Diseases of the Colon & Rectum

A Prospective, Randomized, Controlled Multicenter Trial Comparing Stapled Hemorrhoidopexy and Ferguson Hemorrhoidectomy: Perioperative and One-Year Results

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PURPOSE: There is a growing body of evidence supporting the lesser degrees of pain with stapled hemorrhoidopexy, also called the procedure for prolapse and hemorrhoids. However, there have been few randomized comparisons assessing both perioperative and long-term outcomes of the procedure for prolapse and hemorrhoids and Ferguson hemorrhoidectomy. Results are presented here from the first prospective, randomized, multicenter trial comparing these hemorrhoid procedures in the United States. METHODS: Patients with prolapsing hemorrhoids (Grade III) were randomized to undergo the procedure for prolapse and hemorrhoids or Ferguson hemorrhoidectomy by colorectal surgeons who had training in using the stapling technique. Primary end points were acute postoperative pain, and hemorrhoid symptom recurrence requiring additional treatment at one-year follow-up from surgery. RESULTS: A total of 156 patients (procedure for prolapse and hemorrhoids, 77; Ferguson, 79) completed randomization and the surgical procedure, 18 (procedure for prolapse and hemorrhoids, 12; Ferguson, 6) had significant protocol violations. One hundred seventeen patients (procedure for prolapse and hemorrhoids, 59; Ferguson, 58) returned for one-year follow-up. Demographic parameters, hemorrhoid symptoms, preoperative pain scores, and bowel habits were similar between groups. There were a similar number of patients with adverse events in each group (procedure for prolapse and hemorrhoids, 28 (36.4 percent) *vs*. Ferguson, 38 (48.1 percent); $P = 0.138$). Reoperation for an adverse effect was required in six (7.6 percent) Ferguson patients and in 0 patients having the procedure for prolapse and hemorrhoids ($P = 0.028$). Postoperative pain during the first 14 days, pain at first bowel movement, and need for postoperative analgesics were significantly less in the procedure for prolapse and hemorrhoids group. Control of hemorrhoid symptoms was similar between groups; however, sig-

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nificantly fewer patients having the procedure for prolapse and hemorrhoids required additional anorectal procedures during one-year follow-up (procedure for prolapse and hemorrhoids, 2 (2.6 percent), *vs*. Ferguson, 11 (13.9 percent); $P = 0.01$). Only four of the Ferguson patients (5 interventions) required additional procedures more than 30 days after surgery. CONCLUSIONS: These data demonstrate that stapled hemorrhoidopexy offers the benefits of less postoperative pain, less requirement for analgesics, and less pain at first bowel movement, while providing similar control of symptoms and need for additional hemorrhoid treatment at one-year follow-up from surgery. [Key words: Hemorrhoids; Hemorrhoidectomy; Stapled hemorrhoidopexy; Procedure for prolapsing hemorrhoids; Ferguson hemorrhoidectomy; Randomized controlled trial]

In 1998, Antonio Longo described a method by which prolapsing internal hemorrhoids could be surgically treated in a transanal fashion with a circular stapler, obviating the need for excision of either anoderm or perianal skin.[1] He postulated that hemorrhoidal symptoms were primarily related to prolapse of rectal mucosa and anoderm. The procedure for prolapsing hemorrhoids (PPH) resulted in simultaneous relocation and fixation of the internal hemorrhoids and anoderm. Disruption of the superior hemorrhoidal arteries may also decrease hemorrhoidal blood flow and further enhance symptom resolution and shrinkage of external hemorrhoids. These results were accomplished with significantly less postoperative pain than that with excisional hemorrhoidectomy.

There have been at least 16 randomized trials and a number of case series that have supported the concept that PPH causes less postoperative pain, allows an earlier return to normal activity, and reduces the requirement for analgesics compared with excisional hemorrhoidectomy.[2–19] However, only one trial was multicenter and all of the remaining studies had relatively small numbers of patients. In addition, none of the trials compared PPH with a closed hemorrhoidectomy performed in an outpatient setting as commonly practiced in the United States. Despite the lack of rigorous evidence-based analyses, approximately 350,000 PPH procedures have been performed worldwide according to Ethicon Endo-Surgery, Inc. (Cincinnati, OH). The purpose of this trial was to provide clinical data to support the use of the PPH over the Ferguson closed-wound surgical treatment of hemorrhoidal piles and/or mucosal prolapse, by showing at least a 50 percent reduction in postoperative pain within the first 14 days of follow-up and equivalence of incidence rate of recurrence symptoms over one year.

METHODS

Study Design

A prospective, randomized, parallel-group, multicenter trial was designed to compare PPH with Ferguson closed hemorrhoidectomy. Primary parameters evaluated included most intense pain score and recurrence of hemorrhoid symptoms. The most intense anorectal pain score was assessed at screening and postoperatively at Days 1, 3, 5, 7, and 14. Recurrence of hemorrhoidal symptoms was defined as postoperative bleeding, prolapse, fecal leakage, or mucus discharge assessed at 1, 6, and 12 months postoperatively. Secondary end points included use of analgesics, pain following first postoperative bowel movement (date and intensity), adverse events, frequency of urinary retention (defined as need for straight or indwelling catheterization), hospital admission duration, operative time, fecal impaction (defined as need for enema or manual disimpaction), and quality of life. Additional assessments included intraoperative subject position, skin tag excision, estimated blood loss, assessment of staple line, and requirement for additional hemorrhoid procedures during the follow-up period.

Seventeen centers contributed patients in the trial. Institutional Review Board approval was obtained at each of the participating sites. All primary investigators were required to complete a training program and a minimum of ten pilot PPH procedures before enrolling patients in the trial. Primary investigators were responsible for overseeing all PPH procedures at their institution.

Randomization to either PPH or Ferguson hemorrhoidectomy was determined immediately preoperatively by sequentially numbered sealed envelopes distributed by the sponsor statistician before initiation of the trial. The project was funded by Ethicon Endo-Surgery (Cincinnati, OH). Patients received stipends of $50 at the first month visit for the completion and return of the pain diary and $25 at both the 6-month and 12-month visits, to cover additional expenses incurred related to the follow-up visits and for incentive to return. No additional research costs were passed on to patient or insurer.

