomatic grades 2 to 3 internal hemorrhoids. The primary end point was intraoperative bleeding, defined as bleeding requiring intervention (*e.g.*, placement of sutures, cauterization, or ligation to achieve hemostasis). Secondary end points included staple line location, postoperative pain, quality of life, operative time, length of hospital stay, adverse events, and complication rates. On the primary end point, the rates of intraoperative bleeding requiring intervention were 41.0% (32 of 78) with EEA and 70.4% (50 of 71) with PPH

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($P < 0.001$). Treatment for active bleeding was required in 30.8% versus 57.7% ($P < 0.001$) in the EEA and PPH arms, respectively. There were no significant differences between groups in postoperative pain. Adverse events and perioperative complication rates were generally mild/moderate and were similar between groups: 74.1% (60 of 81) of patients in the EEA group reported at least one adverse event versus 80.9% (55 of 68) in the PPH group ($P = 0.32$). Intraoperative bleeding occurred less often after stapled hemorrhoidopexy with the EEA stapler compared with the PPH03 stapler. Intervention to achieve hemostasis was required less often with the EEA stapler.

Key words: Hemorrhoids/*surgery – Hemorrhoidectomy – Humans – Randomized controlled trial – Surgical staplers

Hemorrhoid disease is the most common anorectal disorder. Results in 2012 showed a 7.6% prevalence in the United States in patients with chronic constipation.[1] A report from Austria showed a 38.9% prevalence in patients undergoing colorectal cancer screening, with about half of the patients being symptomatic.[2] Hemorrhoids are treated nonsurgically or surgically, depending on the severity of symptoms and hemorrhoid grade. Therapy ranges from dietary and behavioral modifications to surgery.[3] Surgical options include the conventional excisional hemorrhoidectomy (Milligan-Morgan or Ferguson operation) and the stapled hemorrhoidopexy (SH); nonsurgical treatments include injection sclerotherapy, rubber band ligation, and infrared coagulation.[3] Although nonsurgical options are typically the first approach in patients with grade 2 hemorrhoids, more aggressive options may be considered for patients who fail conservative measures.

SH, also referred to as the procedure for prolapse and hemorrhoids (PPH), is an alternative to excisional hemorrhoidectomy in patients with grades 2 to 4 internal hemorrhoids who have failed lifestyle modifications and nonsurgical therapy. First introduced by Longo in 1998,[4] the procedure uses a circular stapling device to excise a short circumferential segment of mucosa proximal to the dentate line. This interrupts the vascular component of the hemorrhoidal plexus and lifts the anorectal mucosa higher in the canal, reducing the mucosal prolapse. SH is therefore a combination of both fixation—returning the vascular cushions to their anatomic location high in the anal canal—and excision techniques, thus correcting the anatomic and physiologic abnormalities of prolapsed hemorrhoids.[5]

Both SH and excisional hemorrhoidectomy are associated with more postoperative pain compared with nonsurgical options. With traditional Milligan-Morgan or Ferguson hemorrhoidectomy procedures, hemorrhoidal tissue excision involves an incision the length of the anal canal and distal to the dentate line, resulting in severe postoperative pain. In contrast, SH treats the upper anal canal above the dentate line, an area with fewer to no pain sensory nerve fibers, resulting in improved patient comfort. A systematic review of 25 randomized controlled trials (RCTs) comparing SH to excisional hemorrhoidectomy showed that stapling resulted in reduced postoperative pain and convalescence time, better wound healing, and subsequently greater patient satisfaction.[6]

Staple line bleeding is encountered frequently during SH surgery and should be controlled with hemostatic sutures. Suturing also decreases the risk of postoperative hemorrhage from persistent hemorrhoidal tissue.[7] In a prospective trial comparing SH to excisional hemorrhoidectomy, 84% of patients undergoing SH required hemostatic sutures at the staple line at the time of surgery.[8] Modification of the PPH stapler (from PPH01 to PPH03) resulted in a significant reduction of intraoperative bleeding with stapled transanal hemorrhoid resection.[9]

The hemostatic performance of a circular stapler for hemorrhoidopexy (EEA) was compared to those of the PPH01 and PPH03 staplers in patients with grade 3 hemorrhoids in a multicenter Italian trial.[10] The authors concluded that the EEA stapler has better hemostatic properties than the PPH staplers in this patient population, and can resect a larger amount of mucosa.

