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Consensus Statement

## **Association of Coloproctology of Great Britain and Ireland Consensus Exercise on Surgical Management of Fistulating Perianal Crohn's Disease**

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**Abstract****Background**

Management of fistulating perianal Crohn's disease (fpCD) is a significant challenge for a colorectal surgeon. A recent survey of surgical practice in this condition showed variation in management approaches. As a result we set out to devise recommendations for practice for UK colorectal surgeons.

**Methods**

Results from a national survey were used to devise a set of potential consensus statements. Consultant colorectal surgeons were invited to participate in the exercise via the previous survey and the mailing list of the professional society. Iterative voting was performed on each statement using a 5-point Likert scale and electronic voting, with opportunity for discussion and refinement between each vote. Consensus was defined as agreement >80%.

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## Results

Seventeen surgeons and two patient representatives voted upon 51 statements. Consensus was achieved on 39 items. Participants advocated a patient centred approach by a colorectal specialist, within strong multidisciplinary team-working. The use of anti-TNF $\alpha$  therapy is advocated. Where definitive surgical techniques are considered, they should be carefully selected to avoid adverse impact on function. Ano- and rectovaginal fistulae should be managed by specialists in fistulating disease. Stoma or proctectomy could be discussed earlier in a patient's treatment pathway to improve choice, as they may improve quality of life.

## Discussion

This consensus provides principles and guidance for best practice in managing patients with fistulating perianal Crohn's Disease.

## What this paper adds to the literature

This manuscript reports a consensus exercise on the surgical management of fistulating perianal Crohn's disease and proposes a patient centred approach to select an appropriate treatment strategy, as well as sphincter-preserving and multi-disciplinary management.

## Background

Crohn's disease has been associated with perianal fistulation since the condition was first described, with around 33% of Crohn's patients affected (1). Management of fistulating perianal Crohn's disease (fpCD) presents particular challenges related to heterogeneity in presentation and disease course, and the need for long-term immunosuppressive medical therapy and multiple surgical interventions. (2, 3). There is wide variation both in surgical treatments offered for fpCD and in outcomes following surgery. Recognition of the chronicity of fpCD and its potential negative impact on quality of life for patients has resulted in it being identified as a research priority by the James Lind Alliance and the Association of Coloproctology of Great Britain and Ireland (ACPGBI) (4, 5).

A recent UK wide survey of surgical management of fpCD indicated that some areas of practice had common themes, including antibiotic choice, imaging modalities and use of draining setons. There was variation in other aspects of management such as optimisation of multimodal care and selection of definitive surgical procedures(6).

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Given the lack of level I evidence in surgical management, the aim of this exercise was to establish UK expert consensus on surgical management of fpCD.

## Methods

Potential statements for inclusion in the consensus were developed by an expert group of colorectal surgeons and gastroenterologists with specialist interest in managing inflammatory bowel disease (IBD). All statements were based on a literature review and responses to a wide sampling through use of a questionnaire (6). Statements were considered in five principal areas of practice: i) context, ii) assessment and management of an acute presentation of fpCD, iii) operative and perioperative practice in the elective setting, iv) multidisciplinary management and v) definitive surgical management.

Participants in the consensus were invited as they had indicated interest in contributing through completion of the questionnaire or following invitation and advertisement via the professional society, ACPGBI.

Each statement was presented to the group of experts, and an initial vote undertaken electronically using ResponseCard® (Turning Technologies, UK), allowing contemporaneous but anonymous recording of votes visible to participants. The initial vote was followed by debate amongst experts and refinement of the wording of the consensus statement prior to a reiterative second vote. Voting was undertaken using a five-point Likert scale, ranging from 'strongly disagree' to 'strongly agree'.

Consensus was achieved when more than 80% of respondents voted in agreement (either agree or strongly agree). Participants could change their final vote right up until closing of that vote once all votes were cast.