Patient Selection

Patients greater than 18 years old with Grade III (prolapsing, requiring manual reduction) internal hemorrhoids in at least three quadrants were eligible

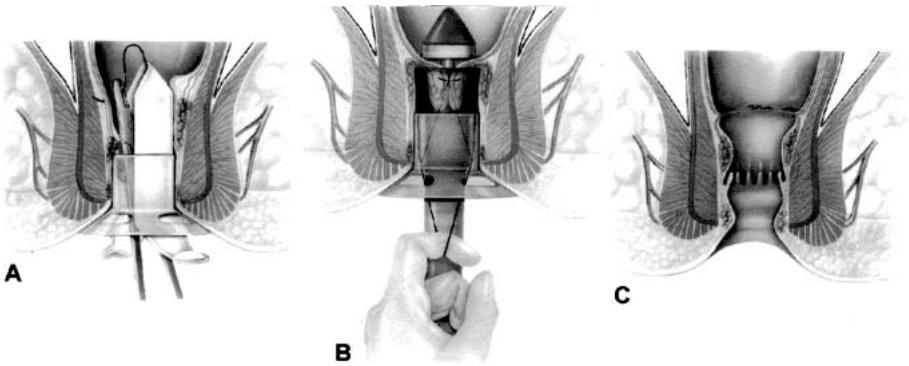


Figure 1. Stapled hemorrhoidopexy. A. The circular anal dilator and the pursestring suture anoscope have been inserted through the anus. The pursestring suture is being placed into the submucosa approximately 2 cm proximal to the apex of the internal hemorrhoids. B. The anvil of the stapler has been introduced across the pursestring suture and the suture has been tied around the shaft. Tension on the suture draws the prolapsing tissue into the head of the stapler. Note that the stapler incorporates the mucosa, submucosa, and only a small amount of hemorrhoidal tissue into the jaws. C. Postoperative appearance of the anus. Note that the staple line is well above the dentate line and that most of the internal hemorrhoidal tissue remains in the anal canal. (Illustrations reproduced with permission from Ethicon Endo-Surgery, Inc.)

for enrollment. External hemorrhoids or perianal skin tags were not exclusion criteria; however, irreducible or acutely thrombosed hemorrhoids were exclusion criteria. Patients with a history of colon, rectal, anal, or pelvic cancers were excluded, as were coagulopathic patients.

Operative Procedures

Anesthesia and perioperative care were provided according to the standard practice of each surgeon. All patients received a preemptive anal block with 15 to 20 cc of 1 percent lidocaine without epinephrine. Prophylactic antibiotics were not recommended. The PPH procedure has been previously standardized and is briefly described below.[2] The Proximate™ HCS Hemorrhoidal Circular Stapler PPH 01 (Ethicon Endo-Surgery) kit was used for all operations. The circular anoscope was inserted to reduce the prolapsing anoderm and allow placement of a circumferential polypropylene pursestring suture 4 cm proximal to the dentate line into the mucosa and submucosa (Fig. 1). In females, a digital vaginal examination was performed to confirm that the posterior vaginal wall was not incorporated into the pursestring suture. The pursestring suture was gently tightened around the shaft of the stapler. The suture threader ("hook") was used to pull the free ends of the suture through lateral channels of the stapler housing. The stapler was closed and advanced into the anal canal as traction was placed on the pursestring suture. Once positioned, the stapler was closed and fired. The staple line was inspected for bleeding and when present, 3-0 polyglycolic acid sutures were used to oversew bleeding. Concomitant anorectal procedures were performed as necessary on an individual basis. Surgeons were instructed not to excise perianal skin tags unless judged to be symptomatic.

Ferguson hemorrhoidectomies were completed according to the standard practice of each participating surgeon. This technique involves an hourglass-shaped excision of the entire internal/external hemorrhoidal complex (centered at the mid-portion of the anoderm), preservation of the internal and external anal sphincters, and primary closure of the entire wound. Occasionally, it is necessary to undermine flaps of anoderm and perianal skin to allow removal of intermediate hemorrhoidal tissue, while preserving the bridges of anoderm between pedicles.

Patient Surveys

A modified version of the validated brief pain inventory instrument (BPI; Pain Research Group, Department of Neurology, University of Wisconsin-Madison) was developed to assess pain at the screening visit and postoperative Days 1, 3, 5, 7, and 14. This survey instrument ascertained the location and intensity of pain, and degree to which pain had interfered with patients' ability to perform daily activities. Pain intensity was assessed *via* a (0, no pain to 10, worst pain) numeric scale for least and most intense pain. The survey was self-administered in the clinic preoperatively and through a home diary dur-

