

Randomized Prospective Trial Comparing Ileal Pouch–Anal Anastomosis Performed by Excising the Anal Mucosa to Ileal Pouch– Anal Anastomosis Performed by Preserving the Anal Mucosa

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Objective

The purpose of the study is to compare the results of ileal pouch–anal anastomosis (IPAA) in patients in whom the anal mucosa is excised by handsewn techniques to those in whom the mucosa is preserved using stapling techniques.

Summary Background Data

Ileal pouch–anal anastomosis is the operation of choice for patients with chronic ulcerative colitis requiring proctocolectomy. Controversy exists over whether preserving the transitional mucosa of the anal canal improves outcomes.

Methods

Forty-one patients (23 men, 18 women) were randomized to either endorectal mucosectomy and handsewn IPAA or to double-stapled IPAA, which spared the anal transition zone. All patients were diverted for 2 to 3 months. Nine patients were excluded. Preoperative functional status was assessed by questionnaire and anal manometry. Twenty-four patients underwent more extensive physiologic evaluation, including scintigraphic anopouch angle studies and pudendal nerve terminal motor latency a mean of 6 months after surgery. Quality of life similarly was estimated before surgery and after surgery. Univariate analysis using Wilcoxon test was used to assess differences between groups.

Results

The two groups were identical demographically. Overall outcomes in both groups were good. Thirty-three percent of patients who underwent the handsewn technique and 35% of patients who underwent the double-stapled technique experienced a postoperative

complication. Resting anal canal pressures were higher in the patients who underwent the stapled technique, but other physiologic parameters were similar between groups. Night-time fecal incontinence occurred less frequently in the stapled group but not significantly. The number of stools per 24 hours decreased from preoperative values in both groups. After IPAA, quality of life improved promptly in both groups.

Conclusions

Stapled IPAA, which preserves the mucosa of the anal transition zone, confers no apparent early advantage in terms of decreased stool frequency or fewer episodes of fecal incontinence compared to handsewn IPAA, which excises the mucosa. Higher resting pressures in the stapled group coupled with a trend toward less night-time incontinence, however, may portend better function in the stapled group over time. Both operations are safe and result in rapid and profound improvement in quality of life.

Surgery for patients for mucosal inflammatory bowel disease and adenomatous polyposis was changed radically in the 1980s when ileoanal anastomosis was rediscovered, perfected and applied widely. Indeed this operation, in any one of several forms, is now considered the procedure of choice when proctocolectomy is indicated for such patients.

Inevitably, operative techniques evolve and sometimes wholly change; ileoanal anastomosis is a good example of such an operation in evolution. This occurred and is occurring because the "perfect" ileoanal has not been achieved. There are several problems with the operation, including primarily anastomotic tension, which leads to strictures, fistulae, pelvic sepsis, and fecal incontinence. In addition, patients sometimes experience multiple stools and pouchitis.¹ Moreover, our standard operative approach—that is, endorectal mucosa resection and handsewn ileal pouch–anal anastomosis (IPAA)—has been found to be most applicable to patients who are young and thin.^{2,3} Principally because up to 50% of patients after endorectal mucosa resection and handsewn IPAA are incontinent of stools at night, a new operation was introduced: double-stapled ileal pouch–anal anastomosis.⁴ In this operation, the ileal pouch is stapled to the top of the anal canal, thus preserving the anal transition zone (ATZ). The hypothesis was that because the ATZ was innervated richly,⁵ by saving the ATZ, sensation would be improved and the frequency of incontinence lessened. Moreover, because the anal canal was pushed up to meet the pouch instead of pulled down and the pouch pulled through for anastomosis to the dentate line, IPAA might be facilitated in patients who would otherwise not be candidates for the operation because of body habitus.

Several studies reporting consecutive operations supported preserving the ATZ because the incidence of incontinence appeared to decrease,^{4,6–9} whereas two prospective randomized trials^{10,11} and one case–control study¹² comparing the operations found no difference. Our aim was to determine the clinical outcomes, in terms of stool frequency, incidence of fecal incontinence, rate of complication, and quality of life parameters, among patients with chronic ulcerative colitis randomized prospectively to undergo either endorectal mucosal excision of the ATZ and a handsewn IPAA or double-stapled IPAA in which the ATZ was preserved. Moreover, we wished to determine if pelvic floor function, determined by physiologic anopouch studies, correlated with outcomes.

MATERIALS AND METHODS

Patients

Forty-one patients with chronic ulcerative colitis were enrolled in the study after giving fully informed written consent to a protocol approved by the Institutional Review Board of the Mayo Clinic. Patients were enrolled between January 1992 and July 1994. Only one patient had undergone abdominal colectomy before IPAA. Because of the complexity of the protocol, most patients who were asked to enroll declined, leading to the prolonged time for accrual.

