

Received Date : 29-Feb-2016
Revised Date : 19-Jul-2016
Accepted Date : 25-Jul-2016
Article type : Original Article

153-2016.R1

Original Article

Quality of life following fistulotomy – short term follow-up

Owen, HA, Buchanan, GN, Schizas, A, Emmanuel, A, Cohen, R, Williams, AB

The Pelvic Floor Unit, Department of Surgery, Guy's & St Thomas' Hospital, Westminster
Bridge Road, London, SE1 7EH, UK

Department of Surgery, St. Mark's Hospital, London North West Hospitals, Watford Road,
Harrow, HA1 3UJ, UK

Department of Surgery, University College London Hospital, 235 Euston Road, London,
NW1 2BU, UK

Corresponding Author:

Miss Harriet A Owen MSc, MD, FRCS, harriet_owen@hotmail.com, 07810 357489

Department of Surgery, St. Mark's Hospital, London North West Hospitals, Watford Road,
Harrow, HA1 3UJ, UK.

This article has been accepted for publication and undergone full peer review but has not
been through the copyediting, typesetting, pagination and proofreading process, which may
lead to differences between this version and the Version of Record. Please cite this article as
doi: 10.1111/codi.13538

This article is protected by copyright. All rights reserved.

Keywords

Anal fistula, Quality of life, Faecal Incontinence

Abstract

Introduction: Anal fistula causes pain, discharge of pus and blood. Fistulotomy has the highest success, however, can risk continence; treatment balances cure with continence. This study assessed the impact of fistulotomy on Quality Of Life (QOL) and continence.

Methods: Patients selected for fistulotomy prospectively completed St Mark's Continence Score (full incontinence = 24) and Short Form - 36 questionnaires pre-operatively at two institutions with an interest in anal fistula, and reassessed 3 months post-operatively.

Results: There were 52 patients median age 44, range 19 - 82 years, 10 were women. Pre-operative continence scores were median 0, range 0 - 23, there was no significant difference compared to post-operative scores, median 1, range 0-24. Quality of life was significantly improved following fistulotomy in 4 of 8 domains: Bodily Pain ($p<0.001$); Vitality ($p<0.01$); Social Functioning ($p<0.05$); Mental Health ($p<0.001$) and returned to that of the general population. QOL for patients with intersphincteric fistula improved post fistulotomy, for those with trans-sphincteric fistula QOL remained the same. Data were further examined in two groups, with and without continence score deterioration. Where continence improved post-operatively, QOL improved in 3 domains; where continence deteriorated QOL also improved, in 2 domains ($p<0.05$). Patients with post-operative continence of <5 points had worse QOL than those scoring 4 or less.

Discussion: QOL at three months follow up significantly improved following fistulotomy where continence was maintained or a small reduction occurred.

'What does this paper add to the literature?'

Quality of Life (QOL) and continence of anal fistula patients were assessed pre and post fistulotomy. Small changes in continence were well tolerated and overall QOL returned to that of the general population. When considering fistulotomy, continence should not be considered the sole assessment, or as a surrogate for QOL.

Introduction

An anal fistula is a track from the anal canal (or rectum) the internal opening, and communicating with the skin around the anus at the external opening ¹. Approximately 5,000 people undergo anal fistula surgery in the United Kingdom per year, though the problem of recurrence gives an incidence of 1:10,000 ². Symptoms include pain, difficulty sitting, discharge of pus/blood ³ and quality of life (QOL) is reduced ⁴. Many operative techniques have been employed in an attempt to treat anal fistula. Fistulotomy is the most common and involves laying open of all tissues encircled by the fistula with a curative rate of over 90% ⁵, however, there is a risk of continence disturbance of up to 53% when the anal sphincter is divided ^{6,7}. The aim of anal fistula surgery is to treat the fistula while minimising impact on continence. Faecal incontinence may have a detrimental impact on QOL ⁸, it has been suggested that QOL following fistula surgery correlates with reduced faecal continence ^{9 10}, and patient satisfaction ¹¹. It is not clear what degree of incontinence affects QOL compared to QOL with a fistula. Most authors agree that length of anal sphincter division is of high importance when considering fistulotomy ⁹, in an otherwise healthy male with no previous anal surgery one third of the anal sphincter can be safely divided ¹².