Weighting was attached to each statement based on the available evidence and strength of recommendation. This classification was based upon modified GRADE criteria, as used in other consensus documents (7, 8). In summary, this method ranks recommendations as '1' (strong) or '2' (weak). These are modified with a letter to indicate the level of evidence supporting this. 'A' denotes high quality evidence such as a well-conducted randomised controlled trial or meta-analysis. 'B' identifies moderate quality evidence such as a non-randomised trial or prospective study. 'C' identifies low quality evidence such as retrospective studies or case series. 'D' is used where expert opinion supports the recommendation. The consensus process is summarised in Figure 1.

This exercise was registered with the University of Sheffield ethics committee (Approval ref:007386)

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## Results

The consensus group consisted of 17 Consultant Colorectal surgeons and two patient representatives. The colorectal surgeons had an interest in inflammatory bowel disease. The patient representatives had engaged with the ACPGBI Delphi process and regularly shared experiences of patients treated for aspects of inflammatory bowel disease, including fPCD. A total of 51 statements were considered. Responses to accepted statements are presented below, along with the results of the final vote (SA – Strongly Agree, A – Agree, N – Neutral, D – Disagree, SD – Strongly Disagree). Rejected statements are summarised after each section, along with reasons for rejection.

### Context – Accepted Statements

*Fistulating perianal Crohn's disease is frequently a chronic condition. 1A*

SA: 82% A: 6% N: 0% D: 0% SD: 12%

It is recognised that patients with fistulating perianal Crohn's disease may heal, although the majority of patients will have recurrent or non-healing fistulating disease(2). This typically requires long-term medical therapy and repeated surgical procedures(3).

*Management of fpCD should take a patient-centred approach. 1C*

SA: 94% A: 6% N: 0% D: 0% SD: 0%

The preferences of surgeons and patients in surgical treatments have been shown not to align in some aspects of Crohn's disease (9). Due to the chronic nature of the disease, treatments should be tailored to the needs and goals of each patient. Some patients may prefer symptom palliation while others may aim for definitive management aimed at fistula eradication. These choices and patient-selected outcomes should be respected and addressed using shared decision-making (10).

#### ***Prognostic factors for successful healing include:***

*Absence of proctitis. 1A. SA: 61% A: 39% N: 0% D: 0% SD: 0%*

*Short duration of fistulating disease. 1C. SA: 28% A: 67% N: 0% D: 6% SD: 0%*

*Non-smoking status. 1C. SA: 67% A: 33% N: 0% D: 0% SD: 0%*

*'Simple' fistula. 1C. SA: 44% A: 56% N: 0% D: 0% SD: 0%*

#### ***Prognostic factors for failure of healing include:***

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*Proctitis. 1A. SA: 72% A: 28% N: 0% D: 0% SD: 0%*

*Active smoking status. 1C. SA: 67% A: 28% N: 6% D: 0% SD: 0%*

*'Complex' fistula. 1C. SA: 67% A: 33% N: 0% D: 0% SD: 0%*

Prognostic factors for healing and failure of healing have been identified in studies ranging from retrospective cohort studies to prospective trials. Proctitis is a predictor for proctectomy in a number of retrospective studies (11, 12). Complex fistulae (i.e. those which are **not** either short ,or consisting of low tracks as per the American Gastroenterology Association classification) (13), are associated with poor healing rates. Smoking status has an impact on the overall activity of Crohn's disease, increasing the rate of relapse (14). The duration of fistulating disease reflects the perception that it may be easier to manage a 'fresh' fistula rather than a well-established, fully epithelialized fistula. This has been identified as a significant prognostic factor in an open label study, where it was treated as a continuous variable with no predictive cut-off reported(15). Despite the importance of these factors in response to treatment, randomised controlled trials have not undertaken adequate stratification to mitigate effects across treatment arms (16, 17). It is worth noting that the ongoing PISA trial has specifically included early seton removal in both interventional arms(18)again suggesting that clinicians place importance on likelihood of successful treatment if fistulae are of relatively recent onset.