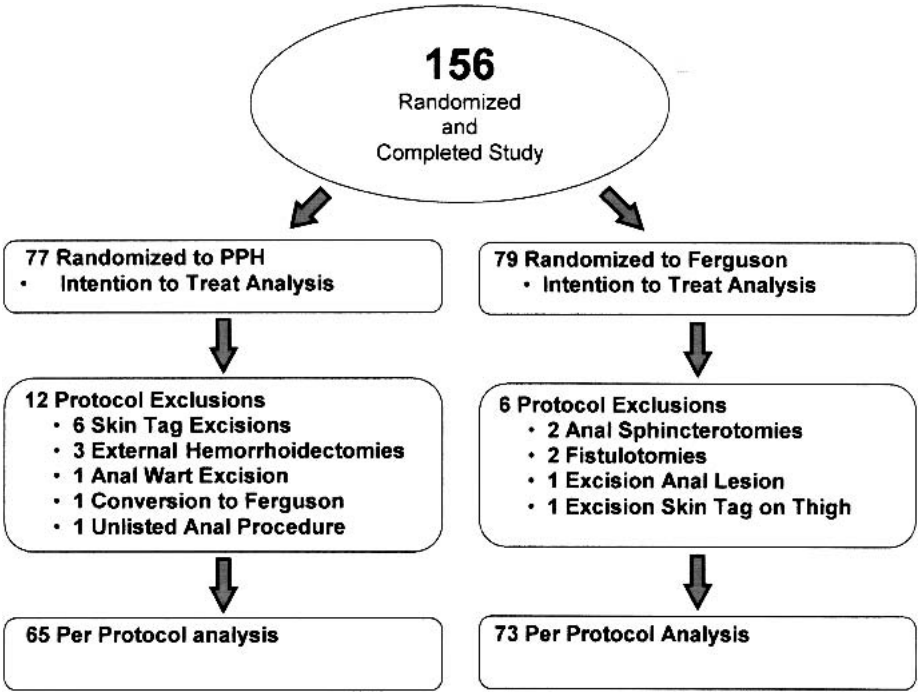


Figure 2. Allocation of patients. Intent-to-treat analysis includes all patients randomized and completing surgery. Per-protocol analysis includes only those patients completing the planned surgery according to their randomized grouping. Therefore, any patient with concomitant surgical procedures in addition to the procedure for prolapse and hemorrhoids (PPH) were not included in the per-protocol analysis.

ing the postoperative period. Patients were instructed to complete the survey in the morning, before taking pain medications. Pain following first bowel movement was assessed with the same numeric intensity scale and documented in the patient home diary.

The SF-12 version 1.0 (standard version) (QualityMetric Incorporated, Waltham, MA) was used at screening and one month postoperatively to assess patient quality of life.

The Fecal Impaction Questionnaire (FIQ)[20] was used to evaluate the number of bowel movements per week, need for suppositories, manual disimpaction, and straining with bowel movements. This was obtained at screening only.

Statistical Analysis

This was a randomized, parallel-group, comparison study with patients randomized in a 1:1 manner. Randomization schemes were generated separately for each site. Patient data were collected on case report forms. The data were monitored for accuracy and completeness. Double-data entry was implemented into a ClinTrial database version 4.2, where inconsistencies were identified. Sites were queried on inconsistent data and resolutions were provided. Following resolution of queries the data were transformed into SAS data sets for further validation and analysis (SAS version 8.2, SAS Institute Inc., Cary, NC). Statistical analysis was performed in SAS version 8.2, and graphs were generated from Microsoft Excel 2000 (Microsoft Corporation, Redmond, WA).

The short-term primary study parameter was most intense pain score as measured with a numeric intensity scale (0, no pain to 10, worst pain). The incidence rate of recurrence of those hemorrhoidal symptoms requiring additional treatments within one year of surgery was summarized. Sample size calculation was performed for the most intense pain score. Because of the lack of established multisite literature, study clinicians determined all estimates used in the sample size calculation.

The sample size required to detect a 50 percent reduction between groups in most intense pain score at any of the follow-up visits (Days 1, 3, 5, 7, or 14) was 110 patients. This assumed 95 percent power, mean pain scores of 6 and 3 for the Ferguson and PPH groups, respectively, and standard deviation of 4.32, for a two-sided test at 0.05 significance level with an analysis of variance model. Sample size calculation was performed by use of nQuery Advisor (Saugus, Massachusetts) 4.0. After assuming a 25 percent dropout rate, approximately 146 total patients were required to detect group differences if any existed. Because of logistical constraints, ten additional patients were added, randomized, and provided the pain diary. Therefore, 156 total patients were assessed for this study.

The intent-to-treat analysis population was considered the primary group for reporting of postoperative pain that was most intense, whereas a secondary group was those patients having the planned surgical procedure and designated as the per-protocol analysis population (Fig. 2). The primary study parameter analysis included analyzing the observed postoperative numeric pain score for most intense pain, and the change from baseline in scores for most intense pain was considered a secondary parameter. The goal of the study was to evaluate the percent difference in pain scores between groups within 14 days of surgery irrespective of any possible time effect. However, convergence of the acute measure of pain at a floor value of 0 was anticipated to provide a source of significant interaction between group and time because of the dependence on the last evaluation point in time, possibly resulting in a misleading statistically significant interaction effect. With the inappropriate applicability of a repeated-measures analysis of variance model to an acute-pain measure, the daily differences in pain provided more clinical relevance; however, independence of observations between visits was forfeited. Therefore, even though most intense pain score is a longitudinal expressed parameter, the primary analysis was performed using analysis of variance at each postoperative day (1, 3, 5, 7, and 14) with group as a fixed effect in the model. A repeated-measures analysis of variance model for most intense pain score was performed as a secondary analysis with group, postoperative day, and group-by-day interaction effects in the model. Other analyses consisted of one-way analysis of variance models for age,

Table 1.
Patient Participation

Characteristic	PPH n (%)	Ferguson n (%)
Randomized and completed surgery	77	79
Completed pain diary	65 (84)	74 (94)
Completed 1-year follow-up	59 (77)	58 (73)
Study completers	59 (77)	58 (73)
Discontinued	18 (23)	21 (27)
Lost to follow-up	17	18
Other	1	3

PPH = procedure for prolapse and hemorrhoids.

Table 2.
Patient Characteristics

Characteristic	PPH (N = 77)	Ferguson (N = 79)	*P* Value
Age (years)			
Mean (95% CIM)	51 (48, 54)	48 (46, 51)	0.131
Median	51	48	
Range	23–78	23–76	
Missing data	2	2	
Race			
Caucasian	49 (66%)	57 (74%)	0.715
Black	12 (16%)	10 (13%)	
Hispanic	10 (14%)	9 (12%)	
Asian	2 (3%)	1 (1%)	
Native American	1 (1%)	0	
Missing data	3	2	
Gender			
Male	49 (65%)	58 (75%)	0.177
Female	26 (35%)	19 (25%)	
Missing data	2	2	
Weight (lbs)			
Mean (95% CIM)	183 (174, 192)	181 (173, 189)	0.718
Median	186	182	
Range	119–315	111–293	
Missing data	2	3	
Height (inches)			
Mean (95% CIM)	67 (66, 68)	68 (67, 69)	0.131
Median	67	69	
Range	56–77	57–8	
Missing data	4	4	

CIM = confidence interval of mean; PPH = procedure for prolapse and hemorrhoids. Age, weight, and height were analyzed by use of a one-way analysis of variance model to test for differences among groups. Pearson's chi-squared test was used to test differences among groups for gender and race.