Other “Sphincter sparing” techniques have been developed, however, thus far these techniques have a higher recurrence rate than fistulotomy. Advancement flap has a success

of between 45% and 75% with incontinence rate of 30%^{13,14}; Anal Fistula Plug™ (Cook Surgical Inc.) with success rates of between 24%¹⁵ and 83%¹⁶; and the LIFT procedure (ligation of fistula track) with success rates 40 to 95%, continence disturbance 6%¹⁷. Alternatively a long term draining loose seton is an option¹⁸, this is associated with a chronic discharge which may affect QOL¹⁹ and removal has an 80% chance of recurrence of the fistula²⁰. The results of sphincter sparing alternatives to fistulotomy are encouraging, however there is a high recurrence rate and care must be taken not to use continence as a surrogate for QOL when assessing patient satisfaction.

To date no study has prospectively investigated QOL in anal fistula or QOL post fistulotomy using a robust generic QOL assessment and an established, validated continence questionnaire. The St Mark's Continence Score has been validated²¹, it assesses continence to solid, liquid, gas, impact on lifestyle and the ability to defer defaecation, scores range from 0 to 24, a higher score correlates to worse continence. The Short Form-36 (SF-36) Questionnaire was chosen as it is a generic QOL tool that has been employed as a measure of patient outcome²² and used to assess the peri-operative QOL of patients with a variety of surgical diseases^{23 24 25}. Population norms for the UK have been calculated, mean scores of 8,000 people of working age is used as reference for the population norms²⁶. This study assesses whether QOL improves post fistulotomy and whether this is maintained when a post-operative continence disturbance occurs.

Methods

Newly referred patients aged 18 or older with cryptoglandular anal fistula were recruited once the decision had been made for fistulotomy. The patients were recruited from the two institutions, one year in each. Both institutions are tertiary referral centres for this disease and include patients from the local population; the results were pooled for analysis. Patients

were asked to complete the SF-36 and St Mark's continence questionnaires at presentation to outpatients or on the day of surgery and these were repeated when healed post-operatively.

Of note in the continence assessment when scoring for pad use patients were specifically asked to distinguish fistula discharge from faecal leakage.

The St Mark's Continence score is from 0 – 24, 0 is fully continent. SF-36 QOL assessment tool generates scores in domains, these are Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. Pre and post-operative QOL data were compared to the population mean scores using the paired t-test. Further SF-36 analysis was conducted using the Wilcoxon Signed Rank test for non-parametric paired data.

This study was designed to be applicable to the majority of patients presenting with cryptoglandular anal fistula. To remove the bias of a tertiary institution the following exclusions were made; patients with Crohn's disease, those with multiple previous operations (3 or more attempts at cure). Patients where consent was not possible due to learning difficulties or language barriers were also excluded. Local Research Ethics Committee approval was granted and written consent obtained.

Results

Pre-operative data were collected on 61 patients, 1 patient was excluded as he was subsequently found to have Crohn's Disease, another was found to have no fistula at Examination Under Anaesthetic (EUA), and 7 patients (12%) declined post-operative questionnaire. Complete pre and post-operative data was available for 52 patients (39 from one institution, 13 from the second) the median age was 44, range 19 to 82, and there were 10

women. There were 41 patients with a primary fistula (no previous attempts at curative surgery) of which 9 had a loose seton in situ at presentation; of the 11 patients with recurrent disease 1 had a loose seton.

Questionnaires were completed pre-operatively and median 3 months post-operatively (range 2 - 36 months) for this short term follow up. The change in continence score varied from a reduction of 11 points to an increase of 11 points. Pre-operative continence scores were median 0, range 0-23, post-operative scores were not significantly different for the group as a whole with median continence score 1, range 0-24. No recurrence was detected at minimum 3 month post-fistulotomy. Across the group SF-36 scores improved post-operatively, this was significant in the domains of Bodily Pain ($p < 0.001$), Vitality ($p < 0.01$), Social Functioning ($p < 0.05$) and Mental Health ($p < 0.001$).

The change in continence score for the 41 patients with primary fistula was median 0, range -11 to 8, 14 of the 41 patients had a deterioration (34%). For the 11 patients with recurrent fistulas continence score change was median -1, range -9 to 11, and 4 patients had a deterioration in continence (36%). SF-36 scores for patients with primary fistula showed a significant improvement in QOL post fistulotomy in the domains of Bodily Pain ($p < 0.01$), General Health ($p < 0.05$), Vitality ($p < 0.05$), Social Functioning ($p < 0.05$) and Mental Health ($p < 0.005$). Patients with recurrent disease had significant increase in QOL in the domains of Bodily Pain ($p < 0.05$) and Mental Health ($p < 0.05$).

