BACKGROUND: Anal fistulas in patients with Crohn’s disease are especially difficult to manage because of nonhealing and incontinence. We reviewed our outcomes for the newer sphincter-preserving techniques of anal fistula plug and fibrin glue compared with standard treatments of advancement flap closure and seton drain insertion.

METHODS: This was a retrospective study of patients with inflammatory bowel disease treated for high transsphincteric anal fistulas. The primary outcome was healing and continence at 12 weeks postoperatively.

RESULTS: Between 1997 and 2009, 51 patients with anal fistulas and inflammatory bowel disease were identified in the St Paul’s Hospital Anal Fistula Database. Postoperative healing rates at 12 weeks for the fistula plug, fibrin glue, flap advancement, and seton drain groups were 75%, 0%, 20%, and 28%, respectively. Continence scores were not altered by these procedures.

CONCLUSIONS: Closure of the primary fistula opening in patients with inflammatory bowel disease using a biologic anal fistula plug had improved healing compared with fibrin glue, seton drain, and flap advancement. Given its low morbidity and relative simplicity, the anal fistula plug should be considered for treating high transsphincteric anal fistulas in patients with inflammatory bowel disease.
Methods

All IBD patients treated for anal fistulas by a single colorectal surgeon at St Paul’s Hospital, University of British Columbia, from January 1997 to January 2009, were identified from a database.

Simple fistulas were defined as low fistulas including subcutaneous, intersphincteric, and low transsphincteric fistulas. Low transsphincteric fistulas involved the lower third of the external anal sphincter mechanism. Conversely, complex anal fistulas were defined as Crohn’s fistulas, low compromised fistulas, and high transsphincteric fistulas. Low compromised fistulas occurred in the lower third of the external anal sphincter in patients who had pre-existing tendency for incontinence. High transsphincteric fistulas involved the upper two thirds of the external sphincter and were subclassified further as direct transsphincteric, horse-shoe, and supralevator fistulas.

Inclusion criteria for this study were age older than 18 years and high transsphincteric fistulas secondary to IBD. Exclusion criteria were simple fistulas, rectovaginal fistulas, previous fistula surgery, and fistulas of cryptoglandular etiology. We did not include low fistulas in IBD patients to compare outcomes with our previous study of complex cryptoglandular fistulas.

Surgical procedures

All procedures were performed under general anesthesia. Fistula tracts were identified and the primary opening was located using a fistula probe, hydrogen peroxide installation, or fistuloscopy. All tracts were irrigated with hydrogen peroxide.

Fibrin glue. Five milliliters of fibrin glue (Tisseal; Baxter, Inc, Mississauga, Ontario, Canada) was reconstituted according to the manufacturer’s directions. The internal opening was closed with a figure-of-8 Vicryl suture (Ethicon, Inc, Cincinnati, OH). Fibrin glue was instilled into the fistula tract by way of the external opening. A nonadherent dressing was placed, and the patient was instructed to avoid lifting and vigorous physical activity for the next 7 days. Patients also were instructed not to take a sitz bath.

Bioprosthetic plug. After flushing the fistula tract with hydrogen peroxide, a conical biologic plug (Surgisis ES, West Lafayette, IN) was inserted through the tract with the wide end of the plug wedged firmly in the internal opening of the fistula tract. Excess plug material was trimmed flush with the mucosa at the internal fistula opening and at the external fistula opening at skin level. An absorbable suture was used to secure the plug to the internal sphincter muscle and to cover the mucosal opening of the fistula and the internal end of the plug. The external end of the plug was secured to one side of the external fistula opening with a single absorbable suture.

Seton drain placement. The fistula tracts were probed and were opened external to the anal sphincter. Transsphincteric Ethibond sutures (Ethicon, Inc) tied loosely were used as noncutting seton drains.

Advancement flap closure. The fistula tracts were probed then opened external to the anal sphincter. A mucosal flap was raised proximally from the internal fistula opening by undermining rectal mucosa for at least 4 cm to prevent tension on the suture line. The distal end of the flap with the internal fistula opening was excised. The transsphincteric fistula opening in the internal sphincter was closed using Vicryl sutures and the mucosal flap was advanced and sutured in place with interrupted Vicryl sutures. The fistulotomy external to the sphincter was left open for drainage.

Data collection and follow-up evaluation

Demographics, previous treatments, details of surgery, and follow-up results were obtained from a review of patient charts. All patients were evaluated in the outpatient clinic. The primary end points were continence and full healing, defined as closure of the external fistula opening with no drainage or infection, at 12 weeks postoperatively for the fistula plug, fibrin glue, and flap advancement groups. Healing for the seton drain group was defined as a persistent fistula opening at the seton site but absence of drainage or infection. Telephone interviews were conducted subsequently to confirm the durability of healing or elicit symptoms and signs of recurrence.