The objective of our RCT was to compare the EEA stapler versus the most recent version of the PPH stapler (PPH03) in patients with symptomatic grades 2 to 3 hemorrhoids, and determine whether the improvements in stapler design reduce intraoperative bleeding and the need for intervention.

Patients and Methods

This study was conducted according to US Food and Drug Administration regulations, the International Conference on Harmonization E6 Guideline for Good Clinical Practice, and International Organization for Standardization 14155-1 and 14155-2 (2003). The protocol was approved by the Institutional Review Boards of all participating sites, and all participants provided written informed consent prior to participation. Surgeons well trained in hemorrhoidopexy operative technique and the use of the EEA and PPH staplers were selected; all investigators and subinvestigators must have completed at least 5 cases prior to performing any hemorrhoidopexy for this clinical trial. The study has been registered on clinicaltrials.gov (NCT01306877).

Devices

Devices compared were the Covidien (Mansfield, Massachusetts) end-to-end anastomosis (EEA) Hemorrhoid and Prolapse Stapling Set with Directional Staple Technology (DST) Series Technology, and the Ethicon (Somerville, New Jersey) Endosurgery PROXIMATE Procedure for Prolapse and Hemorrhoids (PPH) Stapling Set. The EEA stapler (the test device) is designed for use in the control of rectal prolapse and hemorrhoidal disease and places a circular, double-staggered row of titanium staples. The most recent version of the PPH stapler (PPH03) was used as the comparator device.

Participants

Patients who gave consent and who were ages 18 to 85 years with symptomatic grades 2 to 3 hemorrhoids and scheduled for SH surgery were assessed for potential study eligibility via a screening/baseline assessment performed within 30 days of their scheduled procedure. Patients with the following conditions were excluded: (1) those requiring revision to a prior hemorrhoid surgery within the 12 months prior to screening; (2) those who were pregnant, suspected to be pregnant, or nursing; (3) those with a current infection or history of infection within 30 days prior to surgery; (4) those who had undergone prior injection therapy, rubber band ligation, or infrared therapy to treat hemorrhoids within 1 month of screening; (5) those taking aspirin, anticoagulation, and/or antiplatelet therapies within 7 days prior to surgery; or (6) those with a history of substance abuse, venous thrombosis, pulmonary embolism, or fecal incontinence.

Trial design and objective

The objective of the prospective, single (subject) blind, multicenter, 1:1 randomized controlled HEMOSTASIS trial was to compare two hemorrhoidopexy staplers in the treatment of symptomatic grades 2 to 3 hemorrhoids. Randomization was conducted via random number and sealed envelopes (prepared by the sponsor and provided to each study center) and was blocked by study site. Participants were considered to be enrolled after signing informed consent, meeting eligibility criteria, and receiving randomization assignment.

Operative technique

Devices were employed per the manufacturer's instructions and local practice techniques, similar to prior publications.[11–14] Use of preoperative enemas and antibiotics, patient position (prone jackknife or lithotomy), and method of bleeding control, as needed, was per investigator discretion. Bleeding rates, interventions, and duration of treatment to control bleeding were recorded.

Outcome measures

The staple line was inspected for completeness with a visual and a digital examination. The specimen was removed from the stapler and inspected to ensure that a complete "doughnut" of tissue was excised. Surgeons measured the symmetry and weight of the specimen removed and the distance from the dentate line to the staple line with a surgical ruler. For asymmetrical doughnuts, the average of the thick and thin sides of the specimen was measured.

The primary end point was intraoperative bleeding, defined as bleeding requiring intervention (*e.g.*, placement of sutures, cautery, or ligation to achieve hemostasis). If bleeding was present, the method of intervention to achieve hemostasis (at the discretion of the surgeon) was noted, as well as the start and stop time of the intervention.