Of the 52 patients, 21 had intersphincteric fistulas, 25 had trans-sphincteric, data regarding this was incomplete in 4, and 2 patients had superficial fistulas. Of the 21 patients with intersphincteric fistulas 2 were recurrent, of the 25 trans-sphincteric fistulas, 7 were recurrent.

This was not significantly different (Fisher's Exact test). There was no significant change in continence scores for the 21 patients with intersphincteric fistulas (Wilcoxon Signed Rank test). Pre-operative continence scores were median 0, range 0 – 17, with post-operative continence scores median 0, range 0 – 17. The patients with trans-sphincteric fistulas also had no significant difference in peri-operative continence scores with pre-operative median 1, range 0 – 23 and post-operative median 3, range 0 – 24. Although the overall continence scores are not significantly different it can be seen from Figures 1a and 1b (where black is deterioration and grey score improvement) that in patients with intersphincteric fistula continence score deteriorated in 6 patients and improved in 4; in patients with trans-sphincteric fistula continence deteriorated in 7 and improved in 8 patients. Again, this is at 3 month follow up and longer follow up may show a difference.

For the groups of patients with intersphincteric fistulas QOL overall improved in the domains of Bodily Pain ($p < 0.01$), Vitality ($p < 0.05$), Role-Emotional ($p < 0.05$) and Mental Health ($p < 0.05$). Patients with trans-sphincteric fistula had no significant difference in QOL post fistulotomy, neither an improvement nor deterioration was seen.

Figure 2

Overall, continence score remained the same in 19 patients, 15 patients had an improvement in continence with a median change in this group of -3.5, range -1 to -11. A deterioration in continence score occurred in 18 (34%) with a median change in score 3, range 1 to 11. To examine for differences in outcome, the data were divided into Group A, 34 patients with no deterioration in continence; and Group B, 18 patients with a continence deterioration. The fistula classification were similar in the two groups; Group A had 14 patients with intersphincteric fistulas and 18 patients with trans-sphincteric, 1 superficial fistula, (incomplete data in 1). Group B 7 patients with intersphincteric and 7 patients with trans-

sphincteric fistulas, 1 superficial fistula (incomplete data in 3). In Group A QOL improved significantly in the domains of Bodily Pain ($p < 0.005$), Vitality ($p < 0.005$) and Mental Health ($p < 0.05$). In Group B median continence score change was 3, range 1 - 11, there was a significantly improved QOL post-operatively in the domains of Bodily Pain ($p < 0.05$) and Mental Health ($p < 0.001$).

Comparing the post-operative SF-36 scores of Group A with Group B, no significant difference was found in QOL across all 8 domains (Mann-Whitney U test). Within Group B, 12 patients had small changes in continence score from 1 - 4 points and 6 patients had a deterioration of 5 or more points. There was a significant difference in the two groups where the post-operative SF-36 data were divided at continence score change of less than 4 points and compared. Although the numbers are small, a significant difference in SF-36 scores is seen comparing minor (change of 1 - 4) with major (5 or more) change in continence score across 5 domains (Mann-Whitney U test): Physical Functioning ($p < 0.01$), Role-Physical ($p < 0.05$), Vitality ($p < 0.01$), Social Functioning ($p < 0.001$) and Role-Emotional ($p < 0.001$).

Figure 3

With the caveat that this is a sub-group of a sub-group it is interesting to examine in detail the six patients with the largest change in continence score. The individual continence score deterioration for these patients was 5, 7, 8, 8, 8 and 11. There was no statistically significant difference in SF-36 scores when comparing pre-operative and post-operative scores. Reviewing the charts for trends, when the patient with the worse continence score deterioration is excluded, some domains remain the same, and some improve. This is particularly seen the domains of Bodily Pain and Mental Health ($P = 0.06$ using Wilcoxon Signed rank test).

Figure 4

In addition, examining the SF-36 scores for the patient who had the worse continence score deterioration of 11 points, shows an overall deterioration in QOL, scoring zero for Role-Physical, Social Functioning and Role-Emotional. It must however be born in mind that the numbers are small.

