



Porcine dermal collagen mesh (Permacol™) as a bioprosthesis in the ligation of intersphincteric tract (BioLIFT) procedure

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Received: 29 June 2020 / Accepted: 6 August 2020 / Published online: 19 August 2020
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Abstract

Background Ligation of intersphincteric tract (LIFT) is a sphincter-saving technique used to treat anal fistulas. Incorporation of a bioprosthesis in LIFT (BioLIFT) aims to improve healing. The use of cross-linked porcine dermal collagen mesh Permacol™ in BioLIFT has never been investigated. The aim of this study was to compare the healing rates and outcome of LIFT and BioLIFT for complex anal fistulas using the Permacol™ biological mesh.

Methods A retrospective analysis of all patients having LIFT or BioLIFT for complex fistulas from January 2010 to November 2019 was performed in a tertiary referral centre. Patient data from a prospectively collected database of all patients having LIFT or BioLIFT were analyzed.

Results LIFT and BioLIFT were performed in 48 (82.8%) and 10 (17.2%) patients, respectively. All BioLIFT patients had previous interventions for their fistulas compared to 30 (62.5%) of patients who had LIFT, $p=0.023$. The primary healing rate for LIFT was 87.5% (42/48) compared to 80% (8/10) in BioLIFT, ($p=0.42$). Eight (13.8%) patients developed complications, 6 (12.5%) in the LIFT group vs 2 (20%) in the BioLIFT group ($p=0.62$). On univariate analysis, the number of previous operations was predictive of complications ($p=0.03$). BioLIFT was not associated with complication (OR = 1.75, 95% CI: 0.30–10.3, $p=0.54$) or primary healing (OR = 0.57, 95% CI: 0.97–3.36, $p=0.54$). There was no significant difference in recurrence (LIFT 12.5% vs BioLIFT 0%, $p=0.58$). Kaplan–Meier analysis found no difference in time to recurrence between the two groups ($p=0.65$).

Conclusion Permacol™ mesh in BioLIFT is feasible and achieves a high primary healing rate of 80%. Prospective evidence is needed to establish the benefits of BioLIFT and determine whether Permacol™ is superior to the non-cross-linked porcine submucosal mesh.

Keywords Anal fistula · Ligation of intersphincteric tract · BioLIFT

Introduction

Anal fistula is a common proctological condition. Intersphincteric and low transsphincteric fistulas can normally be treated by simple fistulotomy. The treatment of high intersphincteric and other complicated fistulas is less straightforward with faecal incontinence the main concern following sphincter division [1]. Amongst other sphincter-saving procedures, the ligation of intersphincteric tract (LIFT) procedure has gained in popularity due to the impressive

success rates > 90% when first described in 2007 [2]. This technique involves a physical division of the fistula tract at the intersphincteric plane, with the aim of stopping further passage of contamination into the fistula. Ellis described a modification of LIFT 10 years ago by placing a bioprosthesis between the transected ends of the fistula tract to reinforce the closure and enhance healing. The healing rate from this report reached 94% [3]. Subsequent to this initial description, only four other studies on the use of bioprosthetic material in LIFT have been published, but reporting less impressive primary healing rates of 63–75% [4–7].

The theoretical benefit of incorporating a bioprosthetic material in the LIFT procedure is a physical barrier that separates the two ligated fistula ends, allows the ingrowth of fibroblasts and helps to withstand infection. All reported studies of BioLIFT to date have utilized a porcine intestinal

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submucosal mesh, consisting of a non-cross-linked acellular collagen matrix. Further developments of collagen mesh have produced a cross-linked counterpart. Cross-linking is proposed to confer better resistance to collagenase degradation [8]. The cross-linked biological mesh Permacol™ (Medtronic, Minneapolis, MN, USA) is developed using porcine dermis and has gained acceptance in ventral hernia and reconstructive surgery to repair tissue defects [9]. The use of Permacol™ mesh has not been reported previously in BioLIFT. The aim of this study was to compare the success rates of LIFT and BioLIFT for complex anal fistulas using the Permacol™ biological mesh.