General Study Design

After enrollment, patients answered a detailed functional and quality of life questionnaire and then underwent anorectal manometry and testing for presence of the rectoanal sphincter inhibitory response. Patients were randomized the morning of surgery before the operation began. Within 6 months of closure of the temporary stoma, patients returned to the Mayo Clinic for physiologic testing, which included anorectal manometry, assessment of the rectoanal sphincter inhibitory response, determination

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of pelvic floor function using scintigraphic techniques for detecting movements of the anorectal angle and perineal descent, scintigraphic pouch evacuation efficiency, and pudendal nerve terminal motor latency. In addition, the clinical function and quality of life survey instrument was administered again.

Operations

All patients underwent abdominal colectomy, complete mobilization of the small bowel mesentery, and proximal rectal mobilization using a close rectal dissection technique.^{1,3} At this point, the patient underwent IPAA either by the surgeon excising the ATZ and handsewing the pouch to the anal canal or by the surgeon preserving the ATZ and double stapling the pouch to the anal canal. All patients had a diverting ileostomy constructed, which was closed between 2 to 3 months after IPAA.

Endorectal Mucosal Dissection, Excision of the Anal Transition Zone, and Handsewn Ileal Pouch–Anal Anastomosis

The most distal 25 to 30 cm of the terminal ileum was used to construct the J-pouch. Enterotomies were made 5 cm proximal to the intended apex of the pouch and a linear stapler fired toward the apex. The terminal ileal bridge was transected by the stapler. Finally, the linear stapler was fired retrograde, thus completing construction of the pouch. The anterior enterotomy was closed in two layers, and the posterior staple line was inspected for any potential defects and reinforced if necessary. An endoanal mucosal resection of the ATZ was performed using the Lone Star retractor (Lone Star Medical Products Incorporated, Houston, TX) to help eliminate unnecessary anal dilatation. Mucosal resection commenced at the dentate line and extended approximately 4 to 6 cm (Fig. 1). The denuded rectal muscularis then was transected and the specimen removed. The muscular sleeve remaining after mucosal excision consisted of the internal sphincter and perhaps 1 to 2 cm of rectal muscularis. The pouch was pulled through the pelvic floor into the anal canal and anchored to the puborectal muscle. The anastomosis was constructed next using full-thickness sutures of interrupted absorbable suture. The pelvis was drained abdominally. The diverting ileostomy was constructed between 25 and 40 cm proximal to the pouch.

Preservation of the Anal Transition Zone and Double-Stapled Ileal Pouch–Anal Anastomosis

The terminal 25 to 30 cm was used to construct the J-pouch using an apical enterotomy technique. An entero-

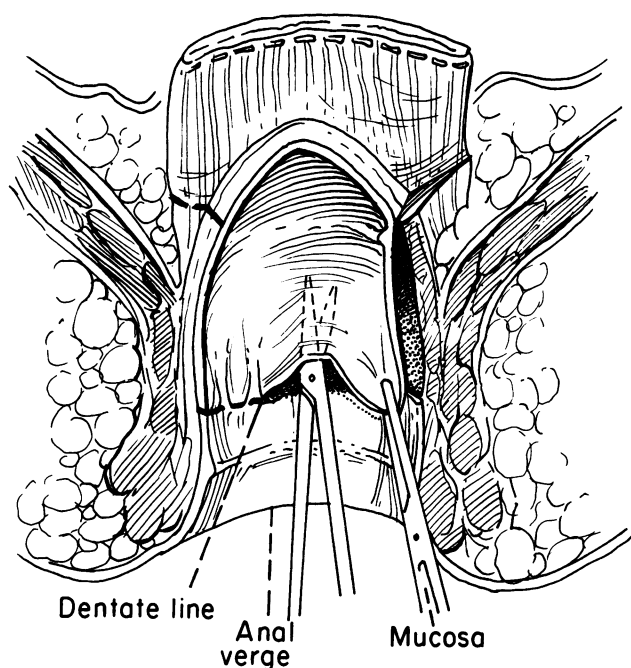


Figure 1. Endoanal resection of the anal transition zone. The dissection begins at the dentate line and the mucosa of the anal transition zone and distal-most rectum is elevated from the underlying internal anal sphincter and rectal muscularis sharply for a distance of 3 to 4 cm. The pouch is advanced through the cuff and anastomosed by hand to the level of the dentate line. Reprinted with permission from Butterworth-Heinemann Limited, Dozois RR. Ileal 'J' Pouch–Anal Anastomosis. *Br J. Surg* 1985;72:S80–S82.

tomy was made at the intended apex of the J, the long linear stapler introduced and fired once, creating a pouch approximately 12 to 15 cm in length. The head of the circular stapling instrument was inserted into the enterotomy and secured in place using a purse string suture. The TA30 instrument (Ethicon Instruments, Cincinnati, OH) was positioned 2 to 3 cm above the dentate line. The level of the instrument above the dentate was measured visually. The stapler then was fired and the specimen removed. The circular stapler was inserted transanally and the trocar advanced through just posterior to the transverse staple line at the top of the anal canal. The head and anvil were mated and the instrument fired (Fig. 2). Both tissue donuts were inspected. Poststapling air insufflation was performed to determine the integrity of the anastomosis. Once again, a defunctioning ileostomy was constructed as in the handsewn group and the pelvis drained abdominally.