Table 3.
Preoperative Characteristics

Characteristic		PPH (N = 77)	Ferguson (N = 79)	*P* Value
Most intense pain score (0–10)				
Mean (95% CIM)		3.2 (2.4, 4.1)	2.5 (1.7, 3.2)	0.164
Median		3.0	1.0	
	Score			
No pain	0	28 (43%)	36 (49%)	0.201
Mild pain	1 to 3	6 (9%)	15 (20%)	
Moderate pain	4 to 6	18 (28%)	12 (16%)	
Severe pain	7 to 9	9 (14%)	9 (12%)	
Maximum pain	10	4 (6%)	2 (3%)	
Missing data		12	5	
Impaction: average bowel movements/week				0.479
1		3 (4%)	2 (3%)	
2		4 (6%)	8 (11%)	
≥3		66 (90%)	66 (86%)	
Missing data		4	3	
SF-12 v1.0 (mental component)		45.8	45.9	0.967
Mean (95% CIM)		(43.1, 48.6)	(43.8, 48.1)	
Median		51.6	48.7	
Missing all or some answers		4	3	0.368
SF-12 v1.0 (physical component)		52.1	53.5	
Mean (95% CIM)		(49.7, 54.5)	(51.6, 55.5)	
Median		56.4	56.6	
Missing all or some answers		4	3	
Hemorrhoid symptoms				
Hemorrhoidal prolapse		68 (88.3%)	66 (83.5%)	0.369
Bleeding		67 (87.0%)	65 (82.3%)	0.413
Mucus discharge		23 (29.9%)	23 (29.1%)	0.918
Fecal leakage		4 (5.2%)	11 (13.9%)	0.064

CIM = confidence interval of mean; PPH = procedure for prolapse and hemorrhoids. One-way analysis of variance models were used to analyze differences among groups for most intense pain score and SF-12 component analyses. The Mantel-Haenszel test was performed on the ordinal categories of pain scoring. Impaction and hemorrhoidal symptoms were analyzed with Pearson's chi-squared test.

weight, height, preoperative SF-12 version 1.0 mental and physical components, and score for pain intensity of first postoperative bowel movement (0, no pain to 10, worst pain). Analysis of variance assumptions were confirmed to be robust. A Mantel-Haenszel test implementing standardized mid-ranks was used to analyze most intense pain score in an ordinal manner (*i.e.,* no, mild, moderate, severe, maximum pain) between groups. The analysis of variance assumptions of equal variance and/or normality were violated for estimated blood loss, length of procedure, and number of days to first bowel movement; therefore, the Wilcoxon rank-sum test was performed. Pearson's chi-squared test was used to analyze the association between group and the categorical response parameters of race, gender, fecal impaction, preoperative hemorrhoid symptoms, hospital stay, operating position, additional concomitant surgical procedures, and incidence of adverse events when total frequency was at least ten. The Fisher's exact test was substituted for frequencies between five and less than ten; otherwise no test was performed. No inferential testing was performed on hemorrhoidal signs and symptoms until completion of this study end point for all patients enrolled. All inferential significance testing was performed assuming a two-sided test at a 0.05 significance level.

RESULTS

One hundred fifty-six (156) patients were operated on between April 2001 and December 2002. Short-term and long-term study results for these consented and randomized patients are shown in Figure 2. Only those patients completing the pain diary were considered for analysis.

From the pain cohort (77 PPH patients, 79 Ferguson patients), short-term pain data were obtained for 89 percent of the patients, and 117 (75 percent) patients completed the one-year follow-up visit. Thirty-nine discontinuations were recorded, with 90 percent of

Table 4.
Operative Characteristics

Characteristic	PPH (N = 77)	Ferguson (N = 79)	*P* Value
Subject operating position			
Prone	40 (54%)	42 (55%)	<0.001
Lithotomy	28 (38%)	12 (16%)	
Left side	3 (4%)	19 (24%)	
Other	1 (1%)	3 (4%)	
Combined	2 (3%)	1 (1%)	
Missing data	3	2	
Length of procedure (hours:minutes)			
Mean	0:31	0:35	0.054
Median	0:26	0:30	
Range	0:05–1:19	0:12–1:29	
Missing data	3	2	
Estimated blood loss (ml)			
Mean	26.4	46.9	0.016
Median	15.0	25.0	
Range	0–200	0–300	
Missing data	4	2	
Length of hospital stay (days)			
Outpatient	65 (88%)	63 (82%)	0.575
1	8 (11%)	12 (16%)	
2	1 (1%)	2 (2%)	
Missing data	3	2	

PPH = procedure for prolapse and hemorrhoids. Estimated blood loss and length of procedure were analyzed by means of Wilcoxon's rank-sum test. Pearson's chi-squared test was used to test differences among groups for length of hospital stay and subject operating position.

these being lost to follow-up. Table 1 illustrates the patient participation characteristics (Table 1). Figure 2 the allocation of patients. Patients were followed for one year in both groups.

Preoperatively, there were no significant differences with respect to age, race, gender, weight, height, preoperative pain, stool frequency, and hemorrhoid symptoms between the two treatment groups (Tables 2 and 3). Bleeding and prolapse were the most common symptoms, followed by mucus discharge and, rarely, fecal leakage.

A variety of operative positions were used by the surgeons, however, prone was most common for both Ferguson and PPH groups (Table 4). There were no significant differences in operating time between the groups (Table 4). Eighty-four percent (84 percent) of PPH procedures required hemostatic sutures to be placed at the staple line to address bleeding, although significantly less blood loss was estimated for the PPH patients. The large majority of procedures were performed on an outpatient basis, and there were no significant differences between groups in patients requiring hospitalization (Table 4).