Materials and methods

This was a retrospective analysis of all patients who had either LIFT or BioLIFT for transsphincteric fistulas from January 2010 to November 2019 in a tertiary referral centre for colorectal diseases. Patient demographics and clinical data were retrieved and analyzed from a prospectively collected database of all patients having LIFT or BioLIFT. Non cryptoglandular fistulas including Crohn's, tuberculosis and intersphincteric fistulas were excluded. Ethical approval was granted by the institutional review board of Queen Mary Hospital, Hong Kong.

Primary healing success was defined as complete healing of the external opening as well as the perianal skin incision. Any patient whose external opening or perianal incision failed to heal or required a further treatment procedure was considered treatment failure. Secondary outcomes of the study were postoperative complications including pain, bleeding, wound infection, constipation, incontinence and recurrence of fistula. *Recurrence* was defined as any new fistula seen during follow-up after primary healing was documented. *Secondary healing success* was defined as complete healing of the external opening and the perianal skin incision after a subsequent procedure in patients who had treatment failure.

Surgery details

Preoperative preparation

Informed consent was obtained for the procedure. Sodium phosphate enema (Fleet Enema, C.B. Fleet, USA) was given in the morning before the procedure as bowel preparation. Prophylactic antibiotic (amoxicillin sodium 1 g + clavulanic acid 200 mg) was given on induction of anesthesia. The procedure was performed under either general or spinal anesthesia at the discretion of the anesthetist.

Surgical techniques

LIFT Our LIFT technique has previously been described in detail [10, 11]. In brief, all patients were placed in the prone jackknife position with retraction of the buttocks by adhesive tapes. Examination under anesthesia (EUA) was performed to determine the degree of anal sphincter involvement. If no seton was inserted previously, the fistula was cannulated using Lockhart–Mummery probes. A silicone vessel loop was threaded through once the fistula tract was identified. A curvilinear skin incision was made over the intersphincteric groove. The Lone Star disposable self-retaining retracting system (Cooper Surgical, Inc., Trumbull, CT, USA) was used to aid visualization and dissection of the fistula tract. A combination of sharp and blunt dissection with S-shaped retractors was used to isolate the fistula tract which was then slung with silicone vessel loop. Suture ligation of the fistula tract was performed at proximal and distal ends (entrance into the external and internal sphincter in the intersphincteric plane) using 4–0 Vicryl sutures. The tract was divided with or without excision of a segment of the fistula tract. The muscle defect medial to the external anal sphincter was sutured and approximated. The perianal incision was closed with interrupted 4–0 Vicryl sutures to complete the procedure.

BioLIFT The initial steps of the BioLIFT procedure were similar to LIFT. After identification and ligation of the fistula tract, a Permacol™ (Medtronic, Minneapolis, MN, USA) mesh, sized 3 × 3 cm, was inserted into the intersphincteric plane in between the divided ends of the tract (Fig. 1a, b). The mesh was secured using 3/0 vicryl sutures. The skin was closed covering the mesh using 4/0 vicryl sutures. The external opening was left open for dressing.