Figure 5

Discussion

In this study QOL was reduced in patients with anal fistula and significantly improved following fistulotomy, including those patients with a small continence disturbance of 1 - 4 points. Patients with a continence deterioration of 5 or more points had a reduction in QOL compared to those with a change of 1 - 4 points. Accepting the very small numbers, review of patients with a greater reduction in continence of 5 - 8 points had no significant change comparing pre- to post-operative QOL scores with some trend to improved QOL, the patient with the greatest reduction in continence of 11 points had a reduction in QOL.

Patients with intersphincteric fistulas had improved QOL post fistulotomy. Those with trans-sphincteric fistulas did not have a deterioration in QOL where continence disturbance was small. These results are a three months follow up and a further review may detect changes.

The work in the literature specifically examining the question of quality of life and anal fistula uses a variety of assessment tools²⁷ and some use continence as a surrogate measure for QOL rather than a specific QOL questionnaire. One study examined patient satisfaction post-fistulotomy¹¹ and found a reduction in patients who experienced reduced continence, and those who developed recurrence. The "Faecal Incontinence Severity Index" (FISI) was

devised²⁸ and validated¹⁰, then used to predict QOL following fistula surgery⁹ deducing that Quality of life measures strongly correlated with FISFI. However, to examine for factors that affect QOL in fistula surgery²⁹ a questionnaire was sent to patients and surgeons; surgeons valued continence above cure, whereas patients valued independent activity as the highest priority with leakage lower down, suggesting that functional impairment and QOL do not necessarily correlate. It could be argued that the SF-36 is not specific to gastrointestinal disease and therefore not able to detect quality of life disturbance related to GI disease. However, the authors of this study intentionally used the SF-36 as it is one of the most widely used quality of life assessment tools in healthcare, includes pain, ability to perform tasks, and social functioning, therefore an overall reflection of global quality of life. Other assessment tools in development may aid further analysis of QOL.

In this study data were collected prospectively however there are limitations in that patients were pre-selected for fistulotomy based on clinical assessment prior to being entered into the study. A limited number of patients had a reduction in continence in this study, subsequently there were not enough data to determine at what level of incontinence QOL was adversely affected, however, patients with a continence score change of greater than 5 points on the St Mark's Continence Score reflected in a worse post-operative QOL. No recurrence was detected at 3 month follow up; this was a short term follow up and longer follow up may detect recurrence, which may affect long term QOL.

The outcomes of anal fistula surgery are measured by the incidence of continence disturbance and recurrence. Continence is reported in most series when discussing anal fistula, differing scoring systems are used depending on local practice^{21 30}. There have been many advances in fistula surgery with the aim of curing anal fistula whilst maintaining continence, however, the recurrence rates are high, overall around 60%. This QOL study excluded patient with

multiple previous attempts at cure and complex anal fistula, the QOL and continence for this group of patients is reportedly worse than for those patients in whom primary fistulotomy was successful³¹.

In this study QOL significantly improved following fistulotomy and returned to that of the general population where continence deterioration was small, similar results have been found using SF-36 for other benign anorectal conditions such as haemorrhoid surgery³² and anal fissure³³. Using a GI disease specific QOL questionnaire the GIQLI³⁴, a similar result has been found with patients undergoing surgery for recurrent fistula³⁵, suggesting that the benefits of successful surgery may outweigh the risks of reduced continence. When investigating QOL in anal fistula surgery is it important to assess both QOL and continence, continence should not be considered the sole assessment, or as a surrogate for QOL, as patients with a small reduction in continence may not have a reduced QOL. However further work needs to be done before continence change and QOL following fistulotomy can be determined pre-operatively.

References

1. Marks CG, Ritchie JK. Anal fistulas at St Mark's Hospital. *Br J Surg* 1977;64:84-91.
2. Ewerth S, Ahlberg J, Collste G, Holmstrom B. Fistula-in-ano. A six year follow up study of 143 operated patients. *Acta Chir Scand Suppl* 1978;482:53-5.
3. Eisenhammer S. The anorectal fistulous abscess and fistula. *Dis Colon Rectum* 1966;9:91-106.
4. Owen HA, Buchanan GN, Schizas A, Cohen R, Williams AB. Quality of life with anal fistula. *Ann R Coll Surg Engl* 2016;98:334-8.