#### **Acute Management – Accepted Statements**

*Perioperative metronidazole should be used in selected cases in the acute setting. 1B*

*SA: 60% A: 40% N: 0% D: 0% SD: 0%*

The majority of the literature assesses both ciprofloxacin and metronidazole (19). The consensus group preferred to use metronidazole, in line with survey results(6). This may reflect UK antibiotic practice and avoidance of ciprofloxacin due to its causative link with *Clostridium difficile* infection(20), although this is thought to be lower in CD populations than other populations (21). Ciprofloxacin has been used in the longer term as an adjunct to anti-TNF therapy in fpCD, although this has had varied results (22, 23). The consensus group did not advocate antibiotics in all patients presenting acutely with fpCD. The specific circumstances where the consensus group would recommend antibiotics were in the presence of local cellulitis or induration, systemic sepsis, immunosuppression, or where there might be a delay before drainage of sepsis.

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*Acute operative management should involve drainage of any abscess. 1B*

SA: 88% A: 12% N: 0% D: 0% SD: 0%

*An experienced colorectal surgeon should consider placing draining seton(s) in readily identifiable fistulae. 1B*

SA: 69% A: 25% N: 6% D: 0% SD: 0%

Sepsis control is the principal aim of surgical drainage in the acute setting, and therefore drainage of any abscess is advised. If fistulae are readily identifiable, then a seton should be placed acutely at the time of abscess drainage(24). In this setting, tissue is potentially friable and oedematous and there is an increased risk of creating false tracks (25). Given this, the expert agreement was that only those with appropriate experience should place a seton in this setting.

*Cutting setons should not be used in perianal Crohn's disease. 1D*

SA: 81% A: 19% N: 0% D: 0% SD: 0%

Historically prevalent, and occasionally still used in fistula surgery, the cutting seton was rejected for use in fpCD by the consensus group. This corresponds with current UK practice;90% of surgeons would never consider a cutting seton in this setting (6). Due to the nature of the disease and recurrent procedures, cutting setons were felt to carry unacceptably high risk of future incontinence(26).

#### **Acute Management - Rejected statements**

*Selected patients should undergo an MRI scan preoperatively*

SA: 0% A: 63% N: 19% D: 13% SD: 6%

*The seton material of choice is a silastic sling*

SA: 13% A: 13% N: 31% D: 38% SD: 6%

The consensus group felt that whilst a 'road-map' MRI might be useful, the primary aim in this setting was control of sepsis and that this should not be delayed. Responses to seton choice in the survey were heterogenous. Participants in the consensus indicated use of Ethibond®, silastic slings and Comfort drains™ (CJ Medical, Truro, UK)(6).

#### **Initial Elective management – Accepted Statements**

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*Draining setons should be placed in fistula tracks at first elective Examination Under Anaesthesia. 1A*

SA: 31% A: 69% N: 0% D: 0% SD: 0%

The use of draining setons in this setting is well described. This allows ongoing drainage of a track as a bridge to immunomodulatory therapy (27). It may not be technically possible to insert a seton in every case.

*Selected patients will require MRI of the perineum. 1C*

SA: 63% A: 31% N: 0% D: 6% SD: 0%

MRI of the perineum is the most commonly used imaging modality in UK fpCD practice (6). Precise indications for MRI did not emerge from discussions but it was apparent that not all surgeons would request MRI in all patients. Some surgeons would prefer to have imaging before undertaking an elective examination under anaesthetic, to aid localisation of fistula openings and any residual sepsis. Other surgeons indicated that they would use MRI post-operatively to assess resolution of fistula-related sepsis after placement of setons (28).

*Selected patients will require repeat examination of rectum under anaesthetic. 1D*

SA: 81% A: 19% N: 0% D: 0% SD: 0%

A second examination may be of benefit in a patient with on-going symptoms, or those where it was not possible to place draining setons at first operation. An experienced colorectal surgeon is usually able to define fistulae and control sepsis, a pre-requisite to biologic therapy (29, 30).

*Presence or absence of proctitis should be established with diagnosis of perianal Crohn's fistula. 1B*

SA: 100% A: 0% N: 0% D: 0% SD: 0%

Proctitis is felt to be a prognostic indicator for successful management of fpCD and presence of proctitis requires focus of attention on disease control with immunomodulation (31-33). As such, presence or absence of proctitis should be confirmed at the first opportunity following diagnosis.