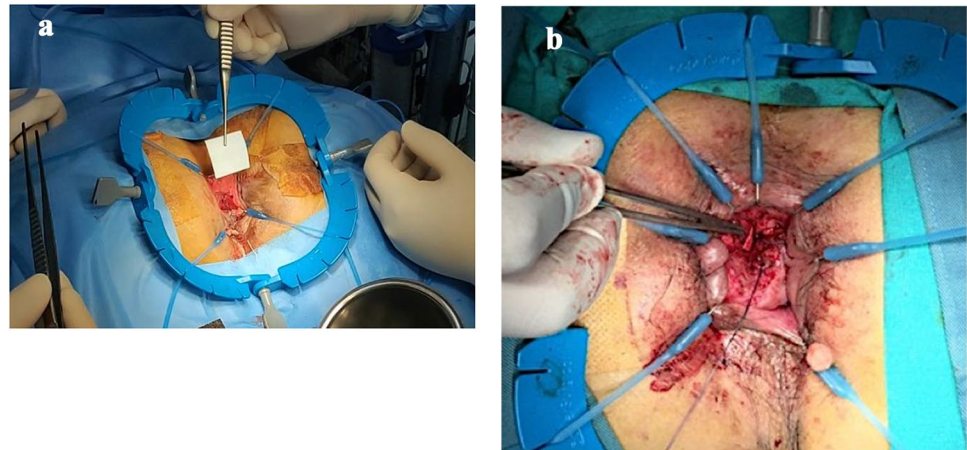
Postoperative care

All patients were prescribed analgesics and stool softener as required on discharge. Patients were followed-up at the colorectal out-patient clinics at 2–4 weeks, 2 months and then at 4–6 monthly intervals. At each visit, fistula opening closure and perianal wound healing were documented and clinical examination performed. Any complications as described above were documented.

Statistical analysis

Categorical variables were compared using the χ^2 or Fisher's exact test where appropriate. Continuous parametric variables were compared using Student's *t* test. The Mann–Whitney-*U* test was used for non-parametric variables. Univariate analysis was performed with logistic regression. The Kaplan–Meier survival analysis was used to analyze

Fig. 1 **a** Permacol™ mesh 3 × 3 cm **b** Permacol™ mesh inserted into intersphincteric plane



differences in time to recurrence. A p value of <0.05 was considered significant. The Statistical Package for the Social Sciences (SPSS) Software for Mac version 24.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

Results

A total of 58 patients were identified and included in the study. BioLift and LIFT were performed in 10 (17.2%) and 48 (82.8%) patients, respectively. The mean age was 48 (range: 22–73) years. The majority of patients were male

47 (81%). All 10 (100%) BioLIFT patients had had previous interventions for their anal fistulas compared to 30 (62.5%) patients with LIFT ($p=0.023$). The median number of previous operations was also significantly higher in patients having BioLIFT (1 [range 0–6] vs 2 [range 1–6], $p=0.005$). None of the patients in either group had diabetes mellitus or immunosuppression. An anterior external opening was more common in patients in the LIFT group (LIFT 75% vs BioLIFT 20%, $p=0.002$). There was no significant difference in age, sex, body mass index or smoking between the two groups (Table 1). Permacol™ mesh was used in all ten BioLIFT patients.

Table 1 Clinical data of patients with LIFT and BioLIFT

	LIFT ($n=48$)	BioLIFT ($n=10$)	p value
Age, mean \pm SD (years)	47.2 \pm 11.1	50.4 \pm 10.0	0.42
Sex (M:F)	38:10	9:1	0.67
BMI, kg/m ² , mean \pm SD	26.6 \pm 6.6	26.1 \pm 4.14	0.82
Smoker, n (%)	7 (14.6)	2 (20)	0.65
Previous intervention, n (%)	30 (62.5)	10 (100)	0.023
Seton	13	5	
Fistulotomy	1	2	
Seton + Fistulotomy	14	2	
Fistulotomy + AFP	2	0	
LIFT	0	1	
Number of previous interventions, median (range)	1 (0–6)	2 (1–6)	0.005
Fistula type			<0.001
Transsphincteric, n (%)	47 (97.9)	3 (30)	
Extrasphincteric, n (%)	1 (2.1)	6 (60)	
Suprasphincteric, n (%)	0 (0)	1 (10)	
Anterior external opening, n (%)	36 (75)	2 (20)	0.002
Posterior external opening, n (%)	12 (25)	8 (80)	0.002
Follow-up, months, median (range)	17.5 (1–115)	4.5 (1–37)	0.001

BMI body mass index, AFP anal fistula plug, LIFT ligation of intersphincteric tract, BioLIFT incorporation of a bioprosthesis in LIFT

