

Ileorectal Anastomosis for Slow Transit Constipation: Long-Term Functional and Quality of Life Results

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The results of colectomy and ileorectal anastomosis (IRA) in patients diagnosed by physiologic testing as having slow transit constipation (STC) have been reported. The durability of functional results and long-term quality of life (QoL) in these patients, however, has not been established. Between 1987 and 2002, 3670 patients were evaluated for constipation at our institution; 110 (3%) fulfilled the criteria for STC and underwent an IRA. Patients were prospectively followed and functional outcomes assessed annually by standardized questionnaires. After a median follow-up of 11 years, 104 eligible patients were mailed validated questionnaires to assess functional outcomes and QoL (Knowles-Eccersley-Scott Symptom [KESS] score, the Irritable Bowel Syndrome Quality of Life [IBS-QOL], and the SF-12 health survey). Prospectively assessed functional data was available on 85 of 104 (82%) eligible patients. At last follow-up, improvement of constipation and satisfaction with bowel function was reported by 98% and 85% of patients, respectively. Performance measures including social activity, household work, sexual life, and family relationships were reported to have improved or were not affected as a result of surgery by 75%, 86%, 81%, and 86% of the patients respectively. Fifty-nine patients (57%) responded to the study questionnaires. All 59 patients reported their constipation to be better since IRA, 83% did not require any medication, and 85% reported being satisfied with bowel function. The KESS scores of patients undergoing IRA for STC (median 6, range 0–35) were lower than reported scores of STC patients not operated upon (median 21, range 11–35, $P < 0.001$) indicating symptomatic improvement after surgery. Mean IBS-QOL scores were similar to reported scores of patients undergoing IRA for other conditions [80 (23) versus 84 (16)], $P = 0.7$. Mean SF-12 physical and mental summary scores were similar to reported SF-12 scores of the normal population (49.5 versus 50 and $P = 0.70$, 48.7 versus 50, $P = 0.42$, respectively). Ileorectal anastomosis in appropriately selected patients with slow transit constipation results in durable symptomatic relief and a long-term quality of life indistinguishable from the general population. (J GASTROINTEST SURG 2006;10:1330–1337) © 2006 The Society for Surgery of the Alimentary Tract

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Chronic constipation is more a constellation of symptoms than a definable disease. Moreover, patients complaining of constipation are a heterogeneous group; the various symptoms representing various pathologic processes.¹ Advancements in defining colonic and anorectal physiology have improved the understanding of colonic motility, the process of defecation and the factors contributing to chronic constipation.^{2,3} Currently, by following an objective evaluation strategy² that quantifies colonic, pelvic, and anorectal function, patients are classified into four diagnostic categories depending upon the presence or absence of various underlying physiologic abnormalities: (1) slow transit constipation (STC),

(2) pelvic floor dysfunction (PFD), (3) combined slow transit constipation and pelvic floor dysfunction (STC + PFD), and (4) constipation predominant irritable bowel syndrome (IBS-C). We have demonstrated previously that patients with slow transit constipation documented by colonic transit studies with or without pelvic floor dysfunction, benefit from colectomy and ileorectal anastomosis (IRA).^{2,3} Subsequent reports have validated this approach by reporting similar improvements in functional outcomes of these patients.^{4–9}

In recent years, however, there has been a growing recognition that in order to assess the true efficacy of any operative intervention, the patient's perspective

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of the outcome needs to be assessed objectively in the same manner as conventional outcome measures are documented. As a result, standard outcome measures are being increasingly supplemented with studies of quality of life (QOL).¹⁰ QOL is a multidimensional construct that reflects the patient's subjective evaluation of the effects of the treatment on their physical, psychological, social functioning and well-being.¹¹ It has been previously suggested that QOL is a soft outcome, although this argument no longer is valid as QOL assessments are now performed using standard questionnaires with documented psychometric properties.¹² There are two basic types of QOL questionnaires: generic and disease/treatment specific. Generic questionnaires assess the ability of patients to cope physically, emotionally and socially as well as their general performance at work and in daily life.¹³ In contrast, the content of disease- or treatment-specific instruments are limited to areas of consequence to the patients' affliction from a particular condition.¹⁴

The purpose of this study was to assess the long-term functional and QOL outcomes of patients who had undergone an IRA for slow transit constipation using both generic and disease-specific validated QOL instruments.