Secondary end points were: (1) postoperative pain as measured by the 11-point Pain Intensity Numeric Rating Scale (PI-NRS) and the intake of analgesic medications; (2) quality of life as measured by the SF-12 scale, and return to normal activity measured via patient feedback; (3) location of the staple line; (4) length of stay; (5) operative room time, defined as anoscope insertion to removal; and (6) adverse events and complications.

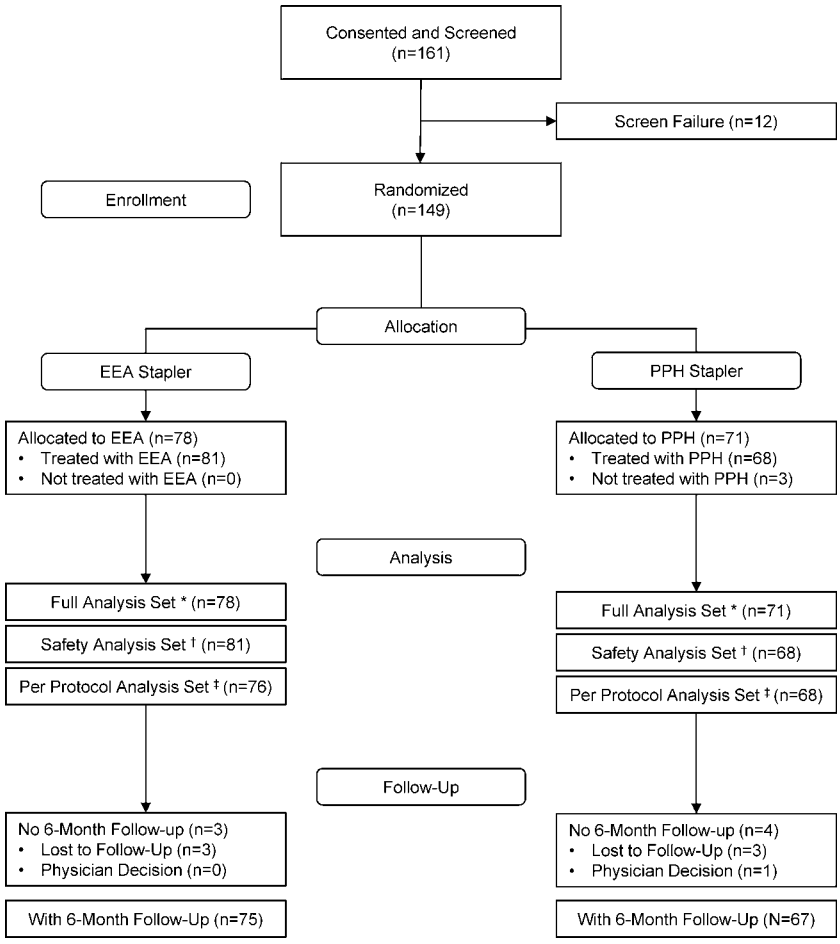

Fig. 1 Patient flow. *All randomized intent-to-treat patients regardless of treatment assignment and or protocol deviations. †All randomized patients who received treatment, according to the treatment actually given, including withdrawn patients. ‡Excludes from the full analysis set 3 misrandomized patients from the PPH arm and 2 patients with inclusion criteria violations (history of venous thrombosis) from the EEA arm.

Statistics

Based on estimated bleeding rates of 20% and 30% for the EEA and PPH groups, respectively, a sample size of 80 evaluable patients per treatment group was required for 80% power to reject an absolute 7% EEA inferiority, using a 1-sided test at the 0.05 level. Assuming 5% attrition, a total of 168 patients were required for randomization.