Follow-Up

All complications were recorded. Ileostomies were closed a median of 2.6 months (range, 1.6 to 10 months) after IPAA. Stomas were closed either by unfolding the stoma and closing the resulting anterior defect in two

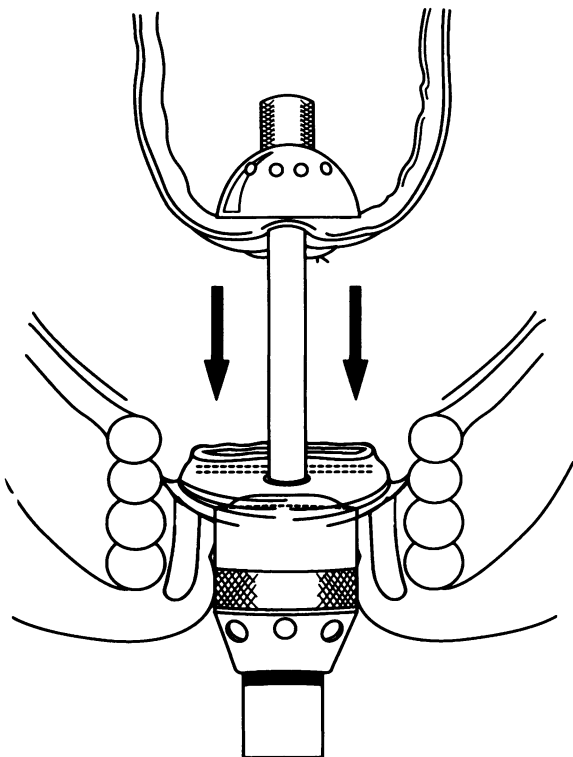


Figure 2. Double-stapled ileal pouch–anal anastomosis. The cross-staple line is actually at the level of the anorectal ring at the top of the anal canal. After opposing the head and anvil, the stapler is fired, leaving the anal transition zone intact for a distance of 1 to 2 cm above the dentate line. (Reprinted with permission from Sagar PM, Pemberton JH. The role of the ileal pouch procedure: pouch construction, the ileoanal anastomosis and complications. In: Allan RN, Keighley MRB, Alexander-Williams J, Fazio VW, Hanauer SB, and Rhodes JM, eds. *Inflammatory Bowel Disease*. 3rd ed. Churchill Livingstone; 1997.)

layers or resecting the stoma entirely and constructing an end-to-end ileostomy in two layers. A mean of 7.5 months (range, 3.9–14.3 months) after closure of the ostomy, patients returned for assessment of functional status and physiologic testing. The quality of life instrument also was readministered.

Physiologic Studies

Anal Manometry and Determination of the Rectoanal Sphincter Inhibitory Response

Perfused, eight-channel anopouch manometry was performed. A stationed pull-through technique was used assessing simultaneous circumferential pressures at 0.5-cm interval from the anal verge to 6 cm above the verge. Maximum average resting and squeeze pressures were analyzed for comparison between groups.

Rectoanal Sphincter Inhibitory Response

The presence or absence of the rectoanal sphincter inhibitory response was assessed at the completion of anal

manometry. The manometry ports were positioned in the high pressure zone of the anal canal during rapid insufflation and desufflation of an intrarectal pouch balloon. The balloon volumes were increased at 15-mL increments until a response was recorded or 60 mL of air was used. The presence of a reflex was documented by real-time depression of anal canal pressures as visualized on a pressure monitor screen.

Scintigraphic Analysis of Pelvic Floor Anatomy and Neorectal Function

Movement of the anorectal and anopouch angles,¹³ perineal descent, and defecation efficiency¹⁴ were determined using scintigraphic techniques described in detail elsewhere. These techniques provided a simple and reproducible methodology to visualize pelvic floor and pouch function with almost no radiation exposure.

In brief, the anopouch angle was determined using a 20-cm cylindrical latex balloon of low compliance, which was inserted transanally into the ileal pouch.¹³ Inside the balloon was a fenestrated 14-French rubber catheter. Technetium (5 Mci) and technetium pertechnetate (15 Mci) were injected into the balloon. Radioactive markers were positioned on the skin over the pubis and the tip of the coccyx. In the lateral decubitus position, lateral images then were made of the patient's anorectal angle at rest and during efforts of maximum anal squeeze and efforts to defecate. These maneuvers were performed while the balloon was held in position by a technician. Next, the line between the two markers was used as a reference point for determination of perineal position at rest, squeeze, and during a Valsalva maneuver. Perineal descent was defined as the difference between the position of the anorectal angle relative to the pubococcygeal line, at rest, and during Valsalva maneuver. After this portion of the study, the balloon was emptied and the catheter removed.