5. Shouler PJ, Grimley RP, Keighley MR, Alexander-Williams J. Fistula-in-ano is usually simple to manage surgically. *Int J Colorectal Dis* 1986;1:113-5.
6. Lunniss PJ, Kamm MA, Phillips RK. Factors affecting continence after surgery for anal fistula. *Br J Surg* 1994;81:1382-5.
7. Garcia-Aguilar J, Belmonte C, Wong WD, Goldberg SM, Madoff RD. Anal fistula surgery. Factors associated with recurrence and incontinence. *Dis Colon Rectum* 1996;39:723-9.
8. Rothbarth J, Bemelman WA, Meijerink WJ, et al. What is the impact of fecal incontinence on quality of life? *Dis Colon Rectum* 2001;44:67-71.
9. Cavanaugh M, Hyman N, Osler T. Fecal incontinence severity index after fistulotomy: a predictor of quality of life. *Dis Colon Rectum* 2002;45:349-53.
10. Rockwood TH, Church JM, Fleshman JW, et al. Fecal Incontinence Quality of Life Scale: quality of life instrument for patients with fecal incontinence. *Dis Colon Rectum* 2000;43:9-16; discussion -7.
11. Garcia-Aguilar J, Davey CS, Le CT, Lowry AC, Rothenberger DA. Patient satisfaction after surgical treatment for fistula-in-ano. *Dis Colon Rectum* 2000;43:1206-12.
12. Williams JG, Farrands PA, Williams AB, et al. The treatment of anal fistula: ACPGBI position statement. *Colorectal Dis* 2007;9 Suppl 4:18-50.
13. Aguilar PS, Plasencia G, Hardy TG, Jr., Hartmann RF, Stewart WR. Mucosal advancement in the treatment of anal fistula. *Dis Colon Rectum* 1985;28:496-8.
14. Schouten WR, Zimmerman DD, Briel JW. Transanal advancement flap repair of transsphincteric fistulas. *Dis Colon Rectum* 1999;42:1419-22; discussion 22-3.
15. Lawes DA, Efron JE, Abbas M, Heppell J, Young-Fadok TM. Early experience with the bioabsorbable anal fistula plug. *World J Surg* 2008;32:1157-9.

16. Champagne BJ, O'Connor LM, Ferguson M, Orangio GR, Schertzer ME, Armstrong DN. Efficacy of anal fistula plug in closure of cryptoglandular fistulas: long-term follow-up. *Dis Colon Rectum* 2006;49:1817-21.
17. Yassin NA, Hammond TM, Lunniss PJ, Phillips RK. Ligation of the intersphincteric fistula tract in the management of anal fistula. A systematic review. *Colorectal Dis* 2013;15:527-35.
18. Thomson JP, Ross AH. Can the external anal sphincter be preserved in the treatment of trans-sphincteric fistula-in-ano? *Int J Colorectal Dis* 1989;4:247-50.
19. Kennedy HL, Zegarra JP. Fistulotomy without external sphincter division for high anal fistulae. *Br J Surg* 1990;77:898-901.
20. Buchanan GN, Owen HA, Torkington J, Lunniss PJ, Nicholls RJ, Cohen CR. Long-term outcome following loose-seton technique for external sphincter preservation in complex anal fistula. *Br J Surg* 2004;91:476-80.
21. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut* 1999;44:77-80.
22. Garratt AM, Ruta DA, Abdalla MI, Buckingham JK, Russell IT. The SF36 health survey questionnaire: an outcome measure suitable for routine use within the NHS? *Bmj* 1993;306:1440-4.
23. Lawrence K, McWhinnie D, Jenkinson C, Coulter A. Quality of life in patients undergoing inguinal hernia repair. *Ann R Coll Surg Engl* 1997;79:40-5.
24. Ko CY, Rusin LC, Schoetz DJ, Jr., et al. Does better functional result equate with better quality of life? Implications for surgical treatment in familial adenomatous polyposis. *Dis Colon Rectum* 2000;43:829-35; discussion 35-7.
25. Quintana JM, Cabriada J, Arostegui I, Lopez de Tejada I, Bilbao A. Quality-of-life outcomes with laparoscopic vs open cholecystectomy. *Surg Endosc* 2003;17:1129-34.