*If Crohn's disease is suspected, then diagnostic confirmation should be sought with colonoscopy and/or imaging 1B*

SA: 88% A: 12% N: 0% D: 0% SD: 0%

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Colonoscopy can be used to assess for proctitis, and also the terminal ileum for evidence of Crohn's disease. This may be useful in cases where perianal fistula is the first presentation of IBD. Choices for cross-sectional imaging typically include CT to assess for terminal ileal pathology, or MRI small bowel series to confirm the phenotype of disease (34). Despite the reported performance of faecal calprotectin (35), variation in levels based on location of disease (36) and the reported sensitivity to other causes of inflammation in the gut meant that it was not recommended in this setting .

### **Multidisciplinary management**

*All patients with perianal Crohn's disease should be discussed in a multidisciplinary setting. 1D*

SA: 94% A: 6% N: 0% D: 0% SD: 0%

*All surgeons managing perianal Crohn's disease should use a multidisciplinary approach. 1A*

SA: 94% A: 6% N: 0% D: 0% SD: 0%

Current best practice in fpCD management uses both medicine and surgery to achieve fistula closure (27, 37, 38). In order to achieve this, it requires both surgeon and physician to work together, along with the wider multidisciplinary team (MDT) including clinical nurse specialists, pathologists and gastrointestinal radiologists. Although there is evidence for multimodal (multidisciplinary) management, there is, at present, no evidence for a formal MDT meeting in the management of these patients (38). However, it is recommended as an IBD service standard by the Royal College of Physicians(39).

*Medical therapy is best directed by a gastroenterologist. 1D*

SA: 81% A: 19% N: 0% D: 0% SD: 0%

*Surgical opinion is important in decisions about medical therapy. 1D*

SA: 69% A: 19% N: 13% D: 0% SD: 0%

In keeping with the multidisciplinary approach, medical therapy should be directed by a gastroenterologist. The surgeon may be able to offer insight on operative findings that could influence multimodal management. These should be taken into account when considering modification of therapy (38).

*Steroids should not be used in isolated perianal Crohn's disease. 1B*

SA: 69% A: 31% N: 0% D: 0% SD: 0%

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There is no evidence for the use of systemic steroid therapy in the treatment of fpCD alone. Steroids may be useful to treat other sites of luminal inflammation in these patients (40).

*Multidisciplinary discussion about anti-tumour necrosis factor- $\alpha$  therapy should occur promptly after sepsis control. 1B*

SA: 75% A: 25% N: 0% D: 0% SD: 0%

Whilst there is no body of evidence on timing of biologic therapy, use of biological agents including anti-TNF- $\alpha$  agents, is considered to be an important aspect of successful symptom control in fpCD (41-43). This is already recognised by the majority of surgeons managing this condition (6). Biological therapy should be addressed soon after control of sepsis and may avoid unnecessary delay in healing.

*Timing of removal of a seton should be a multidisciplinary decision involving the patient. 1D*

SA: 41% A: 47% N: 6% D: 0% SD: 6%

*Optimal timing of seton removal after induction with anti-TNF- $\alpha$  therapy has not yet been established. 1A*

SA: 56% A: 39% N: 0% D: 6% SD: 0%

A number of factors may influence seton use including the anatomy of the track, patient symptoms and therapeutic intent (palliation of symptoms vs. closure of fistula tracks). At present, the evidence base has not defined the optimum time for seton removal. Previous work has discussed the timing of seton removal in relation to induction with biologic therapy (28, 44). Typically reported management in the surgical survey(6) preferred the previously reported strategy of seton removal around the second dose of anti-TNF therapy(45). Given the degree of uncertainty, decision-making should be guided by clinicians, but shared with the patient.

#### **Multidisciplinary Management - Rejected statements**

*Further surgical management should be undertaken by a core member of the IBD multidisciplinary team.*

SA: 13% A: 38% N: 6% D: 25% SD: 19%

The definition of an IBD MDT was felt to be inadequately established, such that defining a 'core member' would be problematic.