Artificial stool (aluminum magnesium silicate; Vee-gum–Ruger Chemical, Irvington, NJ), radiolabeled with technetium 99m, with the consistency of porridge was infused into the ileal pouch.¹⁴ Volumes were infused to the point of a persistent urge to defecate. After repositioning the patient onto a commode, lateral views were used to scintigraphically measure the amount of counts present in the pouch. The patient was asked to evacuate the material into a commode during dynamic scanning. Patients were scanned, in a private setting, for 5 minutes to allow completeness of emptying. The percent decrease in pouch volume from the beginning of evacuation to the end was interpreted as evacuation efficiency.

Pudendal Nerve Terminal Motor Latency

Pudendal nerve terminal motor latency, as described by Kiff and Swash,¹⁵ determines integrity of the pudendal

nerve, which innervates the external anal sphincter. Neuropraxic injury to the pudendal nerve is a vexing cause of fecal incontinence, and we wished to determine if a neuropraxic injury occurred after either handsewn or stapled IPAA. Briefly, an electrode glove is used to both stimulate the pudendal nerve at its exit from the pudendal canal using stimulating electrodes at the tip of the glove and to record arrival of the signal in the anal canal using receiving electrodes located at the base of the glove. Bilateral stimulation was performed and the latency of the external anal sphincter response expressed in milliseconds.

Questionnaire

Quality of Life and Functional Results

We used a standardized instrument that has been used for preoperative and repeated postoperative assessment of patients undergoing IPAA for the past 15 years.^{1,16,17} Questionnaires assessed continence and bowel habits as well as the ability to perform activities of daily living, sports, and other recreational activities. These questionnaires were administered before surgery and after surgery. Comparison of the preoperative and postoperative results was performed to detect any differences in the subjective and functional characteristics of the patients after IPAA.

Part of the questionnaire evaluation included a scaled determination of the effect of bowel disease on the performance of activities of daily living. Scores were recorded by the patients for social activities, sports, work around the home, recreation, family relationships, sexual life, and travel. The impact of colitis on these activities before surgery and the effect of IPAA at follow-up was determined for each category. Scores were assigned as follows: 1, severely restricted performance; 2, moderately restricted; 3, mildly restricted; 4, not affected; and 5, improved performance. A mean score was used to compare the preoperative and postoperative results and to measure the difference in the preoperative and postoperative change between groups.

Statistical Analysis

The data collected on symptoms, functional and physiologic responses, and patient satisfaction with activities of daily living were summarized by treatment groups. The formal statistical comparison of treatments was based on an "intent to treat" paradigm, in which patients were compared based on their randomized treatment assignment. For discrete categorical variables, Fisher's exact test (or its extension) was used, whereas quantitative responses were compared using the Wilcoxon rank-sum test. For descriptive purposes, the actual treatment re-

Table 1. PROTOCOL EXCLUSIONS

Problem	No. of Patients
Technical difficulties with pouch construction or anastomosis	5
Crohn's disease diagnosed intraoperatively; IPAA abandoned	2
Carcinoma	1
Patient withdrawal; randomization but before IPAA	1

IPAA = ileal pouch-anal anastomosis.

ceived was used. The data were summarized as mean \pm standard error unless otherwise noted. A two-sided α -level of 0.05 was used for statistical comparisons.

RESULTS

Patient Groups

Forty-one patients enrolled in the protocol. Nine patients were excluded after randomization for reasons listed in Table 1, leaving 32 patients for evaluation. One additional patient was randomized to mucosectomy, but because of intraoperative difficulties, a stapled ileoanal anastomosis was performed instead (Table 1). This patient was kept in the handsewn group because the analysis we performed was an intention to treat analysis.

Fifteen patients were randomized to the handsewn ileoanal anastomosis (9 men and 6 women). The mean age was 40 and one patient had had a previous operation to remove the abdominal colon. Seventeen patients were randomized to double-stapled ileoanal anastomosis, 9 men and 8 women, and the mean age was 36 years. No patient had a previous operation for chronic ulcerative colitis.

Operative Factors

Operating time (*i.e.*, skin open to skin closed) for ATZ excision and handsewn IPAA was 4 hours \pm 41 minutes (standard deviation), whereas for ATZ preservation and double-stapled IPAA, operating time was 4 hours \pm 60 minutes. The median level of the IPAA in the handsewn group was the dentate line, whereas in the stapled group, the median level was 1.5 cm above the dentate line (range, 0–3 cm).

Postoperative Complications

Thirty-three percent of the patients who underwent handsewn IPAA experienced a postoperative complication,

Table 2. POSTOPERATIVE COMPLICATIONS

Handsewn IPAA (n = 15)	Double-Stapled IPAA (n = 17)
Leak from ileostomy closure, reclosed	Pelvic abscess
IPAA leak, sinus, delayed closure	Leak from ileostomy closure, reclosed
Small bowel obstruction, required diversion	Small bowel obstruction, nonoperative management (2 patients)
Pancreatitis	Pancreatitis
Urinary retention	Mesenteric vein thrombosis

IPAA = Ileal pouch–anal anastomosis.

whereas 35% of the patients who underwent double-stapled IPAA experienced a complication (Table 2).