26. Jenkinson C, Coulter A, Wright L. Short form 36 (SF36) health survey questionnaire: normative data for adults of working age. *Bmj* 1993;306:1437-40.
27. Visscher AP, Schuur D, Roos R, Van der Mijsbrugge GJ, Meijerink WJ, Felt-Bersma RJ. Long-term Follow-up After Surgery for Simple and Complex Cryptoglandular Fistulas: Fecal Incontinence and Impact on Quality of Life. *Dis Colon Rectum* 2015;58:533-9.
28. Rockwood TH, Church JM, Fleshman JW, et al. Patient and surgeon ranking of the severity of symptoms associated with fecal incontinence: the fecal incontinence severity index. *Dis Colon Rectum* 1999;42:1525-32.
29. Wong S, Solomon M, Crowe P, Ooi K. Cure, continence and quality of life after treatment for fistula-in-ano. *ANZ J Surg* 2008;78:675-82.
30. Jorge JM, Wexner SD. Etiology and management of fecal incontinence. *Dis Colon Rectum* 1993;36:77-97.
31. Sygut A, Zajdel R, Kedzia-Budziewska R, Trzcinski R, Dziki A. Late results of treatment of anal fistulas. *Colorectal Dis* 2007;9:151-8.
32. Bouchard D, Abramowitz L, Castinel A, et al. One-year outcome of haemorrhoidectomy: a prospective multicentre French study. *Colorectal Dis* 2013;15:719-26.
33. Tsunoda A, Kashiwagura Y, Hirose K, Sasaki T, Kano N. Quality of life in patients with chronic anal fissure after topical treatment with diltiazem. *World J Gastrointest Surg* 2012;4:251-5.
34. Sailer M, Bussen D, Debus ES, Fuchs KH, Thiede A. Quality of life in patients with benign anorectal disorders. *Br J Surg* 1998;85:1716-9.
35. Seneviratne SA, Samarasekera DN, Kotalawala W. Quality of life following surgery for recurrent fistula-in-ano. *Tech Coloproctol* 2009;13:215-7.

Figure 1a and 1b Continece Score Change for individual patients

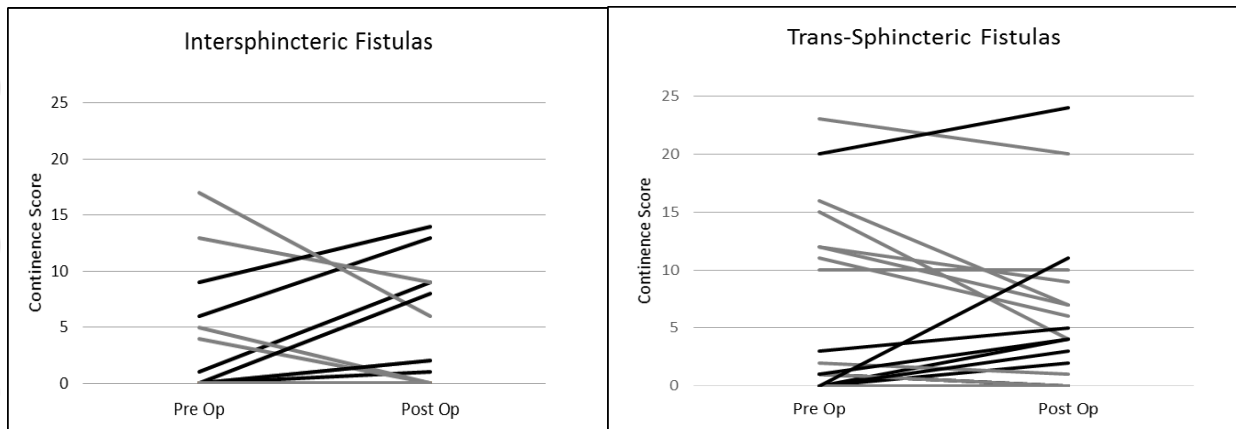
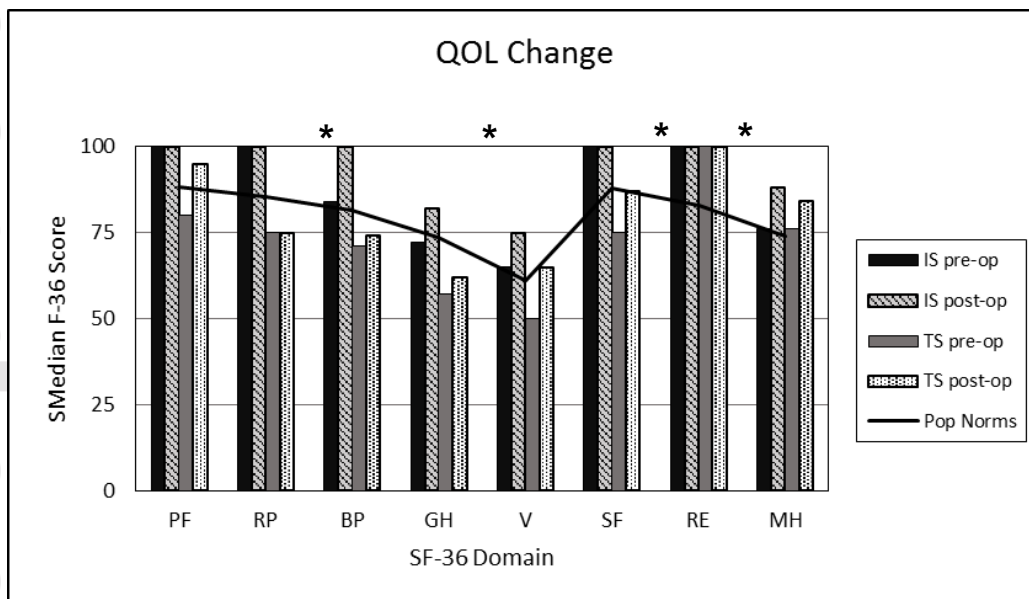