PATIENTS AND METHODS

Three thousand six hundred seventy patients were evaluated for constipation at our institution's specialist gastrointestinal motility unit between 1987 and 2002. All patients underwent a complete history and physical examination, appropriate laboratory investigations and either a colonoscopy or barium enema to rule out anatomic causes of constipation. Patients were then evaluated with standardized colonic transit and pelvic floor studies that have been described in detail previously.² In brief, colonic motility was assessed by either marker¹⁵ or scintigraphic¹⁶ transit, while pelvic floor function studies included anorectal manometry and balloon expulsion. Selected patients underwent defecography. One hundred twelve patients (3%) fulfilled the standardized criteria for slow transit constipation with or without pelvic floor dysfunction. Patients ($n = 92$) with slow transit constipation alone underwent an IRA, while patients ($n = 30$) with slow transit constipation and pelvic floor dysfunction underwent IRA after a successful course of pelvic floor retraining. Patients with PFD alone were treated by pelvic floor retraining (biofeedback) and patients with IBS-C were managed medically.

Data was collected in a prospectively maintained computerized database. Bowel function and functional outcomes were assessed yearly by a standard institution-specific questionnaire. Functional aspects evaluated included social activity, sports, housework, recreation, family relationships and sex life. After a median follow up of 11 years (range 1.5–16.5 years), 104 eligible patients were mailed a study-specific questionnaire and three validated questionnaires assessing bowel function and health-related QOL.

Study-specific Questionnaire

The study-specific questionnaire was composed of questions designed to assess bowel function, change in symptoms of constipation, use of constipating or antidiarrheal medications- and patient satisfaction after an IRA.

SF-12

The SF-12^{17,18} contains items selected from the SF-36 based on their relative efficiency and psychometric performance across eight dimensions of general overall health.¹⁹ The SF-36 health survey is one of the most widely used generic health status instruments to assess health-related quality of life.²⁰ Since it contains 36 items and thus places a considerable burden on the respondents and the investigators, a substantially shorter questionnaire, the SF-12, was developed, reducing the number of items to 12.¹⁹ About 80% of adults studied using a pilot test completed the SF-12 in less than 2 minutes. The SF-12 is scored to produce two summary scores, the physical and mental health summaries (PCS and MCS). These summary scores are estimated using a weighted formula for predicting the original SF-36 summary scores. The SF-12 summary scores have reproduced the psychometric performance of the SF-36 and have been found to be good predictors of the original summary scores as they account for approximately 90% of the variation in the SF-36 summary measures.^{19,21}

Knowles-Eccersley-Scott Symptom (KESS) Questionnaire

The KESS is a structured symptom scoring questionnaire for patients complaining of constipation consisting of 11 items.²² The questions were designed to incorporate internationally recognized criteria and previously reported relevant symptoms of constipation. The KESS score has been validated against the Cleveland Clinic Score (Pearson $r = 0.90$ and 95% limits of agreement $\pm 14\%$), which is itself a validated tool for distinguishing constipated

patients with a proven pathophysiologic abnormality from those in whom physiologic investigations were normal.²² The KESS score has been shown to be able to discriminate between the pathophysiologic subgroups for the majority of patients with constipation. Discriminant scores predict patients with pure slow transit constipation or PFD better than patients with mixed abnormalities.^{22,23} However, the KESS total score clearly differentiates patients with slow transit constipation from healthy controls.²² The questionnaire can be completed in less than 5 minutes. Each question has four or five possible answers, which are scored on an unweighted linear numeric scale to produce a range of between 0 and 3 or 0 and 4 points. Lower scores represented symptom free states and higher scores, increased symptom severity. The total KESS score is the sum of all scores gained on individual questions with a maximum possible score of 39 points. The answers to each question are phrased in such a manner that any patient who fulfilled the standardized criteria for constipation would likely score at least 1 point per question.²²

Irritable Bowel Syndrome–Quality of Life Measure (IBS-QOL)