The concomitant surgical procedures are detailed in Table 5. The most frequent concomitant procedure was perianal skin tag excision, which predominated in the Ferguson patients (9.1 percent PPH *vs.* 27.8 percent Ferguson; $P = 0.003$). Rubber band ligation was used as an adjunct in eight Ferguson patients, but no PPH patients underwent this (0 PPH *vs.* 10.1 percent Ferguson; $P = 0.007$). Three PPH patients (3.9 percent) required excisional external hemorrhoidectomies immediately following their PPH, based on the surgeon's judgment.

There was no significant difference between groups with respect to adverse events (36.4 percent PPH *vs.* 48.1 percent Ferguson; $P = 0.138$) (Table 6). No single complication was significantly more frequent in either group, with the exception of wound complications, which were more common in the Ferguson patients (0 PPH *vs.* 7.6 percent Ferguson; $P = 0.028$). A significantly greater number of Ferguson patients developed complications requiring a return to the operating room (0 PPH *vs.* 7.6 percent Ferguson; $P = 0.028$) during the immediate follow-up period. There were reports of temporary fecal incontinence in each group, all of which were resolved within one week and did not require treatment (3.9 percent PPH *vs.* 5.1 percent Ferguson; $P = 1.000$).

PPH patients had significantly less pain than Ferguson patients when measured as most intense pain (on days 1–14) or as change from baseline (on Days

Table 5.
Concomitant Surgical Procedures (at Time of Initial Surgery)

Event Classification	PPH (N = 77)	Ferguson (N = 79)	*P* Value
Patients with at least 1 concomitant surgical procedure	23 (29.9%)	40 (50.6%)	0.008
Skin tags excised	7 (9.1%)	22 (27.8%)	0.003
Colonoscopy	10 (13%)	8 (10.1%)	0.576
Sigmoidoscopy/proctoscopy	4 (5.2%)	6 (7.6%)	0.541
Rubber band ligation	0	8 (10.1%)	0.007
External hemorrhoidectomy	3 (3.9%)	0	
Anal sphincterotomy	0	2 (2.5%)	
Fistulotomy	0	2 (2.5%)	
Polypectomy	2 (2.6%)	0	
Converted to Ferguson	1 (1.3%)	0	
Excision anal lesion	0	1 (1.3%)	
Excision anal warts	1 (1.3%)	0	
Excision skin tag, right thigh	0	1 (1.3%)	
Fissurectomy	0	1 (1.3%)	

PPH = procedure for prolapse and hemorrhoids. Pearson's chi-squared tests were used when total count was ≥10. Fisher's exact test was used when total count was between five and less than ten, otherwise no inferential tests were performed.

Table 6.
Adverse Events

Event Classification	PPH (N = 77)	Ferguson (N = 79)	*P* Value
Patients with at least 1 adverse event	28 (36.4%)	38 (48.1%)	0.138
Patients requiring return to OR	0	6 (7.6%)	0.028
Urinary retention	10 (13.0%)	6 (7.6%)	0.267
Constipation	5 (6.5%)	12 (15.2%)	0.081
Postoperative hemorrhage	7 (9.1%)	4 (5.1%)	0.326
Dysuria/micturition disorder	2 (2.6%)	6 (7.6%)	0.276
Temporary fecal incontinence	3 (3.9%)	4 (5.1%)	1.000
Wound complication	0	6 (7.6%)	0.028
Perianal itching	3 (3.9%)	3 (3.8%)	1.000
Emesis/vomiting	2 (2.6%)	2 (2.5%)	
Fever	0	4 (5.1%)	
Procedure bleeding	0	3 (3.8%)	
Anal fissure	0	2 (2.5%)	
Anal stricture	2 (2.6%)	0	
Fistula-in-ano	0	2 (2.5%)	
Pruritus	0	2 (2.5%)	
Rectal pain	2 (2.6%)	0	
Abdominal distention	0	1 (1.3%)	
Abscess perianal	0	1 (1.3%)	
Chills	1 (1.3%)	0	
Fecal urgency	0	1 (1.3%)	
Perianal burning	1 (1.3%)	0	
Perianal inflammation	1 (1.3%)	0	
Postoperative wound infection	0	1 (1.3%)	
Temporary incontinence to flatus	0	1 (1.3%)	

OR = operating room; PPH = procedure for prolapse and hemorrhoids. Pearson's chi-squared tests were used when total count was ≥10. Fisher's exact test was used when total count was between five and less than ten, otherwise no inferential tests were performed.

1–7) (Figs. 3 and 4). In fact, the PPH patients' scores were improved over baseline by Day 7. However, group observed pain score profiles were not significantly different over the 14 postoperative days, as suggested in the repeated-measures model approach (P = 0.249). Finally, fewer patients required significantly less pain medication on Days 3 and 5 in the PPH group (Fig. 5). The addition of any concomitant surgical procedures did not significantly increase the pain scores in either the PPH or Ferguson groups (Fig. 6).

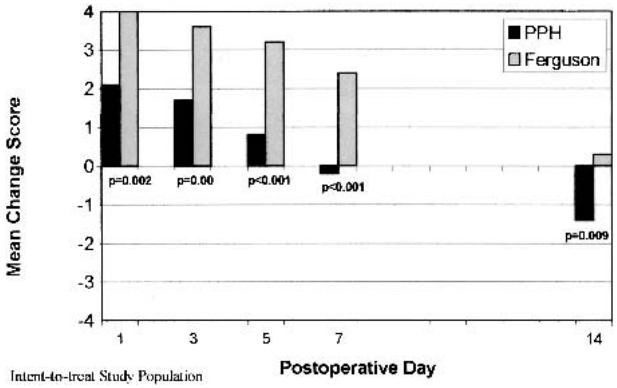


Figure 3. Mean most intense pain score (0, no pain to 10, worst pain) at baseline and on postoperative days. Graphically represented is the observed mean most intense pain score at each assessed day. Note that the pain following the procedure for prolapse and hemorrhoids (PPH) was significantly reduced at all postoperative days.