Clinical Function

The median time to closure of the ileostomy in the handsewn group was 2.7 months (range, 1.9–10 months), whereas in the double-stapled group, the median time was 2.6 months (range, 1.6–7.4 months). All but one patient (handsewn group) were observed and available for assessment of functional outcome (Table 3).

Stool Frequency

Before surgery, the mean (\pm standard deviation) number of stools in 24 hours was ten \pm three in the groups of patients randomized subsequently to handsewn IPAA and ten \pm four in the stapled group. After surgery, the mean number of stools during the day did not differ between groups (handsewn, 7 \pm 3 vs. stapled, 7 \pm 4). Night-time stool frequency likewise was the same (handsewn, 2 \pm 2 vs. stapled, 1 \pm 1).

Fecal Incontinence

Before IPAA, a total of 78% of patients overall experienced episodes of fecal incontinence (Table 3). In those patients who subsequently had a handsewn IPAA, 92% experienced either occasional or frequent episodes of incontinence, whereas among those patients who subsequently underwent a double-stapled IPAA, 66% had episodes of fecal incontinence. The incidence of postoperative episodes of fecal incontinence is listed in Table 3. There was a distinct trend toward more fecal incontinence in the handsewn group during the day and night—nearly double the incidence—but statistical significance was not reached.

Other Outcome Parameters

Stool consistency, incidence of perianal irritation, use of hypomotility and stool bulking, use of pads, and the ability to differentiate gas from stool did not differ between groups (Table 4).

Sexual dysfunction was rather common in our patients before surgery; fully 60% of patients who subsequently were to undergo handsewn IPAA and 40% who were to undergo stapled IPAA reported diminished or absent sexual function. There was striking improvement after surgery in both groups. The low incidence of pouchitis was expected because the follow-up period was short.

Anal Physiology

Anal Canal Resting Pressure

Patients who underwent handsewn IPAA experienced a drop in resting pressure compared with that of preopera-

Table 3. PREOPERATIVE AND POSTOPERATIVE STOOL FREQUENCY AND FECAL INCONTINENCE

Parameter	Handsewn	Double-Stapled
Stool frequency		
Before IPAA		
Number of stools/24 hr		
Mean \pm SD	10 \pm 3	10 \pm 4
Median (IQR)	10 [8; 12]	10 [6; 12]
After IPAA		
Number of stools during		
Day		
Mean \pm SD	7 \pm 4	7 \pm 3
Median (IQR)	6 (5; 9)	6 (4; 8)
Night		
Mean \pm SD	1 \pm 1	2 \pm 2
Median (IQR)	1 (1; 2)	1 (1; 1)
Fecal incontinence		
Before IPAA (% of patients)		
Never	8	33
Occasional (\leq 1/week)	61	40
Frequent (\geq 2/week)	31	27
After IPAA (% of patients)		
Day		
Never	77	84
Occasional	15	8
Frequent	8	8
Night		
Never	36	62
Occasional	50	30
Frequent	14	8

IPAA = Ileal pouch–anal anastomosis; SD = standard deviation; IQR = interquartile range.

Table 4. OTHER PARAMETERS OF FUNCTION AFTER IPAA

Parameter	Handsewn		Double-Stapled	
Stool consistency (liquid/semi-solid/solid)	23/54/23		0/92/8	
Perianal irritation (% yes)	27		35	
Hypomotility agents and/or stool bulking agents (% yes)	64		43	
Wear a pad? (% yes)	7		26	
Differentiate stool from gas? (% yes)	64		79	
Pouchitis (%)	7		14	
	Sexual Function			
	Before IPAA		After IPAA	
	Handsewn	Stapled	Handsewn	Stapled
Sexual problems (% yes)	66	40	0	7

IPAA = Ileal pouch–anal anastomosis.

tive values, whereas the patients who underwent double-stapled IPAA did not (Table 5).

Anal Canal Squeeze Pressure

Although the patients who underwent the stapled procedure had an increase in maximum squeeze pressure, the patients who underwent the handsewn procedure experienced a drop in pressure. This change reached the 0.06 level of significance. The pouch–anal sphincter inhibitory response was found in one patient who underwent the double-stapled IPAA and in no patients who underwent the handsewn IPAA.

Scintigraphic Studies

Anorectal Angle

Movements of the anopouch angle were appropriate and did not differ between groups; that is, the anorectal angle sharpened with squeezing and widened with straining. Moreover, the absolute values for resting, squeeze, and defecation angles and differences between them do not appear to differ substantially from historic controls.¹³ The magnitude of change in the angle similarly was not different among groups or from historic controls.¹³

Perineal Descent

Descent of the perineum was not hindered by either a handsewn or a double-stapled technique. Moreover, the absolute values for descent in these patients did not differ from historic controls reported previously.¹³

Efficiency of Evacuation

Although less than occurs in control subjects,¹⁴ patients from both groups evacuated the pouch efficiently.

Pudendal Nerve Terminal Motor Latency

Pudendal nerve terminal motor latencies approximated latencies reported in the literature¹⁸ and did not differ between groups.