The IBS-QOL is a self-reported QOL measure specific to irritable bowel syndrome (IBS).²⁴ It is made up of 34 items and takes an average of 10 minutes to complete. The IBS-QOL has 10 subscales: Dysphoria, Interference with activity, Body image, Health Worry, Food Avoidance, Social Reaction, Sexual, Relationships, Symptom Frequency Index, and Symptom Bothersome Index. Responses are based on a 5-point Likert scale (not at all ... extremely or a great deal). The individual responses to the 34 items are summed and averaged for a total score that is transformed to a 0–100 scale, with higher scores indicating better QOL.²⁴

Data Analysis and Statistics

Statistical analysis was performed using SAS version 8.2 (SAS Institute Inc, Cary, NC). The analysis focused on comparing responders and nonresponders, and patients with and without pelvic floor dysfunction. In addition, limited QOL outcomes from the cohort were compared to the corresponding parameters from previously published cohorts.^{22,25} Outcomes comprised of discrete, nominal variables were compared using χ^2 tests or Fisher's exact tests when low expected cell counts were observed. Continuous variables were analyzed using two-sample *t*-tests, or Wilcoxon rank sum tests

when the data were not sufficiently Gaussian. The SF-12 mental and physical component summary scores are standardized to have a mean of 50 and standard deviation of 10; comparisons of these scores with an external reference population were performed using a one-sample *t*-test. Significance was assumed at the $P < 0.05$ level.

RESULTS

Between 1987 and 2002, 110 patients (104 females, median age 40 years) after objective preoperative evaluation underwent a colectomy with ileorectal anastomosis (IRA) for slow transit constipation. Six patients were deceased on most recent follow-up. Among the 104 remaining patients, 65 patients had slow transit constipation alone and 39 patients had combined slow transit constipation and pelvic floor dysfunction.

Prospectively assessed functional outcomes were obtained through annual questionnaires for 85 of the 104 (82%) eligible patients. At last follow-up (mean 5.7 years, SD 3.8 years) the median stool frequency was four bowel movements per day and improvement of constipation and satisfaction with bowel function was reported by 98% and 85% of the patients respectively. Performance measures including social activity, household work, family relationships, recreation, and sexual life were reported to have improved or were not affected as result of surgery by 75%, 86%, 86%, 80%, and 81% of the patients respectively. Fifty-nine of the 104 (57%) eligible patients with a median follow-up of 11 years (mean 10 years, SD 4) responded to the validated functional and QOL outcome instruments. All 59 respondents reported their constipation to be better since IRA, 83% did not require constipating or anti-diarrheal medication and 85% reported being satisfied with their bowel function.

The KESS score of the patients (median 6, range 0–35) undergoing IRA for slow transit constipation were less than the reported scores of patients with slow transit constipation not operated upon²² (median score 21, range 11–35, $P < 0.001$) suggesting symptomatic improvement after surgery. Mean IBS-QOL scores were similar to reported scores of patients undergoing IRA for other benign conditions²⁵ [80 (standard deviation 23) versus 84 (standard deviation 16), $P = 0.7$] Mean SF-12 physical and mental summary scores were similar to reported SF-12 scores of the normal population (49.5 versus 50, $P = 0.70$, 48.7 versus 50, $P = 0.42$).

There were no significant differences between the KESS, the IBS-QOL, and SF-12 scores of patients

with slow transit constipation alone and slow transit constipation with pelvic floor dysfunction (Table 1).

Nonresponders

Concerning patients not responding to the functional and QOL outcome questionnaires, we could find no differences between responders and nonresponders in terms of age, gender, length of follow-up, year of surgery, and incidence of PFD. (Table 2). Furthermore, no differences were seen in the yearly assessed functional outcomes. (Table 3).

DISCUSSION

We found that patients diagnosed with slow transit constipation by objective preoperative criteria and who underwent colectomy and ileorectal anastomosis had satisfactory long-term functional results and an excellent quality of life as measured by validated QOL instruments. This is the first report of a large series of patients categorized prospectively using tests of colonic and pelvic floor function and followed for this length of time (median 11 years) documenting QOL outcomes measured by standardized QOL instruments.