Outcome

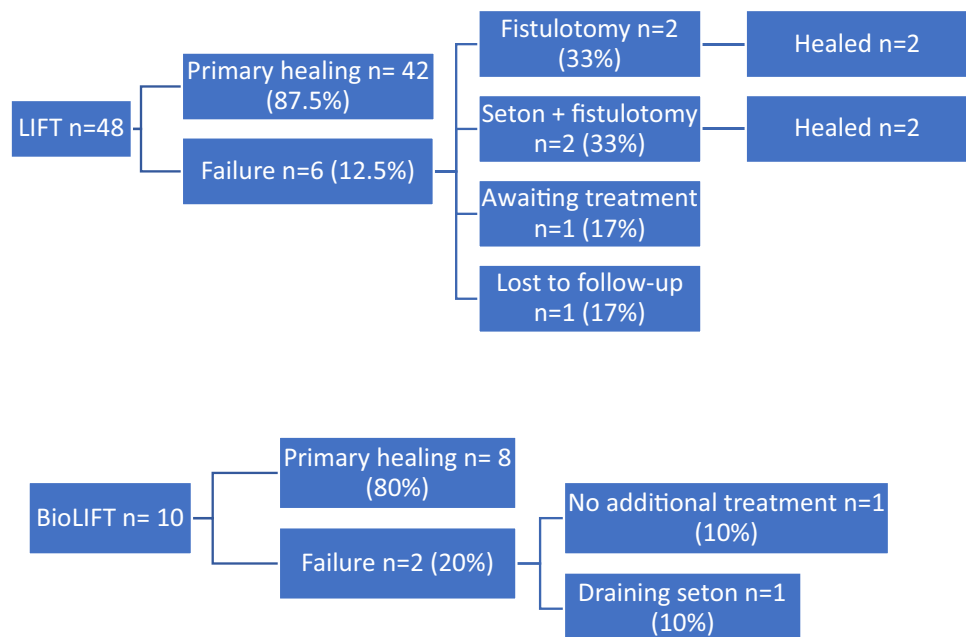
The overall primary healing rate for all patients was 86.2% (50/58) patients. For patients who had the LIFT procedure, the primary healing rate was 87.5% (42/48) compared to 80% (8/10) in patients who had BioLIFT ($p=0.42$) (Table 2). Figure 2 shows the outcome of patients who did not experience primary healing. Of the six patients who had treatment failure after LIFT, two patients had a seton followed by fistulotomy and two patients had fistulotomy alone. These four patients subsequently had complete healing. Of the remaining two patients, one was awaiting

Table 2 Outcome of patients treated with LIFT and BioLIFT

	LIFT ($n=48$)	BioLIFT ($n=10$)	p value
Primary healing rate, n (%)	42 (87.5)	8 (80)	0.42
Secondary healing rate, n (%)	46 (95.8)	8 (80)	0.13
Time to primary healing, weeks, median (range)	8 (1–62)	5.5 (3–20)	0.84
Complications, n (%)	6 (12.5)	2 (20)	0.62
Pain, n	5	0	
Bleeding, n	0	1	
Infection, n	0	0	
Constipation, n	0	1	
Itching, n	0	0	
Incontinence, n	1	0	
Recurrence, n (%)	6 (12.5)	0 (0)	0.3

LIFT ligation of intersphincteric tract, BioLIFT incorporation of a bioprosthesis in LIFT

Fig. 2 Outcomes of patients who did not experience primary healing



treatment and the other was lost to follow-up. Two patients in the BioLIFT group did not experience primary healing. One patient decided against additional treatment. The remaining patient had seton insertion to drain the tract. The secondary healing rates for LIFT and BioLIFT patients were 95.8% vs 80%, respectively, ($p=0.13$). The median time to primary healing was 8 (1–62) weeks in LIFT patients compared to 5.5 (3–20) weeks in BioLIFT patients ($p=0.84$). Overall, eight (13.8%) patients developed complications. There was no significant difference observed between LIFT and BioLIFT patients ($n=6$ [12.5%] vs $n=2$ [20%], $p=0.62$). Univariate analysis revealed the number of previous operations was the only predictor significantly associated with complications (Table 3). Using LIFT as a reference, BioLIFT was not associated with complication (OR = 1.75, 95% CI 0.30–10.3, $p=0.54$) or primary healing success (OR = 0.57, 95% CI 0.97–3.36, $p=0.54$). No other factors were associated with complication or primary healing.