Analyses were performed using SAS Version 9.2 (SAS Inc, Cary, North Carolina), and data were summarized by mean ± SD or median [range] (for continuous variables) or proportions (for categoric variables). The primary end point was compared between groups in a noninferiority setting, based on the per protocol analysis set. The 1-sided 95% confidence upper limit for the difference between treatment groups was constructed by the Newcombe generalized Wilson score method. Following demonstration of noninferiority, a secondary analysis was planned to investigate superiority in the full analysis set using a 2-sided Pearson χ^2 test at an alpha level of 0.05. Secondary end points were compared using Student *t*-test, Wilcoxon rank sum test, or Fisher exact test, as appropriate, based on a 2-sided α level of 0.05.

A planned interim analysis was conducted on the first 92 patients enrolled. Per protocol, early termination was specified if the interim analysis demonstrated a significantly higher bleeding rate in the EEA arm compared with the PPH arm, at an α level of <0.05 (1-sided Fisher exact test). These conditions were not met.

Results

Participants

A total of 149 participants were enrolled between February 10, 2011, and August 21, 2012, at 12 US centers (Fig. 1). Enrollment was discontinued on August 21, 2012, because of a voluntary recall of the PPH device (based on reported difficulty firing the device, potentially leading to incomplete staple line formation).[15]

Table 1 Baseline demographics and characteristics (full analysis set)

	EEA (n = 78)	PPH (n = 71)
Age, y, mean ± SD	55.4 ± 13.8	52.1 ± 13.4
Male, % (n/total n)	50 (39/78)	62 (44/71)
White, % (n/total n)	84.6 (66/78)	81.7 (58/71)
Body mass index, kg/m^2, mean ± SD	27.94 ± 5.06	27.11 ± 4.85
Smoking history, % (n/total n)		
Nonsmoker	62.8 (49/78)	53.5 (38/71)
Past smoker	15.4 (12/78)	33.8 (24/71)
Current smoker	21.8 (17/78)	12.7 (9/71)
At least 1 prior hemorrhoid treatment, % (n/total n)	37.2 (29/78)[a]	50.7 (36/71)
Surgical, % (n/total n)	17.9 (14/78)	22.5 (16/71)
Topical, % (n/total n)	20.5 (16/78)	28.2 (20/71)
Current hemorrhoid grade, % (n/total n)		
1	0 (0/78)	0 (0/71)
2	35.9 (28/78)	28.2 (20/71)
3	64.1 (50/78)	71.8 (51/71)
4	0 (0/78)	0 (0/71)
ASA score, mean ± SD	2.1 ± 0.6	2.0 ± 0.6

ASA, American Society of Anesthesiologists.

[a]One patient in the EEA group had both a surgical and a topical prior treatment.

Demographics and medical history

Participant demographics and baseline characteristics are provided in Table 1. There were no statistically significant differences between groups. Obesity (defined as BMI >30) was present in 28.9% of participants. Most patients (67.8%) had grade 3 hemorrhoids, and 43.6% had received at least 1 prior hemorrhoid treatment (20.1% with prior surgical treatment).

Procedural characteristics

Procedural characteristics are shown in Table 2. The weight and thickness of the tissue specimen removed were significantly greater in the EEA arm. There were no significant differences in the secondary end points of location of the staple line, distance from the dentate line to the staple line, length of hospital stay, or operative room time.

Intraoperative bleeding

The primary end point (the rate of intraoperative bleeding requiring intervention to achieve hemostasis) was met for both noninferiority and superiority of the EEA stapler versus the PPH stapler (Fig. 2), with a significantly lower rate of intraoperative bleeding requiring intervention in patients treated with the EEA stapler in the full analysis set [32/78 (41.0%) EEA versus 50/71 (70.4%) PPH; $P < 0.001$]. Results were consistent in the per protocol analysis set. Details on intraoperative bleeding are shown in Table 3. Treatment for active bleeding (including 4 EEA patients and 2 PPH patients who received treatment both prophylactically and for active bleeding) was required in 24 patients (30.8%) in the EEA group compared with 41 patients (57.7%) treated with PPH ($P < 0.001$).