Inconsistent functional results have been reported in the literature for surgery for slow transit constipation.⁷ This variability may be due to the lack of standardized preoperative physiologic testing in some of these reports.^{26–29} We have found that patients with slow transit constipation, documented by colonic motility studies, were the patients most likely to benefit from an IRA.^{2,3} Patients with pelvic floor dysfunction alone or constipation-predominant

Table 1. Comparison of functional and QOL outcomes of patients with STC alone and STC and PFD (N = 59)

	STC (N = 42)	STC and PFD (N = 17)	P-value
Median KESS score (IQ range)	6 (4–9)	6.5 (3–13)	0.77
Median IBS-QOL score (IQ range)	93 (80–96)	88 (73–93)	0.19
Median SF-12 (physical scale) (IQ range)	54 (48–56)	50 (40–57)	0.61
Median SF-12 (mental scale) (IQ range)	54 (42–58)	51 (44–57)	0.59

IQ = interquartile range; STC = slow transit constipation; PFD = pelvic floor dysfunction.

Table 2. Comparison of the responders and nonresponders to the study questionnaires (N = 104)

	Responders (N = 59)	Non responders (N = 45)	P- value
Gender (females)	97%	91%	0.40
Mean age, yr (SD)	41 (11)	38 (14)	0.13
Follow-up from surgery, in mo (SD)	73 (47)	59 (42)	0.21
STC	75%	63%	0.21
STC and PFD	25%	37%	0.44

SD = standard deviation; STC = slow transit constipation PFD = pelvic floor dysfunction.

irritable bowel syndrome who are managed surgically do not show the same functional improvement and may account for the poor functional results associated with IRA in these various studies. The group of patients with IBS, which actually forms the great majority of patients evaluated for chronic constipation (>60%), can be reliably diagnosed with physiologic testing and be managed by aggressive medical therapy. Studies using standardized preoperative evaluation to select patients for surgery consistently report superior outcomes as compared to studies in which patients did not undergo formal evaluation.^{3,7,9,30}

In our study, we evaluated functional and QOL outcomes using standardized validated instruments at a median of 11 years following IRA. Previous reports evaluating functional results of surgery for slow transit constipation have used instruments which were unreliable and not validated.^{1,3,6,8,9,31–33} Knowles et al.⁷ suggested that studies evaluating outcomes of surgery for slow transit constipation should be independent, prospective, have long-term follow-up, and use validated questionnaires that assess QOL and gastrointestinal function. We agreed, and thus all patients who underwent surgery for slow transit constipation at our institution were entered into a computerized database and prospectively evaluated through annual questionnaires administered by a nurse not directly involved in their care. Analysis of these prospectively collected data suggests that the majority (85%) of patients report improvement of their bowel function and functional outcomes following surgery. After a median follow-up of 11 years, we then evaluated the functional and QOL outcomes of this cohort in a cross-sectional manner using validated instruments; the data confirmed the long-term benefit of surgery on functional and QOL outcomes.

Table 3. Comparison of responders and nonresponders to study questionnaires based upon prospectively collected yearly data (N = 85)

Questionnaire issue	Responders (N = 53)	Non responders (N = 32)	P-value
Satisfaction with bowel function	87%	75%	0.04
Constipation (better)	100%	94%	0.13
Median stool frequency (IQ range)	4 (2–6)	4 (3–6)	0.73
Social life (not affected/improved)	77%	72%	0.63
Housework (not affected/improved)	87%	84%	1.00
Relationships (not affected/improved)	91%	78%	0.29
Recreation (not affected/improved)	83%	75%	0.56
Sex life (not affected/improved)	85%	75%	0.24

IQ = interquartile range.

The functional results following surgery were assessed using the KESS Questionnaire, which was designed to incorporate standardized criteria and relevant symptoms of constipation. The median KESS score of our patients was significantly better than the median score of patients with slow transit constipation prior to surgery confirming that IRA is beneficial for patients with STC. On the study-specific questionnaire, the majority of the patients reported an improvement of their bowel function and their overall QOL. This improvement in functional outcome is consistent with the results of others that have demonstrated the success of surgery in properly selected patients.^{5,7–9,30,34} The definition of “success” for IRA, however, has been nebulous, as successful results have variably been equated to normal bowel frequency,³³ spontaneous passage of stool,² or the patient’s satisfaction with their outcomes.³⁰ We agree with Fitzharris and colleagues⁵ that these definitions are arbitrary and not reliably reproducible, making comparisons across studies difficult. Although stool frequency is a primary outcome measure, the prevalence of other symptoms like abdominal pain, diarrhea, and incontinence needs to be included in any global outcome assessment. The KESS scores not only assess bowel frequency but also evaluates associated symptoms like pain and bloating. While there were no specific questions regarding incontinence or diarrhea, our study-specific questionnaire had items pertaining to bulking and antidiarrheal agents, which are reasonable markers for incontinence and loose stools. Since the majority of our patients did not require any medications, either to hasten or slow gastrointestinal function, the incidence of these symptoms, we believe, was likely low.