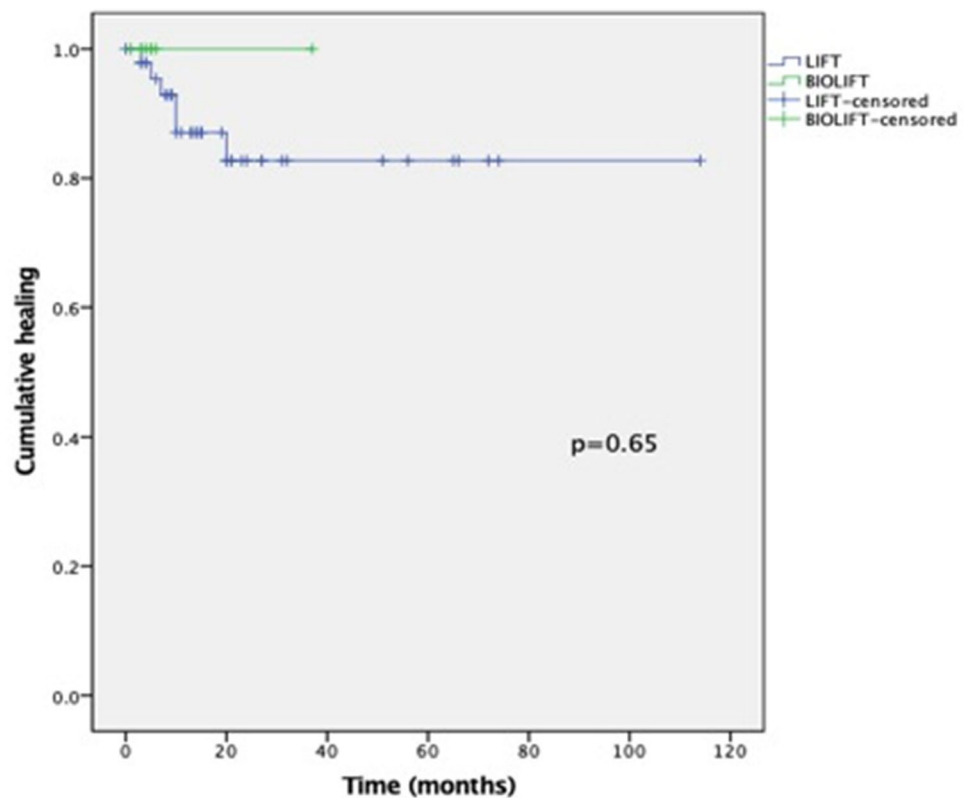
Recurrence

The median duration of follow-up between LIFT and BioLIFT patients was significantly different (17.5 months vs 5 months, $p=0.009$). Six (12.5%) patients in the LIFT group had recurrence, while none of the BioLIFT patients did ($p=0.3$). Kaplan–Meier analysis showed no difference in the time to recurrence between the two groups, $p=0.65$ (Fig. 3).