Procedural blood loss was also significantly lower in the EEA arm. When intervention was required, sutures were the primary means of treatment. Rate of suture usage was significantly lower in the EEA arm. Rates of bleeding requiring intervention were similar among the first half and second half of patients enrolled per site (based on full analysis set), indicating no detectable learning curve for either group [EEA: first half, 38.1% (16/42); second half, 44.4% (16/36); $P = 0.57$; PPH: first half, 69.2% (27/39), second half, 71.9% (23/32); $P = 0.81$).

Pain and quality of life

There were no significant differences between PI-NRS pain scores (Fig. 3) or analgesic consumption between groups. Return to normal activity was not

Table 2 Procedural characteristics (full analysis set)

	EEA (n = 78)	PPH (n = 71)	*P* value
Tissue specimen			
Thickness, mm, mean ± SD	19.33 ± 7.98	16.27 ± 7.71	0.02[a]
Weight, g, mean ± SD	6.86 ± 1.80	5.49 ± 1.60	0.0004[a]
Device malfunctions, % (n/total n)	5.1 (4/78)	5.6 (4/71)	>0.99[b]
Normal staple line: yes, % (n/total n)	93.6 (73/78)	91.5 (65/71)	0.63[b]
Distance from dentate to staple line, mm, mean ± SD	25.94 ± 8.23	24.00 ± 8.39	0.18[a]
Operative time, min, mean ± SD	25.4 ± 14.5	25.6 ± 13.2	0.91[a]
Length of hospital stay, h, mean ± SD	4.16 ± 6.17	4.37 ± 6.64	0.56[a]

[a]*P* values based on 2-sample *t*-test or Wilcoxon rank sum test.

[b]*P* value is based on χ^2 test or Fisher exact test.

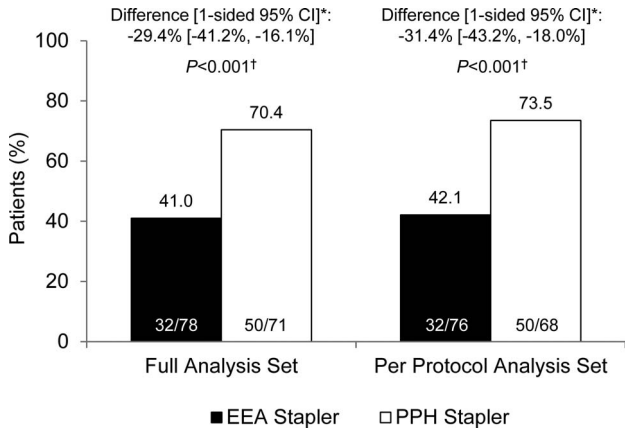

Fig. 2 Analysis of the primary end point, intraoperative bleeding requiring intervention. *EEA – PPH; noninferiority setting; confidence interval (CI) is based on the Newcombe generalized Wilson score method. †Superiority setting; *P* value is based on a 2-sided Pearson χ^2 test at an α level of 0.05.

significantly different between groups. There were no significant differences in SF-12 Physical Component or Mental Component Summary scores at any time point.

Device malfunctions, complications, and adverse events

Device malfunctions occurred in 4 patients in each treatment arm, including the following in the EEA and PPH arms, respectively: incomplete incision (1, 0); incomplete staple line (1, 4); broken pursestring (1, 1); and other (1, 0). Two device malfunctions occurred in 1 patient in the PPH arm. As a conservative estimate of the impact of the PPH device recall on the primary end point, analysis of intraoperative bleeding requiring intervention, excluding the 4 patients with device malfunctions in the PPH arm, superiority of the EEA device [32/78 (41.0%)] versus PPH [46/67 (68.7%); $P < 0.001$] was maintained.

Perioperative complications are shown in Table 4. There were no statistically significant differences between groups. The rate of perioperative hemorrhage was 9.9% in the EEA arm and 16.2% in the PPH arm ($P = 0.25$).