We used the SF-12 and the IBS-QOL health survey instruments to assess QOL outcomes. The SF-12 is a generic health survey instrument which is based on the SF-36, one of the most widely used QOL

instruments. Several studies have used the SF-36 to assess QOL after gastrointestinal surgery and has found it to be a reliable method of assessing QOL.^{10,35,36} Although the SF-12 has been modified from the SF-36 in order to reduce the number of items and decrease the burden on the respondents, it maintains the psychometric properties of the SF-36 and is a good predictor of the original summary scores.¹⁹

We are not aware of any validated disease-specific instruments that assess QOL in slow transit constipation patients before or after surgery. Fitzharris et al.⁵ used the Gastrointestinal Quality of Life Index (GIQLI) to assess QOL in their surgical cohort of patients with slow transit constipation. Although the GIQLI is a validated QOL instrument, it contains QOL questions that are related to upper and lower gastrointestinal symptoms. The IBS-QOL was designed for patients with irritable bowel syndrome, and because a significant proportion of patients with slow transit constipation also have symptoms such as abdominal pain, nausea, and bloating that are similar to IBS, we believe it to be a suitable instrument for assessing bowel function related QOL. It also has been previously used to assess QOL in patients who have undergone colon surgery.^{25,37} Further studies are required to validate these findings and identify a better method of assessing disease-specific QOL in these patients.

A subgroup of patients with slow transit constipation has associated pelvic floor dysfunction, the incidence of which is between 15% and 50%.³⁸ There is much debate regarding the optimal treatment strategy for these patients, because surgery results in almost uniformly poor functional outcomes.^{34,38} In our practice, these patients undergo successful biofeedback training prior to being considered for surgery. Our long-term functional and QOL data support this approach as there was no difference in the outcomes of patients who had slow transit constipation alone or in combination with pelvic floor

dysfunction. Bernini and colleagues³⁸ have reported that of the 16 patients with colonic inertia and nonrelaxing pelvic floor diagnosed on physiologic testing and who underwent preoperative biofeedback, six patients still complained of incomplete evacuation that was severe in two and unresponsive to postoperative biofeedback. Differences in patient selection, duration of follow-up, diagnostic criteria, and outcomes measured could account for this discrepancy in results. We disagree with Lubowski and colleagues,³¹ who do not advocate treating patients with pelvic floor function preoperatively with biofeedback; not addressing pelvic floor dysfunction preoperatively may compromise the postoperative functional outcomes of IRA for STC.

One potential limitation of our study was the 57% response rate of patients to validated functional and QOL questionnaires. In order to minimize the chance of a response bias, we compared the demographics and prospectively collected annual functional outcomes of responders and nonresponders; importantly no differences were found. Although not eliminating the possibility that a response bias was present, such an approach minimizes such an outcome.

In conclusion, IRA for STC in patients selected for surgery based on objective preoperative physiologic testing results in excellent long-term outcomes with a high degree of patient satisfaction. Functional results as measured by the KESS score and IBS-QOL documented improved patient outcomes following surgery and SF-12 scores documented that after IRA for STC, patients had a quality of life indistinguishable from the normal population.

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Discussion

Scott A. Strong, M.D. (Cleveland, OH): I would like to congratulate Dr. Hassan, Dr. Pemberton, and their colleagues for this very interesting study that has long been due on this cohort of very difficult to manage patients. What they have been able to show is that with appropriately selected patients, a colectomy with ileorectal anastomosis provides both a durable long-term improvement in functional results as well as an acceptable quality of life. There are a few questions or items I wish to have elaborated on based on both the presentation and review of the manuscript that I appreciated receiving.

The first is obviously selecting the right patient cohort. You only operated on 3% of those patients who were evaluated for constipation, and I would like you to comment specifically on the role of excluding whole gut dysmotility. Are you still using only scintigraphy at this point, or do you still use some type of transit marker study with an evaluation of the more proximal bowel? Second, do you use any type of psychological testing in these patients preoperatively?