### **Definitive Surgical Management – accepted statements**

*Sphincter preserving techniques should be used in a stepwise fashion based on functional risk. 1C*

SA: 61% A: 39% N: 0% D: 0% SD: 0%

With repeated surgical procedures and metachronous fistulae, options for surgical management should be considered in light of their likelihood of success and impact on immediate and future continence. Selection of initial procedures aimed at healing should weigh up success rate against risk of incontinence in the context of patient preference, with individual patient trade-off preferences guiding therapy, rather than clinician selection (9).

In many patients, long-term management with a seton may be an acceptable option (27). This provides symptomatic relief and carries little risk to continence. It may avoid repeated surgery in up to 90% of patients (46).

*Secondary tracks should be successfully treated before definitive surgical management of primary tracks. 1D.*

SA: 39% A: 50% N: 6% D: 0% SD: 6%

For the purposes of this consensus, the following definitions were used: a primary track has an internal opening in anorectum and an external opening on the perineum; a secondary track has an external opening on the perineum but does not have an opening into the anorectum but rather communicates indirectly via a primary track; a secondary tract is the blind sinus or sideways branch off either. Closure of a primary track may impede drainage of a secondary tract, leading to further abscess formation and recurrent symptoms. Secondary tracks should be addressed prior to closure of the primary or 'feeding' track. This will ensure clearance of residual sepsis and diminish chances of failure in treating the primary track(47). In some cases, treatment of the secondary track may be as simple as seton removal in a patient on biological therapy. It was also emphasised that surgery for the secondary track could be carried out immediately prior (ie under the same anaesthetic) to surgery on the primary track, and may include procedures such as drainage, laying open, seton removal or insertion of anal fistula plug.

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*Fistula plug is a continence preserving option in perianal Crohn's disease. 1B*

*SA: 47% A: 37% N: 16% D: 0% SD: 0%*

Anal fistula plug (AFP) for fpCD has been described in several papers. A recent meta-analysis reported complete closure in 58.3% of patients, with little change in continence (48). A subsequent RCT was performed using this therapy in fpCD and achieved closure in 31.5% of patients at 12 weeks(16). In this study 54 Crohn's patients underwent an anal fistula plug, with fistula closure at 12 weeks achieved in 31.5%. The closure rate was similar to that achieved with seton removal alone (RR 1.31 95% CI 0.59-4.02; p=0.19). This study excluded patients with proctitis but included both complex and simple fistula treated. Complexity of fistula was not associated with outcome. In review of source material, abscess formation occurred in 3.7-53.8% of patients(49-52). Additional complications included one wound dehiscence(51), five plug extrusions and two episodes of significant perianal pain(52).

There is a conflict between the meta-analysis and RCT data that is reflected in the acceptance of the consensus agreement that the anal fistula plug may still have a role. The meta-analysis included both prospective non-randomised cohorts and retrospective cohort data. It is likely that these patients were entered based on clinician preference and reflect 'real world' data, although results may be affected by the relatively small sample sizes, and bias towards reporting favourable results. There is also limited data on the co-incident medical therapy in these studies. The RCT was selective in certain aspects (absence of rectal disease) and less prescriptive in others (fistula anatomy not standard). This could mean that patients were entered into the study who may not have received a fistula plug based on clinician preference. It is plausible that fistula plug offers benefit in some anatomical configurations, but not others (e.g. simple vs complex, long vs short track). Whilst the evidence for this intervention is not overwhelming, there are relatively few reports of complications. Coupled with the minimal invasiveness, a fistula plug may be considered an acceptable option for the treatment of this condition.

*Permacol™ paste (Covidien, Mansfield, MA), Over the scope clip (OTSC®, Ovesco Endoscopy AG, Germany), FiLaC® (Fistula Laser assisted Closure Biolitec AG, Jena, Germany) and autologous stem cells may have potential as continence preserving techniques. 2C*

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SA: 42% A: 58% N: 0% D: 0% SD: 0%

These therapies have been used in Crohn's disease in small numbers, with success rates of 54%, 83%, 71% and 57% respectively, and little in the way of adverse outcomes (53-55). As yet, no large randomised controlled trials have reported on their use in fpCD. Only a small number of UK surgeons regularly use these emerging technologies in clinical practice (6).