Figure 2 QOL Intersphincteric (IS) and Trans-Sphincteric (TS) Fistulas

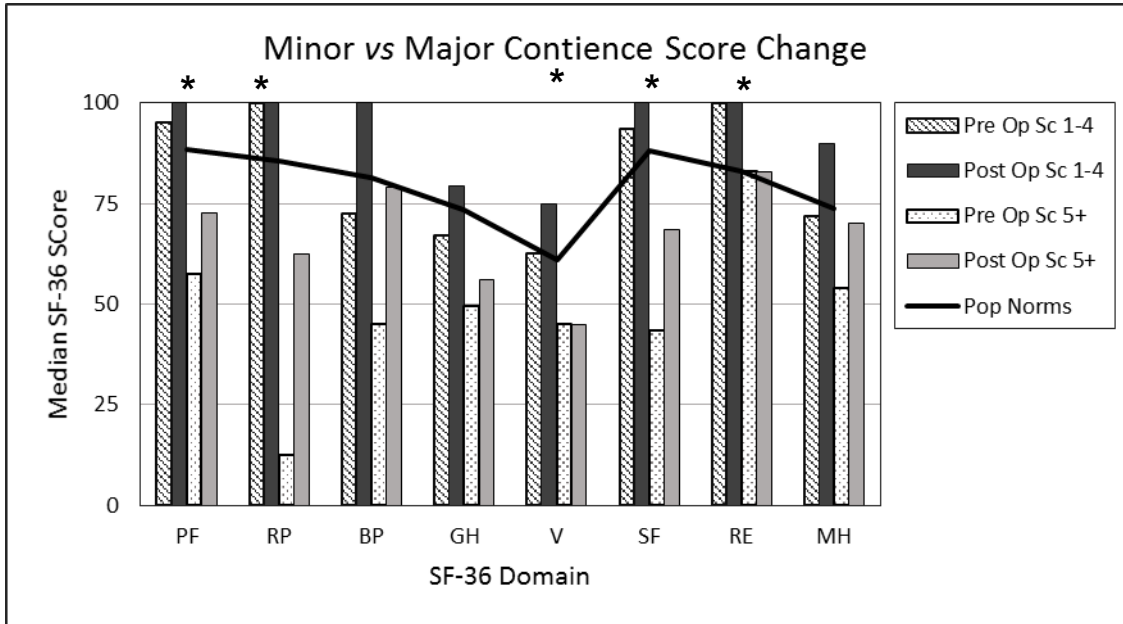
*p<0.05 Wilcoxon



Key
 PF - Physical Functioning
 RP - Role Physical
 BP - Bodily Pain
 GH - General Health
 V - Vitality
 SF - Social Functioning
 RE - Role Emotional
 MH - Mental Health