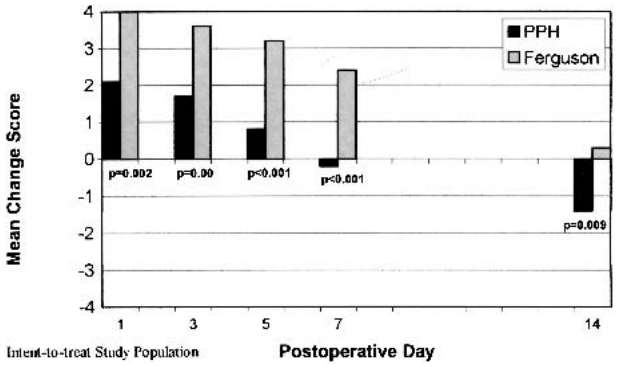


Figure 4. Mean change from baseline in most intense pain score (0, no pain to 10, worst pain) for each postoperative day. The change from baseline score represents the difference between the most intense pain score and the preoperative screening pain score for a given postoperative day. Change scores are plotted at each assessed postoperative day. PPH = procedure for prolapse and hemorrhoids.

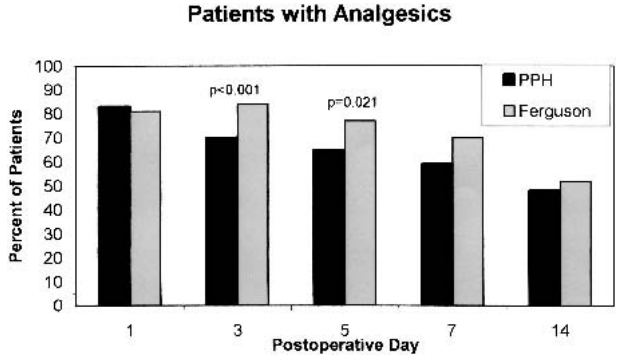


Figure 5. Percent of patients taking postoperative analgesics for pain relief. Note that significantly less patients undergoing the procedure for prolapse and hemorrhoids (PPH) were taking less medication for pain relief at postoperative Days 3 and 5.

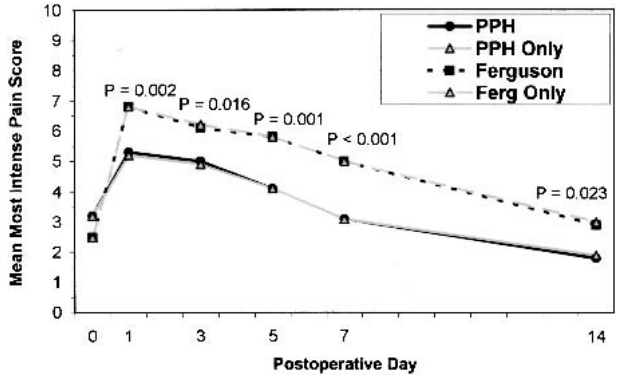


Figure 6. Comparison of mean most intense pain score (0, no pain to 10, worst pain) at baseline and postoperative day for intent-to-treat (ITT) and per-protocol populations. Graphically represented are mean most intense pain scores at baseline and each assessed postoperative day for ITT (procedure for prolapse and hemorrhoids (PPH) and Ferguson groups) and per-protocol populations (PPH and Ferguson only). Note the slight differences between ITT and per-protocol study populations, which excludes patients who underwent an additional perianal procedure. *P* values represent group differences for the per-protocol study population only.

The time until first bowel movement was shorter for PPH patients (1.4 days, PPH *vs.* 2.0 days, Ferguson; $P = 0.02$). In addition, the mean pain reported for the first bowel movement was significantly less for PPH patients (4.9, PPH *vs.* 6.6, Ferguson; $P = 0.003$), with 40 percent of PPH patients reporting no or mild pain at the first postoperative bowel movement *vs.* 17 percent of Ferguson patients (Table 7).

Table 8 details the additional procedures required by patients in each group at any time subsequent to the initial hemorrhoid operations, including treatment of immediate postoperative complications. The PPH patients required significantly fewer additional anorectal procedures than the Ferguson patients (2.6 percent PPH *vs.* 13.9 percent Ferguson; $P = 0.01$). Two PPH patients required rubber band ligation for control of hemorrhoid symptoms. None of the PPH patients required delayed excision of perianal skin tags within the first postoperative year. Eleven Ferguson patients required 12 procedures to address anorectal symptoms.

The index symptoms (bleeding, prolapse, soiling, leakage) were assessed at each postoperative visit. The number of patients reporting at least one symp-

Table 7.
First Postoperative Bowel Movement

Characteristic	PPH (N = 77)	Ferguson (N = 79)	*P* Value
No. of days to first movement			
Mean (95% CIM)	1.4 (1.0, 1.8)	2.0 (1.6, 2.5)	0.02
Median	1.0	2.0	
Maximum	9 days	8 days	
Missing data	8	14	
Pain intensity of movement (0–10)			
Mean (95% CIM)	4.9 (4.1, 5.8)	6.6 (5.9, 7.4)	0.003
Median	5.0	7.0	
	Score		
No pain	0	10 (15%)	1 (2%)
Mild pain	1 to 3	17 (25%)	10 (15%)
Moderate pain	4 to 6	12 (18%)	19 (29%)
Severe pain	7 to 9	21 (31%)	16 (25%)
Maximum pain	10	7 (10%)	19 (29%)
Missing data		10	14

CIM = confidence interval of mean; PPH = procedure for prolapse and hemorrhoids. One-way analysis of variance models were used to analyze differences among groups for pain intensity of movement score, whereas the Wilcoxon rank-sum test was used to analyze group differences in the number of days to first movement.