The results of a randomised controlled trial of autologous stem cells versus a control of physiological saline, both with sutured closure of the internal fistulous opening in patients maintained on biological therapy, has been published since the consensus, with results significantly favouring the use of autologous stem cells, even in the context of a high rate of fistula closure in the control arm(56).

*Advancement flap is a treatment option in perianal Crohn's disease. 1C*

SA: 32% A: 58% N: 0% D: 0% SD: 11%

Eight retrospective(57-64) and two prospective observational studies(65, 66) reported the outcome of mucosal advancement flaps in both Crohn's and idiopathic perianal fistulous disease. Of the 624 reported procedures, 240 of these were performed for Crohn's fistula. Success in short term healing was seen in 50.0%-85.0% of patients. Where reported, recurrence at >1 year was 30.0%-50.0%(59, 65). Complications were reported in only one study, with occurrence of haemorrhage and flap retraction occurring in 6.6%(58). The experience of endoanal advancement flap in CD was summarised by Soltani et al in 2010 (67). They found a success rate of 64%, with incontinence rates at 9.4% in fpCD.

Selection criteria for these procedures typically avoided proctitis, but there was no consistent reporting on medical therapy required to induce favourable local conditions, nor was there reporting on the medical therapies required to maintain favourable conditions and support healing post-operatively. Therefore, consideration of this procedure should be tempered by the potential impact of concomitant medical therapy and disease activity, as well as potential for impaired continence in a patient group who prioritise preservation of continence.

Further (high-quality) information may be gained from the current PISA trial, which incorporates endoanal advancement flap as one of the intervention arms (18). On current evidence an advancement flap might be considered in the absence of proctitis, significant fibrosis or stricturing disease.

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*Ano/recto-vaginal fistulae will rarely heal on anti-TNF- $\alpha$  therapy alone. 1A*

*SA: 32% A: 63% N: 5% D: 0% SD: 11%*

*Definitive treatment of ano/recto-vaginal fistulae should be by specialist surgeons in specialist centres. 1D*

*SA: 53% A: 42% N: 0% D: 5% SD: 11%*

Ano/Recto-vaginal fistula represents a unique challenge in fpCD. Genital fistulae in Crohn's will rarely heal with biologic therapy alone (17, 68). Not all UK surgeons will manage this condition, and consequently it is managed in fewer centres with expertise in a range of operative techniques (6, 69, 70). Treatment of ano/rectovaginal fistulae should be under combined surgical and luminal gastroenterological care.

*Diverting stoma may improve quality of life for patients with perianal Crohn's disease. 1B*

*SA: 84% A: 16% N: 0% D: 0% SD: 11%*

*Faecal diversion is indicated in uncontrollable sepsis. 1C*

*SA: 63% A: 37% N: 0% D: 0% SD: 11%*

*Faecal diversion may be considered for symptom control. 1C*

*SA: 68% A: 26% N: 5% D: 0% SD: 11%*

*Faecal diversion may be considered if proctitis cannot be medically managed. 1C*

*SA: 69% A: 26% N: 5% D: 0% SD: 0%*

Use of a stoma is often considered a 'failure' by clinicians. Evidence highlights that patients affected by perianal Crohn's disease see improvement in some quality of life domains following formation of a stoma (71), and some patients have indicated that they would like to discuss this early in their treatment(72). Therefore, quality of life as reported by the patient may be an indication for stoma. Both colostomy and ileostomy have been used for this indication. Selection of stoma location should take into account distribution of disease (i.e. rectal, colonic) and previous surgery(73).

Uncontrollable or recurrent sepsis, incontinence, or ongoing discharge are indications for faecal

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diversion, although up to two thirds of patients may subsequently require further surgery including proctectomy (73, 74).