Adverse events were generally mild/moderate and similar between groups. Throughout the study period, the rates of rectal hemorrhage were 17.3% (n = 14, all mild) in the EEA arm and 27.9% (n = 17 mild, 2 moderate) in the PPH arm ($P = 0.07$). There were no severe rectal hemorrhage events in either arm. Serious adverse events were fecaloma (n = 1) and urinary retention (n = 1) in the EEA arm and proctalgia (n = 1), tooth abscess (n = 1), and procedural pain (n = 1) in the PPH arm.

Discussion

It has been estimated that more than 50% of the US population older than 50 years has experienced some form of hemorrhoid problem.[16] Dietary modification constitutes the first line of recommended therapy,

Table 3 Details of intraoperative bleeding (full analysis set)

	EEA (n = 78)	PPH (n = 71)	*P* value
Blood loss, mL, mean ± SD (n)	4.6 ± 5.7 (77)	7.0 ± 8.1 (71)	0.009[a]
Cause for intervention, % (n/total n)			<0.001[b]
None	59.0 (46/78)	29.6 (21/71)	
Preventative	10.3 (8/78)	12.7 (9/71)	
Treatment for active bleed	25.6 (20/78)	54.9 (39/71)	
Preventative and treatment for active bleed[c]	5.1 (4/78)	2.8 (2/71)	
Intervention type, % (n/total n)[d]			
Cautery	6.4 (5/78)	14.1 (10/71)	0.12[a]
Other	0.0 (0/78)	1.4 (1/71)	0.48[a]
Pressure	1.3 (1/78)	1.4 (1/71)	>0.99[a]
Sutures	35.9 (28/78)	66.2 (47/71)	<0.001[a]
Total intervention time, min, mean ± SD (n)[e]	8.2 ± 7.3 (32)	8.6 ± 6.1 (48)	0.38[a]
No. of hemostatic stitches, mean ± SD (n)[f]	4.0 ± 3.7 (28)	3.9 ± 3.8 (47)	0.70[a]

[a]*P* value is based on 2-sample *t*-test or Wilcoxon rank sum test to test for a difference in mean between treatments

[b]*P* value is based on χ^2 test to compare the cause for intervention between treatments.

[c]Includes patients treated for both active bleed and prophylactically.

[d]Some partients had more than one intervention type.

[e]In patients requiring intervention.

[f]Among patients requiring sutured intervention.

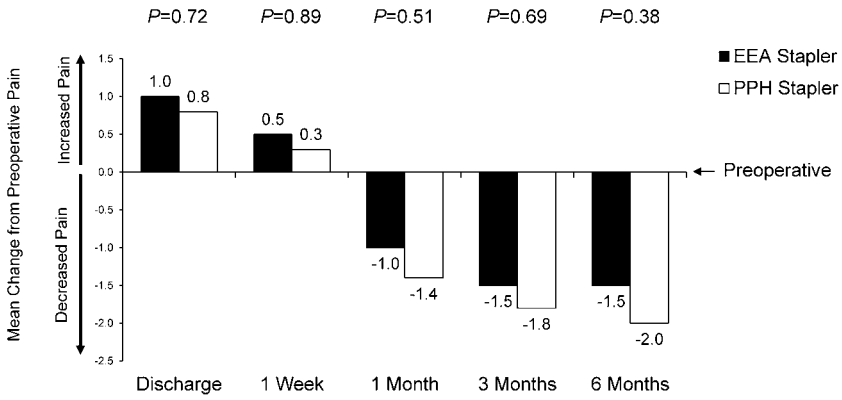

Fig. 3 PI-NRS. Mean change from baseline screening on a scale where 0 = no pain; 1 to 3 = mild pain (nagging, annoying, interfering with activities of daily living); 4 to 6 = mild pain (significantly interferes with activities of daily living); and 7 to 10 = severe pain (disabling, unable to perform activities of daily living). Data are presented as mean ± SD. There were no significant differences in preoperative pain between the EEA (2.0 ± 2.3) and PPH (2.1 ± 2.6) groups ($P = 0.90$).