Quality of Life

Answers to a quality of life questionnaire, designed to elicit the status of patients' experience with daily living, are detailed in Table 6. Before surgery, the mean score in patients who subsequently underwent handsewn IPAA did not differ from those recorded by subjects who subsequently underwent a double-stapled IPAA. The preoperative median score of 2.4 (range, 1–3.9) in the handsewn group and 2.3 (range, 1–3.6) in the double-stapled group was not different and was quite low, showing a restricted lifestyle in all the patients. After surgery, both groups of patients (handsewn and double-stapled) reported a significantly increased score, the median of which approximated 5 (range, 1–4.9) in the patients in the stapled group and 4 (range, 1–5) in the patients in the handsewn group. Ileal pouch–anal anastomosis clearly improved the daily living score in both groups.

DISCUSSION

We found that double-stapled IPAA and handsewn IPAA differed little in their capacity to improve the quality of life, decrease stool frequency, and return patients with ulcerative colitis to an active lifestyle promptly. These results support and extend results reported previously but in the setting of a randomized prospective trial.^{1,16,17} Because the groups were small, differences between operations, primarily in terms of stool frequency

Table 5. PHYSIOLOGIC RESULTS

	No. of Subjects		Result		p Value
	Handsewn	Stapled	Handsewn	Stapled	
Patient groups	15	17			
Anal manometry					
Maximum resting pressure (mmHg)					
Preoperative	15	15	87.7 ± 17.1	92.6 ± 20.1	0.56
Postoperative	12	12	49.4 ± 18.5	78.3 ± 24.5	0.004*
Maximum average squeeze pressure (mmHg)					
Preoperative	15	15	171 ± 37.0	184 ± 53.4	0.74
Postoperative	12	12	144 ± 44.1	195 ± 63.5	0.06
Scintigraphic studies					
Pouch angle (°)	10	11	129 ± 18.1	126 ± 19.3	0.62
Rest (°)	10	11	116 ± 14.3	119 ± 21.7	0.97
Squeeze (°)	10	11	130 ± 14.0	135 ± 19.3	0.48
Push (defecation attempt) (°)	10	11	-2.3 ± 23.9	-9.27 ± 9.0	0.77
Angle change (rest to push) (°)	10	11	2.04 ± 1.70	1.93 ± 1.7	0.72
Perineal descent (cm) (°)	10	12	60.0 ± 19.8	56.1 ± 18.0	0.70
Defecation efficiency (%)	12				
Pudendal nerve terminal motor latency (ms)					
Right	12	12	1.86 ± 0.37	2.08 ± 1.19	0.93
Left	11	11	1.87 ± 0.33	1.54 ± 0.58	0.34

*p < 0.05. All ± SD.

and fecal incontinence, were difficult to find. Nonetheless, differences in resting and squeeze pressures seem to point toward a more perilous postoperative physiologic environment for the patients who underwent the handsewn procedure *versus* patients who underwent the double-stapled procedure. Clearly the double-stapled group experienced less fecal incontinence as measured by the questionnaire. This difference is likely of biologic significance to the patients, but did not achieve statistical significance.

This study did not lay to rest the arguments that patients who undergo the double-stapled procedure “do better” than do patients who undergo the handsewn procedure. We and others^{1,3,12,19–22} have reported stool frequencies, rates of fecal incontinence, and rates of postoperative

complications that appeared to differ hardly at all from others reporting their results of double-stapled operations.^{4,7,8,23} It is sometimes instructive to note frequency of stools, frequency of incontinence, and rate of complications reported from several centers; in some reports, the results for handsewn IPAA were quite marginal and were indeed improved remarkably when the double-stapled technique was instituted. One reason we and others find little difference between operations may be that results of handsewn IPAA are good and have proved to be durable.

Double-stapling is only the latest in a series of technical innovations of the IPAA operation spurred by a desire to decrease complications and improve function. For instance, adding a pouch to the ileoanal operation (as first described by Ravitch and Sabiston²⁴) significantly improved outcomes.^{19,25} Shortening the rectal muscular cuff shortened operative time and decreased the rate of pelvic sepsis,²⁶ and the addition of a W-pouch may indeed decrease the number of stools that occur each day.^{21,27} When double-stapling was introduced by Johnston et al.,⁴ the hypothesis was that by preserving the ATZ, fecal incontinence would improve. This indeed did seem to be the case in theirs⁴ and several other series.^{7,8,23,28} The problem was that the evidence for such improved function may have relied not only on double-stapling, but may have occurred because patients were not randomized and differences in operative experience, learning curve, case selection, and excessive dilatation of the anal canal were

Table 6. QUALITY OF LIFE SCORES*

	Handsewn	Double-Stapled
Before		
Mean ± SD	2.4 ± 1	2.5 ± 0.8
Median (range)	2.4 (1–3.9)	2.3 (1–3.6)
After		
Mean ± SD	3.6 ± 1.3	3.2 ± 1.6
Median (range)	4 (1–5)	4.7 (1–5)

* Score: 1 = restricted (severe); 2 = restricted (moderate); 3 = restricted (mild); 4 = no restriction; 5 = improved.

not controlled. Indeed, a good example of this is the recent report by Ziv et al.²⁹ When such confounding factors are eliminated by randomizing patients prospectively, only slight differences between operations can be documented.