*Proctectomy provides improved symptom control and quality of life in selected patients. 1D*

SA: 84% A: 16% N: 0% D: 0% SD: 0%

This statement highlights the importance of patient priorities and their role in decision-making. As such, it might be considered early in the treatment process. Current UK practice would consider proctectomy in the face of recurrent or refractory perianal sepsis, rectal disease refractory to medical therapy, to improve quality of life or at patient request(6). As well as the indications highlighted for stoma formation, proctectomy might also be considered in patients with strictures, and cancers forming in fistula tracks (75, 76). This is not an absolute panacea as a number of patients may still have perineal morbidity and altered pelvic function, including dyspareunia in 10%(77, 78).

*There may be a role for myo-cutaneous flap-based perineal reconstruction after proctectomy for perianal Crohn's disease. 2C*

SA: 53% A: 42% N: 0% D: 5% SD: 0%

Proctectomy in the setting of severe fpCD is often associated with poor perineal healing, with delayed healing at or beyond 12 months in 58% of patients(77, 79). A retrospective study of a cohort of 145 patients who had undergone proctectomy for Crohn's disease found persistent perianal sinus in 23% of patients, and was associated with rectal involvement and faecal contamination of the surgical field. Despite numerous interventions, closure was achieved in only 9 patients(80). While a sinus may result in an occasional perineal discharge, in some the non-healing perineal wound may re-establish considerable discharge and sepsis. For this reason reconstruction with a rectus abdominis, gluteal or gracilis based myocutaneous flap should be considered (81, 82).

***Definitive Surgical Management - Rejected statements:***

*Fistulotomy has a role in perianal Crohn's disease where there is minimal sphincter division.*

SA: 17% A: 44% N: 17% D: 17% SD: 6%

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*Fibrin glue may be effective in long or complex tracks.*

SA: 0% A: 0% N: 0% D: 56% SD: 44%

*LIFT procedure is a continence preserving option in perianal Crohn's disease.*

SA: 5% A: 42% N: 42% D: 11% SD: 0%

It should be noted that there is evidence to suggest laying open of a superficial fistula is not associated with problems of healing in the large majority of patients (83), although one third of patients may have long term incontinence (84). Various permutations of this statement were discussed including 'no' and 'minimal' sphincter division. The consensus group expressed concern that without clear indications and limits to what might be laid open, patients might come to harm from repeated fistulotomy.

The evidence for fibrin glue in fpCD arises from two small trials of patients with perianal Crohn's disease. One found that fistulae closed in 38% of those treated vs 16% of controls. The second study assessed outcomes in refractory fpCD (n=14) and achieved clinical improvement in 75% of patient at 3 months, with complete healing in 57% at two years. Poor results from studies in cryptoglandular disease have tempered the enthusiasm of the consensus group for this treatment (85).

The Ligation of the Inter-Sphincteric tract (LIFT) procedure was rejected as the evidence for its' use arises from a small single centre study, where 9/15 patients treated were healed at two months (86).

The consensus group felt that this was insufficient to recommend use in fpCD. Concerns were expressed around the conversion of anatomy to intersphincteric fistula, precipitating subsequent fistulotomy. There was also concern that sphincter disruption and long term incontinence with this procedure. Despite the fact that no sphincter is divided in this procedure, there is disruption of the intersphincteric space and significant traction on the sphincters.

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## Discussion

This paper reports on a consensus meeting, describing agreed practice in the treatment of fistulating perianal Crohn's disease. Due to the likelihood of repeated procedures, conservative or continence sparing procedures are preferred in the first instance. The role of the multidisciplinary team is reinforced and the need for adjuvant medical therapy highlighted. In contrast to other guidelines on the topic, this consensus has provided practical advice for surgeons managing this condition in the UK in light of prevailing management trends. A summary of the recommended steps in management is shown in figure 2.