Table 8.
Additional Surgical Procedures (Posthemorrhoidectomy)

Event Classification	Total PPH (N = 77)	>30 Days Post Procedure Ferguson (N = 79)	*P* Value	PPH (N = 77)	Ferguson (N = 79)	*P* Value
Patients with at least 1 surgical procedure	2 (2.6%)	11 (13.9%)	0.010	2 (2.6%)	4 (5.1%)	0.681
Delay excision of perianal tags	0	2 (2.5%)		0	1 (1.3%)	
Examination under anesthesia	0	2 (2.5%)		0	1 (1.3%)	
Fistulotomy	0	2 (2.5%)		0	2 (2.5%)	
Rubber band ligation	2 (2.6%)	0		2 (2.6%)	0	
Anal sphincterotomy	0	1 (1.3%)		0	1 (1.3%)	
Cauterization of rectal bleed	0	1 (1.3%)		0	0	
Incision and drainage of perianal abscess	0	1 (1.3%)		0	0	
Ligation of bleeding vessel	0	1 (1.3%)		0	0	
Sigmoidoscopy/proctoscopy	0	2 (2.5%)		0	0	
Suture ligation of hemorrhoid pedice	0	1 (1.3%)		0	0	

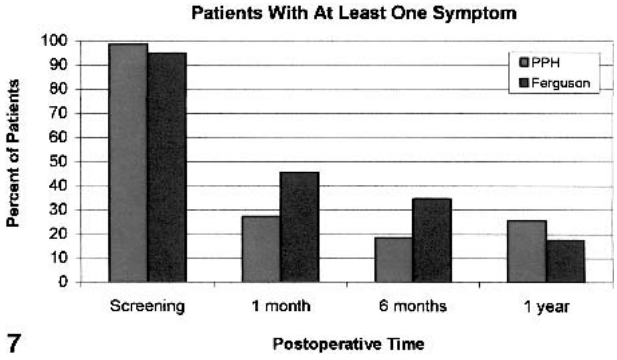
PPH = procedure for prolapse and hemorrhoids. Pearson's chi-squared tests were used when total count $\geq$10. Fisher's exact test was sued when total count was between five and less than ten, otherwise no inferential tests were performed.

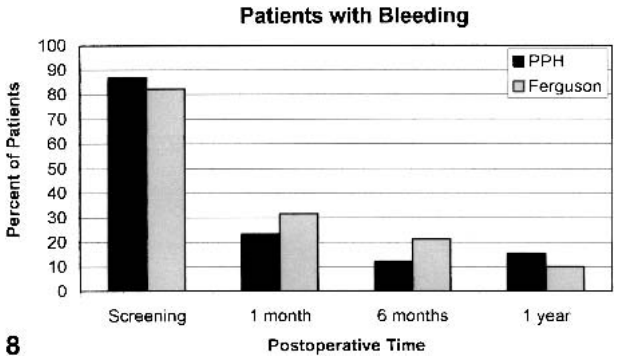
tom at each time period is reported in Figure 7. At one month postoperative, there were fewer symptomatic PPH patients; however, by one year this trend was reversed. The numbers of patients reporting each index symptom are illustrated in Figures 8 to 11. Finally, the patients reporting new onset or worsening intensity of index symptoms is demonstrated in Figure 12.

DISCUSSION

The safety and efficacy of the Ferguson hemorrhoidectomy are well defined, however, severity of postoperative pain is legendary. Patients avoid hemorrhoidectomy for many reasons, but primarily they avoid the notorious postoperative pain. The avoidance of surgery is confirmed by these data indicating that patients had significant pain and other anorectal symptoms for a mean of seven years.

The reported benefits of PPH have been primarily reductions in postoperative pain and shortened hospital stay. The latter is inconsequential in the United States because over 80 percent of patients in this trial were managed as outpatients. We confirmed a substantial reduction in maximum pain at each of the measured postoperative days, ranging from a 22 percent reduction on postoperative Day 1 to 38 percent





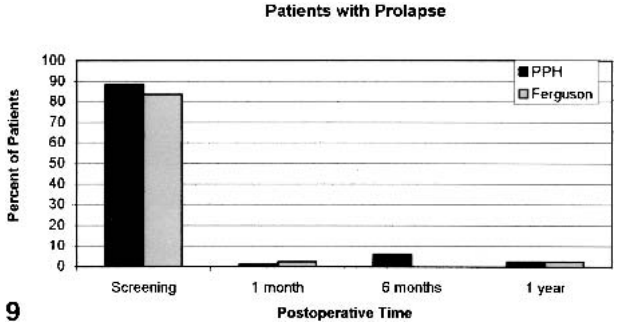
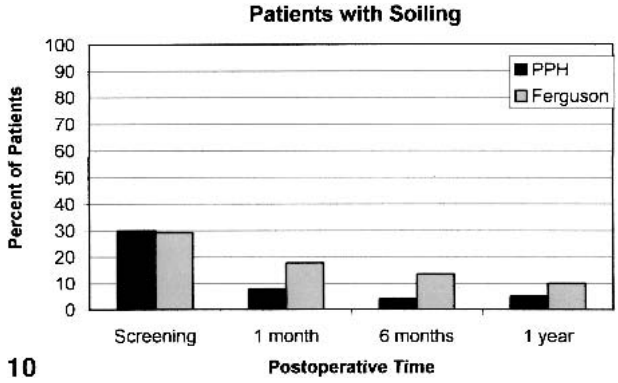
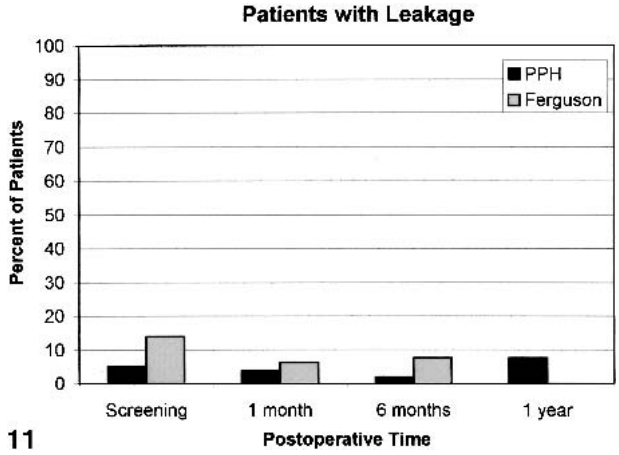


Figure 7. Postoperative symptoms. Shown is a graphical representation of the number of patients reporting at least one index symptom at each time point. PPH = procedure for prolapse and hemorrhoids.