These differences, however, are likely real, considering that after stapling, the patients had improved fecal continence at night compared with that of the handsewn group at the $p = 0.06$ level. These findings are supported by the physiologic data; high resting ($p < 0.05$) and squeeze pressures ($p < 0.06$) point to a more "robust" anal canal in the patients who underwent the double-stapled procedure, one that perhaps is able to withstand the constant challenge to the pouch-anal canal pressure gradient posed by high pressure waves in the pouch.^{30,31} These observations are similar to those of others who found a stapled anastomosis preserved anal canal pressures better than did a handsewn anastomosis.^{32,33}

Few patients had pouchitis in this series, principally because the follow-up was short. Nevertheless, the incidence of pouchitis does not appear to be influenced by the type of anastomosis constructed. However, the issue may have been made somewhat confusing by the introduction of the term "strip pouchitis."³⁴ Strip pouchitis is actually inflammation remaining in the preserved ATZ and should be better named ATZ inflammation rather than strip pouchitis.

This observation leads inevitably to a central issue: what is the risk of leaving the mucosa and the ATZ in place after double-stapling? We reported recently that the ATZ consisted primarily of transitional epithelium, but that columns of the rectal columnar epithelium traversed the ATZ such that in 89% of patients, rectal epithelium came within 1 cm of the dentate line.³⁵ Further, we showed that although the transitional epithelium was not inflamed, the rectal epithelium was. We concluded that preserving the ATZ may preserve the potential for persistence of chronic ulcerative colitis in most patients. Sugerman et al.⁷ reported that 20 of 21 patients showed inflammation in the distal donut after stapling, whereas similar findings were reported by Kmiot and Keighley.²³ Lavery et al.³⁶ reported that the ATZ was inflamed in 22% of patients, but was symptomatic in only 14% of patients. Moreover, the anal canal mucosa in patients with chronic ulcerative colitis has been shown to harbor dysplasia, although this is rather uncommon. The incidence of focal dysplasia in the preserved ATZ in patients with chronic ulcerative colitis varies by author. Emblem et al.³⁷ reported 0% incidence, whereas Haray et al.³⁸ reported a 0.9% incidence. This is the same rate reported by Ziv et al.³⁹ and Tsunoda et al.⁴⁰ It appears that the malignant potential of the ATZ after stapling is indeed slight.

Further complicating the argument, we have documented that retained rests of rectal mucosa are present in the denuded rectal cuff after total endorectal excision of

the ATZ in 20% of specimens removed from patients requiring excision of their ileoanal anastomosis.^{41,42} Although these rests consisted clearly of rectal mucosa, there was no evidence of generalized re-epithelialization of the rectal muscularis. Nonetheless, it was sobering to find rectal mucosa after complete rectal mucosal resection in fully 20% of patients. Our series reported here included no patient with familial adenomatous polyposis; double-stapled IPAA for familial polyposis is not recommended based on the experience by Emblem et al.³⁷ that 10 of 13 patients had regrowth of polyps in the ATZ, which had been preserved during ileoanal anastomosis.

It seems reasonable to conclude from these data that the ATZ, although harboring rectal epithelium that may be inflamed, has in turn nearly no malignant potential and can be left *in situ* during IPAA safely when operating on patients with chronic ulcerative colitis and not familial adenomatous polyposis. Indeed, the ATZ after double-stapling can be inspected and a biopsy can be performed for dysplasia directly, whereas the rectal cuff after mucosectomy is difficult to evaluate.

We continue to perform IPAA in two stages because most of our patients are receiving large doses of steroids and we prefer to deal with the complications of stoma closure rather than those of overwhelming pelvic sepsis.³ This is said knowing that single-stage IPAA is gaining in popularity quickly^{7,8} as double-stapled IPAA becomes more mainstream.

There is little doubt that double-stapled IPAA is a straightforward operation to perform. Indeed, in several ways, it is an easy operation, but it is just as easy to make a serious error in judgment when stapling the rectum; the TA30 instrument (Ethicon Instruments) must be positioned within 2 to 3 cm of the dentate line to ensure that the ATZ remaining after double-stapling is only 0.5 to 1.5 cm in length. It is quite easy to come across the rectum much too high and in the process construct an ileorectostomy rather than an ileoanal anastomosis.

Finally, double-stapling has facilitated the adaptation of IPAA to patients who are less than perfect candidates (*i.e.*, those patients who are extraordinarily tall, short, overweight or who are a combination of the three). Moreover, willingness to include older patients because of the ease and simplicity with which this procedure is done and the fact that resting pressures may be better preserved after double-stapled IPAA is indeed an interesting evolution of the procedure.⁴³ Double-stapling thus seems to have widened the envelope of patients who are eligible. As familiarity grows with the double-stapled technique, willingness to perform a single-stage operation likely will increase also.