There are a number of contrasts and similarities with the two recent publications from the World Gastroenterology Organisation (WGO) and European Crohn's and Colitis Organisation (ECCO) (7, 87). All papers agree on 'staging' the disease by assessment of the rectum for proctitis. The WGO publication further advocates assessment of the small bowel to complete staging. The ECCO paper was published in 2010, prior to a number of relevant publications on operative approaches to fpCD. Consequently, non-cutting fistulae and/or fistulotomy are recommended for simple fistulae. Surgical therapy is advocated for complex fistulating disease, but no specific procedures are mentioned. Ano/rectovaginal fistulae are discussed, and a combined medical and surgical approach (including stoma formation) is advocated (87). The WGO consensus advocates the use of fistulotomy as a surgical procedure and suggests a number of treatments which may be considered in definitive surgical management including mucosal advancement flap, fistula plugs, LIFT and mesenchymal stem cells, and proposes a structured algorithmic approach(7). In contrast, the UK-based consensus presented here advises that procedures are selected with patient aims in mind.

The recommendations from this exercise have two key limitations or sources of bias: the participants and the information they used. The consensus group was by its nature self-selected and included surgeons with an interest in the condition. This has potential to skew results away from more nationally generalised recommendations. Despite this, none of the agreed statements show major conflict with the results of previous national survey of current practice (6). Some recommendations were undoubtedly limited by the quality of available evidence. While large trials of medical therapy have been reported, there are fewer quality trials of surgical or multimodal therapies for this condition. Consequently recommendations are based on either small trials or retrospective studies with inherent bias. These challenges have been identified in a recent review of guidelines for the management of anal fistula (88). An ongoing trial aimed at improving outcomes for patients with perianal Crohn's disease has utilised best available evidence and guidelines to optimise the

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intervention arms, but also acknowledges the relatively poor evidence base for the selected components of each pathway(18).

In making recommendations, the consensus group considered both clinical outcomes and qualitative patient-reported outcomes. The body of literature on this condition reports widely on healing rates following use of setons and biologics (27), but limited focus on qualitative data following surgery. Quality of life data comparing fpCD patients, with and without faecal diversion, show that diverted patients have better quality of life (71). There is a need to explore these aspects of care further to identify the patient benefits conferred by the various surgical options, and even consideration and discussion of diversion earlier in the patient journey than is currently offered. As highlighted following each recommendation, there is a limited evidence base from which we can draw strong recommendations and virtually no head to head comparisons of surgical therapies. It would not be appropriate to report economic data on these therapies as existent economic analyses consider 'mixed' fistula cohorts(89), ignoring the highly recurrent nature of these fistula. Surgical studies also fail to consistently report medical therapies associated with treatment, which are the main cost drivers in the treatment of perianal Crohn's disease(3).

One of the strengths of this exercise is that it recognises uncertainty and the need to involve patients in decisions about their care. Shared decision making has been investigated for patients undergoing surgery for breast and rectal cancer (90, 91). Following sepsis control, it would be appropriate to discuss the possible surgical options and relevant information to patients to support decision making (92). The management of fpCD should involve a multidisciplinary approach combining the knowledge of a gastroenterologist and colorectal surgeon who have appropriate experience. The use of best evidence should involve patients at the centre of their own care, with management of expectations considering the potential for chronicity and relapsing nature of the disease (93).

This exercise has identified areas for further research, including work around optimum timing of seton removal and, by extension, timing of biologic therapy. The wide range of surgical procedures available reflects lack of evidence of their efficacy, but may also reflect heterogeneity within the disease. We are also lacking data to enable us to make robust judgements on the cost effectiveness of surgical options. Further work to understand this could take the form of clinical trials, and should include assessment of patient preferences and choices in decision-making, quality of life and functional outcome at several time-points, as well as objective and subjective healing outcomes. This consensus exercise should be repeated at a future date when stronger prognostic data may be

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available, as well as further information on the short and longer term outcomes of novel therapies including over the scope clip, stem cells, and trials using endorectal advancement flaps.

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Figure 1: Process for developing consensus statements.





Figure 2: Summary of recommendations arising from consensus statement, showing patient preferences at centre of treatment, and highlighting the balance between procedures that affect function and those that do not.