followed by nonsurgical office-based procedures, such as banding, sclerotherapy, or infrared coagulation in patients who fail medical treatment.[3] Although rubber band ligation is an effective treatment with minimal pain when placed successfully,[17] it may require multiple procedures compared with surgical excision[18] and may be associated with greater pain compared with other nonsurgical modalities[19] if placement is not ideal. Surgical excision has been recommended as an effective treatment for patients with grade 3 hemorrhoids. Although traditional excisional hemorrhoidectomy has been associated with pain and bleeding,[3,19] recent advances, such as hemostatic sealing devices, have been developed to reduce pain and bleeding.[20]

SH may provide an alternative, more permanent solution than nonsurgical modalities[21]; however, staple line bleeding was a common complication and may have been a barrier to the earlier adoption of this technique.[6–8] The purpose of the current study was to determine whether a new hemorrhoidopexy stapler design could improve outcomes and potentially allow a greater acceptance of SH as an alternative treatment in patients who fail more conservative approaches.

Table 4 Perioperative complications (safety analysis set)

	EEA, % (n/total n)[a]	PPH, % (n/total n)[b]
Anal injury	0.0 (0/81)	1.5 (1/68)
Perioperative hemorrhage*	9.9 (8/81)	16.2 (11/68)
Incision site pruritus	1.2 (1/81)	0.0 (0/68)
Laceration	0.0 (0/81)	1.5 (1/68)
Procedural pain	0.0 (0/81)	1.5 (1/68)

[a]n = 81.

[b]n = 68.

*$P = 0.25$.

The current study compared two hemorrhoidopexy staplers (EEA and PPH03) in a multicenter 1:1 randomized design. This study achieved a statistically significant primary end point despite the recall of the PPH03 stapler prior to study completion. The rate of intraoperative bleeding requiring intervention was significantly lower with the EEA stapler (41.0%) compared with the PPH stapler (70.4%; $P < 0.001$). Treatment for active bleeding was also significantly lower in the EEA arm (30.8% versus 57.7%; $P < 0.001$). In addition, there were no significant differences between groups in postoperative pain or adverse event rates. Our study supports the findings of Giuratrabocchetta *et al*,[10] who compared the EEA and PPH staplers in patients with grade 3 hemorrhoids and reported better hemostatic outcomes with the EEA stapler, including fewer hemostatic overstitches required and no cases of postoperative bleeding in patients treated with the EEA stapler.[10]

The reduction in staple line bleeding with the EEA stapler may be due to the circular stapler design, which uses 32 staples in either 3.5-mm or 4.8-mm staple heights compared with the PPH stapler, which includes 28 staples in a single 4.0-mm staple height. The EEA device also demonstrated overall greater weight and volume of the extracted tissue, which is also consistent with the study by Giuratrabocchetta *et al*.[10] Larger tissue specimens with the EEA stapler may be related to the incorporation of a transparent anoscope that allows better visualization of the rectal anatomy and easier pursestring placement, as well as multiple center rod anchor points and a detachable anvil, which enable a consistent method of tissue incorporation and the ability to determine the proper amount of prolapse to resect prior to firing the circular stapler. In the context of hemorrhoid stapling procedures, the results of this study suggest

that the EEA stapler may provide reduced intraoperative bleeding and potentially greater adoption.

Prior studies have reported complications following SH. In a meta-analysis of 78 published articles including 14,232 patients, the most common complication was early bleeding, with rates ranging from 0% to 68%, although these rates were lower than those seen with other hemorrhoidectomy methods and were lower with second-generation compared with first-generation staplers. Other early complications included pain (rates ranging from 2.1% to 23.8%), early thrombosed external hemorrhoids (0%–13%), urinary retention (0%–22%), and fecal urgency (0%–25%). Late complications included bleeding (0.2%–33%), anal strictures and stenosis (0%–15.6%), incontinence (0.1%–17.8%), and fecal urgency (0%–25%).[22] Sepsis was reported in 16 cases (0.1%)[22] and death associated with rectal perforation and sepsis in 4 cases (0.03%) using a PPH stapler.[23,24] The primary end point rate of intraoperative bleeding requiring intervention with the EEA stapler in the current study (41%) is consistent with prior publications and lower than that observed with the PPH stapler.