Patient incontinence was evaluated preoperatively and postoperatively using the Vaizey et al5 incontinence grading system. The validated Vaizey et al5 scale consists of items concerning the type and frequency of incontinence and changes in lifestyle, with a score ranging from 0 (complete continence) to 24 (complete incontinence). The Vaizey et al5 score has been shown to be a superior scoring system compared with other scores in terms of reproducibility and sensitivity to change produced by definitive treatment.5

Our secondary objective was comparison of fistula healing rates for our IBD versus non-IBD patients.

Differences between groups of patients were assessed using analysis of variance and proportional data using a chi-squared test. Statistically significant differences were defined by a P value of less than .05. Statistical analysis was performed using SPSS (version 9.0; Chicago, IL).

The study received approval from the University of British Columbia/Providence Health Care Research Ethics Board.

Results

Fifty-one patients with high transsphincteric fistulas concomitant with IBD were included. Table 1 shows demographic information. The median age was 39 years (range,
There was no significant difference in age or sex between the treatment groups.

Healing rates at week 12 in patients with IBD are reported in Table 2 and range from 0% for fibrin glue to 75% for the fistula plug. Healing rates were not statistically significantly different between the 4 treatment groups. Healing rates at week 12 in non-IBD patients previously reported in an earlier study are shown in Figure 1 in comparison with the IBD group by procedure type. IBD patients treated using the fistula plug showed a healing rate of 75% compared with 59.3% in the non-IBD group. All other procedures showed a reduction in healing rates at 12 weeks for IBD patients compared with non-IBD patients. These differences did not reach statistical significance.

Postoperative Vaizey et al scores were not statistically significant from preoperative scores for any of the 4 groups, the mean preoperative Vaizey et al score was 6.2 ± 3.9 whereas the mean postoperative score was 3.6 ± 3.3.

Risk factors assessed for possible association with treatment failure were age, fistula classification, and comorbidities (diabetes, human immunodeficiency virus, and perioperative infliximab). None of these factors were associated significantly with healing at 12 weeks using multivariate analysis.

**Comments**

Complex fistulas are notoriously difficult to manage and particularly so in patients with Crohn’s disease. The tendency for nonhealing and nonsphincterotomy strategies including long-term seton drains results in a poor chance of permanent fistula closure in these patients. We retrospectively evaluated healing of high transsphincteric anal fistulas in IBD patients using the newer treatment techniques (fistula plug and fibrin glue), comparing them with conventional treatments (flap advancement and seton drain placement). We found that healing rates at 12 weeks were highest for the anal plug procedure and lower for the other procedures compared with non-IBD patients.

When comparing the healing rates in IBD and non-IBD patients (the latter reported in our previous study), all IBD patients showed a reduction in healing rate except for the anal fistula plug group, although this difference was not statistically significant, perhaps because of the low numbers. The lower healing rate likely is secondary to poorer wound healing in IBD patients. Others have reported similar decreased healing of anal fistulas using various surgical techniques.

Healing rates for the fistula plug group was 75% in IBD patients and 59% in non-IBD patients. Twenty-five percent of plug failures were secondary to extrusion within the first week postoperatively. Our healing rate for the fistula plug in IBD patients is similar to previously reported small series that have shown success rates of 80% to 86% (Table 3). Both fibrin glue and fistula plug treatments have minimal risk of incontinence. Failure of these newer treatments does not compromise subsequent surgical options. Lower healing rates seen with fibrin glue treatment may be secondary to the liquid consistency of the glue in a short fistula tract causing early extrusion. Conversely, the higher healing rate seen with the fistula plug likely is owing to a more secure

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**Table 1** Patient demographics

<table>
<thead>
<tr>
<th>Fistula plug</th>
<th>Fibrin glue</th>
<th>Seton drain</th>
<th>Flap advancement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with IBD, n</td>
<td>4</td>
<td>2</td>
<td>40</td>
</tr>
<tr>
<td>Median age, y</td>
<td>43</td>
<td>42</td>
<td>40</td>
</tr>
<tr>
<td>Age range, y</td>
<td>23–52</td>
<td>28–55</td>
<td>26–66</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>3</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td>Females</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Patients with Crohn’s disease, n</td>
<td>4</td>
<td>1</td>
<td>32</td>
</tr>
<tr>
<td>Patients with ulcerative colitis, n</td>
<td>0</td>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

**Table 2** Fistula healing at 12 weeks in patients with IBD

<table>
<thead>
<tr>
<th>Fistula plug</th>
<th>Fibrin glue</th>
<th>Seton drain</th>
<th>Flap advancement</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>3/4 (75%)</td>
<td>0/2 (0%)</td>
<td>11/40 (27.5%)</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>3/4 (75%)</td>
<td>0/1 (0%)</td>
<td>10/32 (31.3%)</td>
</tr>
<tr>
<td>Ulcerative colitis</td>
<td>N/A</td>
<td>0/1 (0%)</td>
<td>1/8 (12.5%)</td>
</tr>
</tbody>
</table>

N/A = not applicable.
fixation than glue in the fistula tract, resulting in less early extrusion. The conical shape of the plug inserted in the high-pressure area of the primary opening and suture fixation to the internal sphincter also adds to mechanical stability. However, plug extrusion accounted for 25% of plug failures in the current study. It is likely that infection or placement of a plug in a large-size fistula tract contributed to early plug extrusion. Potential solutions for early extrusion include resolution of infection and maturing the fistula using a seton drain and the addition of a button sewn to the plug at the external opening.