Table 3 Univariate analysis of predictors associated with complication and primary success

	Complication			Primary success		
	<i>p</i> value	OR	95% CI	<i>p</i> value	OR	95% CI
BioLIFT	0.54	1.75	0.30–10.3	0.54	0.57	0.97–3.36
Previous treatment	0.22	2.41	0.59–9.81	0.25	0.27	0.31–2.44
No. of previous intervention	0.03	1.57	1.05–2.36	0.72	0.92	0.57–1.48
Fistula type	0.98	1.03	0.18–5.93	0.33	0.15	0.03–0.86
Anterior external opening	0.13	2.94	0.73–11.93	0.85	1.17	0.25–5.41
Posterior external opening	0.13	0.34	0.08–1.37	0.85	0.86	0.18–4.03

BioLIFT incorporation of a bioprosthesis in ligation of intersphincteric tract, *OR* odds ratio, *CI* confidence interval

Fig. 3 Kaplan–Meier curve showing comparison of time to recurrence between LIFT and BioLIFT

Discussion

Preservation of sphincter function is crucial in anal fistula surgery. Over the years, sphincter-saving procedures including anal fistula plug, advancement flap, fibrin glue, video-assisted anal fistula treatment (VAAFT) and laser ablation of fistula tract (LAFT) have been developed but have only yielded modest results with longer term follow-up [12–14]. The first description of the LIFT procedure by Rojanasakul reported such successful outcomes that it led to a wave of LIFT procedures in many countries [2]. Subsequent reports of LIFT, however, did not achieve such impressive results and the latest meta-analyses reported

pooled mean success rates of only 76% [3]. BioLIFT was a modification of LIFT made when Ellis noticed a 92% healing rate when a bioprosthesis was used in rectovaginal fistulas [15]. This healing rate was just as impressive when adopted in anal fistulas.

Of the four studies later published on BioLIFT, three originated from the same centre and all used Surgisis[®], a non-cross-linked porcine intestinal submucosal biological mesh. The earlier reports were two case series of BioLIFT and reported primary healing rates of 63% and 69% [4, 6]. The two more recent publications were comparative studies with LIFT. Lau et al. [5] reported primary healing rates of 62.9% and 34.9% for LIFT and BioLIFT, respectively ($p=0.087$). Anal manometry measurements were

similar before and after surgery as well as between LIFT and BioLIFT groups. Zwiep et al. [7] reported a much higher healing rate for BioLIFT, although statistically, there was no difference (LIFT 58.7% vs BioLIFT 75%, $p=0.08$). Using a multivariate analysis model, however, BioLIFT was found to be significantly associated with primary success compared to LIFT, OR 2.38 (95% CI 1.01–5.62, $p=0.048$). In the present study, the primary healing rate for BioLIFT patients was 80%. This is currently the highest success rate reported since Ellis' series in 2007. The primary healing rate for the LIFT procedure in this study, 87.5%, was also towards the higher range of reported rates in the literature [16]. Consistent with Zwiep et al., the present study did not find a difference in primary ($p=0.42$) or secondary healing rates ($p=0.13$) between LIFT and BioLIFT. It is worth noting that in this study by Zwiep et al. [7], treatment failure was judged as recurrence identified during postoperative visits.

To the best of our knowledge, this is the first study reporting the outcomes of Permacol™ mesh in BioLIFT. Permacol™ originated from porcine dermis, processed to leave only the extracellular matrix. Supplementary cross-linking using hexamethylene diisocyanate provides a collagen matrix which is more resistant to bacterial collagenase degradation facilitating fibroblastic ingrowth and neovascularization [9]. The use of a biological prosthesis in the treatment of anal fistulas is not new. Permacol™ collagen paste has been used as an infilling agent alone with reported healing rates of 50–60% [17, 18]. In a European multicentre prospective observational study, 100 patients with anal fistula received Permacol paste. At 6 and 12 months post-surgery, the healing rate was 56.7% and 53.5%, respectively. Adverse events reported were minor and similar to those commonly observed after fistula surgery [18]. Permacol™ mesh has been evaluated in hernia and ventral rectopexy surgery [9, 19]. The prosthesis has been shown to exhibit limited contraction after implantation and a higher tensile strength after a period of enzymatic degradation compared to non-cross-linked prosthesis. Whether Permacol™ is superior to Surgisis® in healing rates of BioLIFT remains to be investigated.