Although our study enrolled symptomatic patients with grades 2 to 3 hemorrhoids, nonsurgical options are typically the first line of treatment in patients with grade 2 hemorrhoids. However, more aggressive options may be considered for patients who fail conservative measures or who, because of multiple rubber band treatments, patient preference, or physician recommendation, may prefer a more permanent approach. Furthermore, although the study was limited to patients with symptomatic grades 2 to 3 hemorrhoids that had failed conservative measures, use of the EEA and PPH staplers in grade 4 patients is not contraindicated. The EEA stapler has been designed to remove a larger specimen size, which may make it more suitable to manage grade 4 hemorrhoids. Outcomes of PPH stapler use in grade 4 patients have been reported.[14,25–28] In a cohort of 159 patients, Festen *et al*[25] reported no significant differences in recurrence of prolapse after PPH surgery between grades 2/3 (16.8%) and grade 4 (15.0%) patients, whereas in a series of 403 patients, Cosenza *et al*[28] noted recurrence rates of 3.7% in grade 3 patients and 1.7% in grade 4 patients.

Limitations

Results may have been impacted by limited investigator experience with the EEA stapler versus the PPH stapler. A 5-procedure minimum per device was required by the protocol. In addition, investigators were necessarily not blind to the treatment device. Although the reasons behind the voluntary recall of the PPH device may also have impacted our results, the superiority of the EEA device in reducing intraoperative bleeding was maintained even after excluding the 4 patients with device malfunctions in the PPH arm. Finally, although discontinuation of enrollment due to the recall of PPH would have impacted the statistical power, noninferiority and superiority of the EEA device relative to PPH was nevertheless achieved.

Conclusions

The advent of SH has offered surgeons and their patients a less painful alternative to excisional hemorrhoidectomy in the management of symptomatic hemorrhoids after conservative measures have failed. Staple line bleeding is often encountered with SH, requiring the placement of hemostatic sutures. The current study was undertaken to evaluate a new stapler design (EEA), and it demonstrated that the EEA stapler was significantly superior to the PPH03 stapler with regard to staple line bleeding and a reduced need for intervention to achieve hemostasis. In the future, larger randomized trials will help to elucidate the full spectrum of the safety and effectiveness of SH compared with alternative treatments.[29]

Acknowledgments

Study sponsorship, funding, and data analysis were provided by Covidien (Mansfield, Massachusetts). Medical writing and editorial support was provided by Kristin L. Hood, PhD, and John Hauschild of Covidien based on content and conclusions determined by the authors. Statistical analysis was provided by Ming Teng (Covidien). The authors thank the following investigators for participation in the study: William C. Wallace (South Orange Country Surgical Medical Group), Zuri Murrell (Cedars Sinai Medical Center), Michael Arvanitis (Monmouth Medical Center), Eddy Hsueh (St Louis University), Sandra Beck (University of Kentucky), Joseph Carmichael (University of California Irvine Medical Center), and Kirk Ludwig (Medical College of Wisconsin). This study was sponsored and funded by Covidien. All authors (or their institutions) received research support from Covidien to conduct this study. Nonmonetary medical writing and editing

support was provided by a medical writer employed by Covidien. In addition, Dr Marcet discloses receipt of lecture/speaker bureau fees unrelated to the submitted work from Covidien. An interim analysis of this study was presented as a poster at the American College of Surgeons 2012 Clinical Congress, Chicago, Illinois, September 30–October 4, 2012. Author contributions: substantial contributions to conception and design (J.M.); acquisition of data (J.M., A.F., D.E.R., J.E., H.T.P.); interpretation of data (J.M., A.F., D.E.R., J.E., H.T.P.); drafting the article (J.M.); critical revisions of the article (J.M., A.F., D.E.R., J.E., H.T.P.); final approval of the version to be published (J.M., A.F., D.E.R., J.E., H.T.P.).

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