Continence was not affected in any of the treatment groups. Preservation of continence is an important goal for any type of fistula surgery. Others have reported decreased continence from fistula surgery.9

There were several limitations to our study. First, our study had a short follow-up time of 12 weeks compared with other studies with follow-up durations of 9 to 10 months.10,11 Longer-term follow-up evaluation currently is in progress. Second, the small sample size of our treatment groups made it difficult for any statistical significance to be established (type II error). With only 51 patients total, the regression model evaluating potential factors contributing to healing (diabetes, human immunodeficiency virus, and immunosuppression perioperatively with infliximab) was underpowered to show a significant effect. Third, the retrospective methodology used in our study has potential significant inaccuracy and bias that would be improved using prospective data collection. A larger randomized, multicenter prospective trial of plug repair in IBD patients is indicated to determine the more effective treatment for outcomes of healing, morbidity, and cost. Presently, there are no comparative trials of surgical procedures for IBD anal fistulas. Fourth, we compared outcomes between patient groups that did not have previous fistula surgeries because multiple fistula surgeries may predict poorer outcome. As such, our data do not reflect our outcomes with fistulas that have had previous surgery including seton drains. Finally, the use of anti-inflammatory medications for Crohn’s disease was variable between groups. In particular, infliximab was used in 8 patients preoperatively in the seton drain group but not in the other groups.

In summary, we found that healing rates for the fistula plug in IBD patients was similar to non-IBD patients in this small preliminary study. Despite small sample size, this reasonable healing rate using the plug in IBD patients is contrasted with reduced healing rates for fibrin glue, seton drain, and flap advancement when comparing IBD with non-IBD patients. Given the low morbidity and relative simplicity of the procedure, the anal fistula plug should be considered an option in the surgical management of IBD patients with complex anal fistulas.

### Discussion

**Dr Kim C. Lu** (Portland, OR): Anal fistulas in Crohn’s disease have been notoriously difficult to treat. Since these are often complex, fistulotomy would lead to incontinence. Traditionally, the gold standard sphincter-sparing technique has been the endorectal advancement flap. Since flap advancement has led to some problems with altered continence, surgeons have tried fibrin glue, the anal fistula plug, and ligation of the intersphincteric tract (the LIFT [ligation of the intersphincteric tract] procedure). Currently, 2 randomized controlled trials are recruiting patients to compare the anal fistula plug with either the endorectal advancement flap or the LIFT procedure in non-Crohn’s patients.1

In 51 Crohn’s patients with anal fistulas, Phang et al used 40 setons, 5 endorectal advancement flaps, 2 fibrin glue injections, and 4 anal fistula plugs. His healing rates at 12 weeks were 27.5% (seton), 20% (flap), 0% (fibrin glue), and 3%

### References

75% (plug). His previously published rates in non-Crohn’s patients were better (32.6% seton, 60.4% flap, 39.1% fibrin glue). This fits with prior studies showing that healing rates have been worse in Crohn’s patients.

However, his healing rates after anal fistula plug were better in Crohn’s patients than in non-Crohn’s patients: 75% versus 59.3%. This finding conflicts with a recent prospective cohort study. Ky et al found that the healing rates after anal fistula plug were 28.6% (4 of 14) in Crohn’s patients versus 66.7% (20 of 30) in non-Crohn’s patients. Since Dr Phang’s study had only 4 patients treated with the anal fistula plug, statistical comparisons are difficult.

Unfortunately, not everyone can reproduce the excellent results of Dr Phang. In a recent systematic review, Garg et al looked at 3 different studies of anal fistula plugs in Crohn’s patients. The healing rates varied from 29% to 86%, with an overall rate of 63.4% (26 of 41 patients).

Two critical questions remain unanswered by the literature. Would Crohn’s patients with fistula-in-ano benefit from the anal fistula plug? A current trial sponsored by Cook (manufacturer of the Surgisis plug) is trying to recruit 50 Crohn’s patients to determine the 12-week 6-month, and 1-year healing rates after insertion of the Surgisis plug.

Which technique is the best? In a randomized controlled trial with non-Crohn’s patients, Ortiz et al found the flap had a much lower fistula recurrence rate than the plug (2 of 16; 12.5%; vs 12 of 15; 80%).

Dr Phang’s results suggest that the anal fistula plug has promise in Crohn’s patients. Hopefully, these larger clinical trials will give further evidence.

References