The authors' preference is to use BioLIFT for patients with large caliber tracts and where surrounding tissues are judged to be fibrotic and unhealthy from prior infection. In these patients, closure of the muscle defects as in conventional LIFT may be precarious. It is also our usual practice to ensure adequate drainage of any sepsis before a definitive procedure. All of the BioLIFT patients had previous intervention in the form of seton insertion (9/10 patients) or fistulotomy (1/10 patients) for their fistulas prior to BioLIFT. This policy is in agreement with other authors performing BioLIFT. Drainage seton also has the effect of promoting fibrosis and maturation of the fistula tract. In our experience, this facilitates the identification and ligation of the

tract, although current evidence on the role of seton prior to LIFT or BioLIFT remains controversial [6, 20]. Lau et al. [5] reported a high primary failure rate (63.6%) when BioLIFT was used as a primary procedure, whereas 100% of salvage BioLIFTs had primary success. In three of their patients, prior seton drainage was not performed. It is unclear whether persistent sepsis in these patients had contributed to their failure.

A clear disadvantage with the use of bioprosthesis in LIFT is cost. The price of a 3 × 3 cm Permacol™ mesh is approximately 378 USD. It is still unknown whether the benefits of BioLIFT can outweigh its costs. If the primary healing rates continue to be promising compared to other sphincter-saving procedures then BioLIFT may potentially lower the overall cost by mitigating the cost of patients returning for seton management, multiple operations and treatment of recurrent fistulas. Another potential drawback of BioLIFT is the relatively more extensive dissection around the fistula tract that is required for placement of mesh. Scarring, sphincter damage, wound infection and pain are some of the possible consequences. However, we have not noticed obvious differences in these parameters compared to LIFT in our patients.

One limitation of this study was the assessment of continence pre- and post-LIFT/BioLIFT. Prior studies have used anal manometry to objectively evaluate the sphincter function as it has been reported that direct patient questioning is an insensitive method for detection. No differences were identified between pre- and post-BioLIFT resting or maximum squeeze pressures [4, 5]. It is not our routine practice to perform manometry assessments on these patients as from our experience the sphincter mechanism is rarely affected. Even if incontinence is reported, the symptom is mild and temporary in most patients. Inherent bias is inevitable in a retrospective study of this nature. To add to the strength of the study, all the BioLIFT and > 96% of the LIFT procedures were performed by the senior author, using a standardized technique. The difference in follow-up length was significant between the two groups. A Kaplan–Meier analysis was used to assess for any difference in the time to recurrence between the two groups, and none was found ($p=0.65$). Nevertheless, the small number of BioLIFT patients in this study makes it difficult to make meaningful comparisons.

Conclusion

BioLIFT is an effective sphincter-saving procedure in anal fistulas. Permacol as the biosprosthesis is safe, feasible and achieves a high primary healing rate of 80%. Current data on BioLIFT are still limited and it remains unclear whether the use of biological mesh has a clear advantage over LIFT alone. Future prospective evidence is needed to establish

the benefits of BioLIFT and whether Permacol™ is superior to the non-cross-linked porcine collagen submucosal mesh.

Author contributions All authors contributed to the study conception and design. The first draft of the manuscript was written by Julian Tsang and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript. Conceptualization: JST, TYC, HHC, RW, CCF, OL. Data collection: JST, TYC, HHC, OL. Data analysis: JST, TYC, HHC, OL. Manuscript drafting: JST, TYC, HHC, RW, CCF, OL. Review and editing: JST, TYC, HHC, RW, CCF, OL. Final approval: JST, TYC, HHC, RW, CCF, OL.

Funding The authors did not receive support from any organization for the submitted work.

Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare that are relevant to the content of this article.

Ethical approval Ethical approval was granted by the institutional review board of Queen Mary Hospital, Hong Kong.

Informed consent Preoperative written informed consent was taken from all patients receiving LIFT and BioLIFT.

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