Figure 8. Postoperative bleeding. Shown is a graphical representation of the number of patients reporting bleeding at each time point. PPH = procedure for prolapse and hemorrhoids.

Figure 9. Postoperative prolapse. Shown is a graphical representation of the number of patients reporting hemorrhoidal prolapse at each time point. PPH = procedure for prolapse and hemorrhoids.





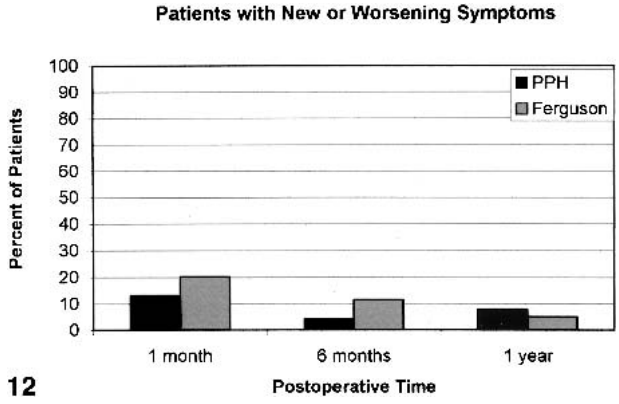


Figure 10. Postoperative soiling. Shown is a graphical representation of the number of patients reporting soiling at each time point. PPH = procedure for prolapse and hemorrhoids.

Figure 11. Postoperative leakage. Shown is a graphical representation of the number of patients reporting fecal leakage at each time point. PPH = procedure for prolapse and hemorrhoids.

Figure 12. Postoperative new or worsening symptoms. Shown is a graphical representation of the number of patients reporting new onset or worsening severity of index symptoms at each time point. PPH = procedure for prolapse and hemorrhoids.

reduction by Day 7. The average maximum pain reduction over the first 14 postoperative days was 29 percent.

An unexpected but interesting finding in this trial was the degree of preoperative pain reported by patients. Traditional surgical teaching dictates that hemorrhoids are painless unless thrombosed, strangulated, or gangrenous.[21,22] Thrombosis or strangulation

was the exclusion criterion and associated fissures were rare in both groups. Despite this, preoperative screening data obtained with a validated numeric intensity scale revealed significant pain symptoms that were equivalent between groups. It appears that surgeons may have greatly underestimated the degree to which the perianal skin becomes irritated by the chronic prolapse and inflammation of hemorrhoids. It is equally intriguing that the PPH group demonstrated less pain symptoms compared with baseline within a week of surgery, indicating effective and earlier symptom resolution with PPH.

Seven patients (3 PPH, 4 Ferguson) experienced temporary postoperative incontinence. Each instance lasted approximately one week and was self-limiting. This finding is consistent with other data that demonstrate a low incidence of sphincter damage with either technique. This type of temporary sphincter dysfunction may in fact be due to the dilation with the anoscope in addition to postoperative tissue edema and reduction in anal sensation. The most common complications in both groups were urinary retention and constipation, but these complications may be related more to the anesthetic and analgesic regimen than to postoperative pain severity.

Few patients experienced any of the major complications reported in the literature, such as rectovaginal fistulas,[23] pelvic sepsis,[24] rectal obstruction, retrorectal hematomas, and Fournier's gangrene,[25] rectal perforation (anal fissure in 2 Ferguson patients), retropneumoperitoneum, retropneumomediastinum,[26] persistent pain, or fecal urgency (1 Ferguson patient).[27] No patients experienced thrombosis of their external hemorrhoids after PPH, as suggested by Ho *et al.*[8] Excellent training of the surgeons, careful patient selection, attention to the rectovaginal septum, and careful pursestring suture placement can minimize the incidence of these technical complications. Staple line bleeding is a common occurrence with PPH; 84 percent or our patients required suturing of the staple line. However, none of the PPH patients required a return to the operating room for control of postoperative hemorrhage.

The benefit in reduced postoperative pain is primarily the result of the lack of operative trauma to the anoderm. However, several PPH patients in the trial underwent concomitant anorectal procedures involving perianal wounds such as skin tag excision, anal wart excision, or external hemorrhoidectomy. When these patients were excluded from the pain analysis, PPH without other anorectal procedures yielded an average of 30 percent pain reduction during the first two weeks (Fig. 6), only a 1 percent improvement. However, the benefits of reduced pain with PPH may be diminished by concomitant anorectal procedures. Symptomatic lesions such as fissures or fistulas must be addressed, but in general perianal skin tags and external hemorrhoids are best left untreated and reassessed at a later time. After restoration of the normal anatomy of the anal canal and disruption of the superior hemorrhoidal arteries, the external hemorrhoids and perianal skin tags tend to shrink in size and the large majority of patients will not request additional treatment. In fact, none of the PPH patients required a delayed excision of skin tags or external hemorrhoids.

Long-term performance of PPH was assessed by the incidence of hemorrhoidal symptoms and need for additional anorectal procedures. The percent of patients with persistent or recurrent symptoms was similar between groups at one year postoperatively (25.6 percent PPH *vs.* 17.5 percent Ferguson). The number of symptomatic patients was higher than expected but similar between groups. The severity of symptoms was also assessed, although patient perception of severity can be subjective and variable. Therefore, the requirement for additional anorectal procedures was also assessed as an objective measure of control of symptoms. The number of PPH patients requiring an additional anorectal procedure was significantly lower (2.6 percent PPH *vs.* 13.9 percent Ferguson; $P = 0.010$). This difference was largely because of the number of Ferguson patients requiring operative treatment of complications or persistent symptoms within the first 30 postoperative days. After 30 days, only four (5.1 percent) Ferguson patients and two (2.5 percent) PPH patients required additional treatment.

CONCLUSION

These data demonstrate that stapled hemorrhoidopexy offers the benefits of less postoperative pain, less requirement for analgesics, and less pain at first bowel movement, while providing similar control of symptoms and need for additional hemorrhoid treatment at one year.

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