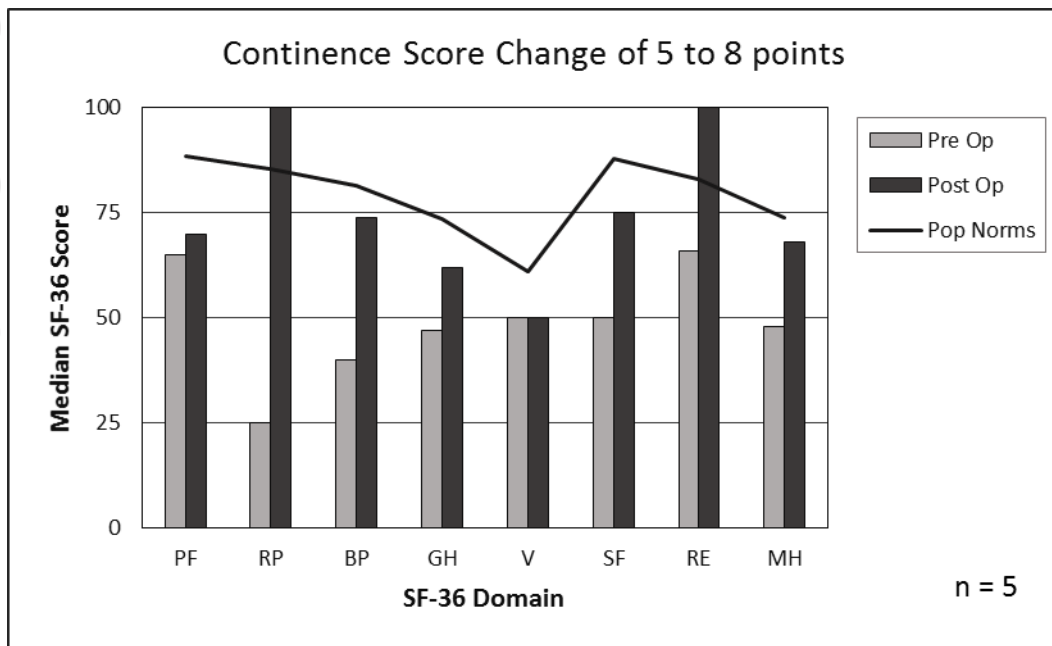
Figure 3 Minor vs Major Contience Score (Sc) Change

*P<0.05 Mann-Whitney U comparing post op scores



Key
PF - Physical Functioning
RP - Role Physical
BP - Bodily Pain
GH - General Health
V - Vitality
SF - Social Functioning
RE - Role Emotional
MH - Mental Health

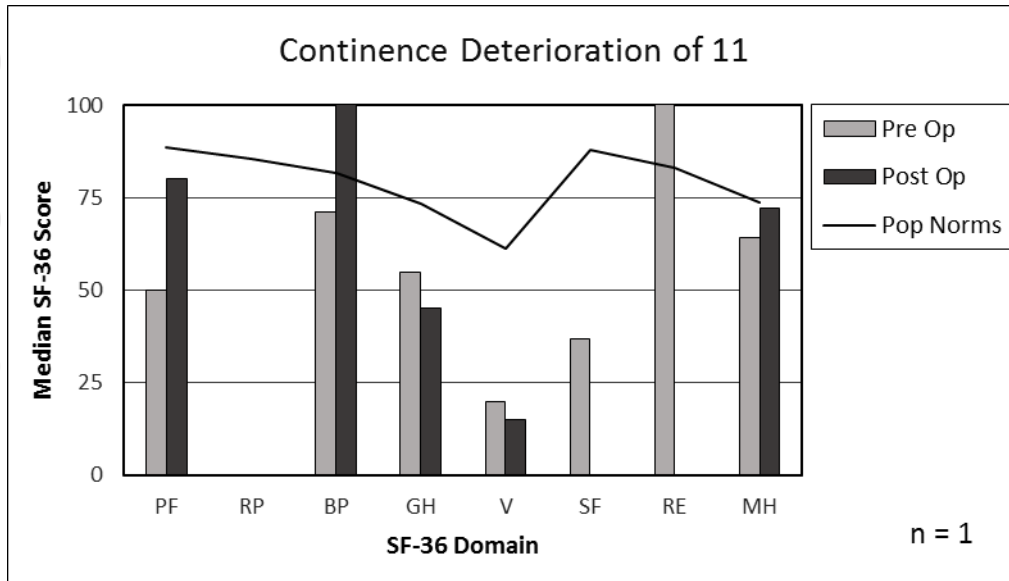
Figure 4 Continenence Score deterioration 5 or more points.



Key

- PF - Physical Functioning
- RP - Role Physical
- BP - Bodily Pain
- GH - General Health
- V - Vitality
- SF - Social Functioning
- RE - Role Emotional
- MH - Mental Health

Figure 5 Patient with the greatest deterioration in continence, score of zero for RP, SF and RE.



Key
PF - Physical Functioning
RP - Role Physical
BP - Bodily Pain
GH - General Health
V - Vitality
SF - Social Functioning
RE - Role Emotional
MH - Mental Health