In conclusion, double-stapled IPAA is a simple, straightforward operation to perform, the major shortcoming of which remains the distinct possibility that surgeons

will construct an ileorectostomy by mistakenly cross-stapling the rectum too high; the result will be recurrent ulcerative colitis and the need for excision. The operation can be done quickly and appears to leave the anal canal in a more robust condition than that of the handsewn technique. The implications for this over time may be that patients will experience better long-term continence with this procedure than with handsewn IPAA.

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Discussion

DR. HARVEY J. SUGERMAN (Richmond, Virginia): The Mayo Clinic randomized prospective trial of a stapled ileal pouch-anal anastomosis versus a mucosectomy with a hand-sewn anastomosis is an impressive and interesting study. I appreciate the authors having sent the manuscript to me in advance.

This study supports two previous randomized studies that failed to show a significant difference with a stapled ileal-anal procedure. But, like the other studies, the number of patients randomized was small. As in our non-randomized study, which was presented to this Association in 1990, as well as several other reports, the Mayo Clinic study did find a significantly higher resting sphincter pressure following the stapled procedure. Although the authors noted that the mucosectomy hand-sewn patients had a 50% frequency of nocturnal incontinence, in contrast to half as much in the stapled group, this did not reach statistical significance. This was probably because of a Type II statistical error, that is, not enough patients were enrolled into the study.

One of the patients, randomized to mucosectomy, had a stapled procedure for technical reasons, and I wonder if that patient's inclusion further improved the mucosectomy incontinence data.

The 30% frequency of nocturnal accidents noted by the Mayo Clinic in this stapled group is also much higher than our current experience, where nocturnal accidents and spotting averages approximately 10% at six months in the absence of pouchitis with the triple-stapled procedure—and it is a triple-stapled procedure that is shown here. That is, you use a GIA stapler, a TA30 stapler, and an EEA stapler.

Pouchitis is associated with watery stools and accidents, and it was not excluded in our 1990 study that reported a 20% incidence of nocturnal incontinence. Because these data presented today were collected by Mayo questionnaires, I suspect that many of the Mayo Clinic patients may have had pouchitis at the time of the survey, which could have been responsible for the relatively higher incontinence rates.

It is important that the patients be queried about accident rates when their pouchitis has been controlled with antibiotics or other medications.

The authors attribute the possible improved continence to preservation of the anal mucosa by intentionally stapling 1 to 2 cm above the dentate line. We have been able to staple at the

dentate line in 40% of our patients with excellent results in fecal continence. I do not believe that preservation of the anal transition zone is the mechanism for the improved sphincter tone and improved continence rate that we and others have noted with the triple-stapled ileal-anal pouch procedure. Therefore, we try to remove as much of this potentially troublesome tissue as possible.

There is a second major advantage, probably the primary benefit to the stapled ileal-anal procedure, as suggested in the closing comments, which, unfortunately, was not addressed in this study. This benefit is a much more secure anastomosis that enables the procedure to be performed as a one-stage operation without a temporary diverting ileostomy in the vast majority of patients. Even in our experience, most of those patients are on steroids with acute colitis.

A one-stage procedure markedly reduces the overall hospitalization time and permits a much earlier return to a functional life without the noxious effects of having to have an ileostomy and undergo another surgical procedure for its closure, and it permits the procedure to be done even for severely obese patients.

The ileostomy is not a free ride. It is associated with a significant risk of complications, including anastomotic leak, incisional hernia, dehydration, and small bowel obstruction. We have performed 142 stapled ileo-anal pouch procedures without an ileostomy. There has been a 13% risk of anastomotic leak, and two thirds of these have healed without need for a diverting ileostomy. There has not been a statistically significant increased risk of leak in patients taking steroids or having acute ulcerative colitis than for those off steroids with chronic colitis. That is not to say that every patient is a candidate for this operation as a one-stage procedure. Severely malnourished and severely debilitated patients should not be offered that approach. Our small bowel obstruction rate is < 4%, which is much lower than the literature rate of about 15% for the standard two-stage procedure. The previous Mayo Clinic experience with a one-stage mucosectomy and hand-sewn pouch procedure without ileal diversion had a high incidence of permanent pouch dysfunction. With two exceptions, all of our patients who have had pouch leaks have excellent pouch function.

We have also performed this procedure in patients with dysplasia and with carcinoma. We have not had recurrence of carcinoma in this group of patients or carcinoma in the residual tissue left behind in the 60% of patients where there is tissue left behind. One can excise this tissue if there is dysplasia in it and then advance the anoderm up.

Have you considered using the stapled ileal-anal pouch procedure without temporary ileal diversion? I believe they will be a much happier group of patients if they don't have to fly back to Rochester, Minnesota, for another operation, or two, if they get a bowel obstruction.

DR. SUSAN GALANDIUK (Louisville, Kentucky): Dr. Cameron, Dr. Copeland, Ladies, and Gentlemen. There has been a long controversy between surgeons that do ileal pouch-anal anastomosis as to whether they hand-sew or staple, with the difference being that a portion of rectum is left *in situ* in the stapled group. There are advantages of the hand-sewn approach, namely, you