Regarding the outcome, my experience is that those patients who have a component of pelvic floor dysfunction with their slow transit constipation will occasionally relapse back into difficulties with pelvic floor dysfunction and require retraining with repeat biofeedback following their operation at varying time intervals.

Lastly, what was indicated from the manuscript is that you have very good follow-up in this cohort of patients with these annual mailings regarding their bowel function and other items. However, this 57% response rate of this particular study seems like it is quite disparate from that, and I wonder if you could speculate on the reason for that disparity and perhaps how that may have impacted the results.

Thank you.

Imran Hassan, M.D. (Rochester, Minn): Thank you, Dr. Strong, for your insightful comments and questions. Regarding the evaluation of patients with chronic constipation, they undergo a medical workup including a history, physical examination and laboratory investigations, a colonic evaluation with either a barium enema or a colonoscopy, and transit studies with either Sitz markers or scintigraphy. They also undergo pelvic floor evaluation that usually includes anorectal manometry and balloon expulsion tests.

Based upon these tests, patients are divided into four categories. Patients in whom both these tests are normal fall in the category of constipation predominant irritable bowel syndrome and are the majority of these patients. The second group is the group of patients who have pelvic floor dysfunction but have normal colonic transit studies; these patients undergo biofeedback and pelvic floor retraining and don't benefit from surgery. The last

two groups include patients with slow transit constipation with or without pelvic floor dysfunction. Patients with slow transit constipation undergo surgery, while patients with pelvic floor dysfunction undergo pelvic floor retraining followed by surgery.

Regarding the possibility of whole gut dysmotility, that is certainly a concern. Dr. Michael Camelleri from our institution a few years back showed that because of colonic dysmotility, the small bowel and the stomach slow down because the colon acts as a physiologic brake; therefore if we take care of the colon, the motility in the small bowel and the stomach eventually normalize. That at least has been our experience, although there probably is a small subset of patients with actual whole gut dysmotility who probably won't benefit from surgery. If there is any question of that, one can do a temporary loop ileostomy and see if the patient's symptoms significantly improve. Depending on the extent of symptomatic improvement one can decide to take out the colon or not.

The issue of psychologic testing is valid and relevant; definitely the group from Minneapolis has shown that a significant number of patients have significant psychiatric disorders. We did not specifically look into this, but it is certainly something that needs to be kept in the back of the mind, as there may be psychiatric issues that need to be addressed prior to surgery.

Regarding the question about relapse of pelvic floor dysfunction after surgery, this can certainly happen. I don't have the exact number, but about 10% to 20% of the patients do so and redevelop pelvic floor dysfunction. However, if these patients undergo pelvic floor retraining again, their function improves and can return to baseline.

The last question is about the response rate. This is something that everybody who does survey research has had to deal with in recent years. In our experience, some of it is due to HIPAA regulations and some of it

is the tertiary referral nature of our practice with patients coming from all over the country, making reliable follow-up difficult; furthermore, this is a young group of patients who at their stage of life tend to move because of personal and/or professional reasons.

Regarding why there was a difference in the response rates to the study questionnaires compared to the annual questionnaire, I think some patients may have initially replied to the annual questionnaires for a few years but did not continue to do so in the long run and therefore may not have answered the study questionnaires that were mailed after a median follow-up of about 120 months. In order to minimize a potential response bias, we compared the available data on responders and nonresponders and were unable to find any significant differences. While this does not necessarily exclude a response bias, it hopefully minimized it.

The other issue is that of patient burden. We tried to minimize the number of questions, yet there were about 50 questions we had to ask. The annual questionnaire has only about five or 10 questions. So it is a balance of what we need to know; and what is nice to know.

Janice F. Rafferty, M.J. (Cincinnati, Ohio): Were any of your patients operated on laparoscopically during that time period, and if so, did it affect their quality of life questionnaires that they completed?

Dr. Hassan: Toward the end, from about 1998 onward, about 80% of them had laparoscopic colectomies. We didn't do a subset analysis because we started getting smaller numbers. Like the previous presentation showed, patient-related outcomes in the long term for laparoscopic and open surgery become equal. I am sure if we tortured the data hard enough we would probably get it to show a difference, but I wasn't very keen on doing that.