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Ligation of the Intersphincteric Fistula Traject with Placement of a Prosthesis: A New Technique in the Treatment of Fistula-in-Ano at Yaounde Central Hospital (Cameroon)

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Abstract

Background: Ligation of the inter-sphincter fistula tract associated with anal plug (LIFT-Plug) is a new anal fistula treatment procedure at the Yaoundé Central Hospital. A two-sided prosthesis piece bent in the shape of a cone is used here as an anal plug. The aim of this work was to evaluate the therapeutic results and the safety of this device. **Patients and Methods:** The clinical data of patients operated by the LIFT-Plug technique from January 1, 2020 to June 30, 2021 for a high anal fistula were analyzed prospectively. The variables evaluated were operative time, cure rate, postoperative complications and recurrence rate. **Results:** We included 28 patients with a mean age of 42 years. The sex ratio was 1.15. No patient presented preoperative continence disorder. The fistula was high trans-sphincteric in 89.3% of cases. The average duration of surgery was 55.2 minutes (45 to 66 minutes). The postoperative course was straightforward, although 60.7% of the patients had experienced tingling that resolved spontaneously. Three patients (10.7%) presented with transient gas incontinence (WIS of 4) which completely resolved after one month. All patients healed within a mean of 63.21 days (25 to 95 days). At the end of the 6-month follow-up, no case of recurrence had been recorded. **Conclusion:** The LIFT-Plug is a simple, safe and effective technique for the treatment of upper anal fistula without major impairment of continence despite delayed healing. The adapted two-sided prosthesis is a good alternative to the conventional anal plug.

Keywords

High Anal Fistula, LIFT-Plug, Healing, Postoperative Complications, Recurrence

1. Introduction

Anal fistula is characterized by an abnormal communication between the anal canal and the surrounding perineal skin with a permanent purulent or faecal discharge and pain that impairs the patient's quality of life. Its treatment, which aims to dry up the suppuration while preserving continence, has always been a challenge for practitioners. This condition thus remains difficult for both the patient and the practitioner.

The treatment of anal fistula is almost exclusively surgical and involves many techniques. Fistulotomy and fistulectomy are historical techniques that have shown high cure rates. However, they require varying degrees of sphincter transection, putting the patient at high risk of incontinence [1] [2] [3] [4] [5] and preservation of continence often requires multiple operations or the use of sphincter-sparing techniques [6]. These include fibrin sealant injection, anal plug and ligation of intersphincteric fistula tract (LIFT).

Johnson *et al.* were the first to describe the anal plug, a bio-resorbable xenograft made from freeze-dried porcine intestinal submucosa [7]. They achieved an initial success rate of 86.7% at three months. LIFT was first reported by Rojanasakul *et al.* in 2007, with a promising initial cure rate of 94.4% [8]. These results have not always been confirmed in many subsequent publications that showed variable cure rates and often high recurrence rates [7] [9]-[22]. In an attempt to improve these figures, the two techniques were combined, resulting in an initial cure rate of 95% [23]. Following the description of the technique by Han *et al.*, several studies have been published on inter-sphincter ligation with anal plug (LIFT-Plug), with success rates ranging from 68.8% to 96.5% without major continence problems [17] [18] [24] [25] [26].

The treatment of anal fistula at Yaoundé Central Hospital (YCH) has involved many techniques, including constrictor fistulotomy, with a cure rate of 85% without major alteration of continence [27]. The LIFT-Plug has recently been introduced into the therapeutic arsenal of anal fistulas in this facility. Here, the anal plug uses a non-absorbable material not designed for this indication. We therefore proposed to evaluate the therapeutic results and medium-term safety of this plug associated with LIFT in a group of patients with a high anal fistula.

2. Patients and Methods

2.1. Patient Selection

From January 1, 2020 to June 30, 2021 (18 months), patients over 18 years of age with a high anal fistula with or without diverticular tracts or a horseshoe fistula,

and having history of prior drainage and tapping of their fistula, were operated on by the LIFT-Plug technique in the Visceral Surgery Department of the YCH (Cameroon).

The YCH is a second category hospital in the health pyramid of the country. It is a university hospital with almost all specialised services and receives patients from all social strata living in Yaoundé, its surroundings, and from more distant localities.

Patients with fistula associated with inflammatory bowel disease, radiotherapy, malignancy, pre-existing incontinence or chronic diarrhea were excluded from the study; as well as those with other proctological pathology (anal fissure and haemorrhoids) or with a defect that could impede the healing process (diabetes, cancers, chemotherapy, and corticosteroid therapy) were excluded.

The diagnosis of anal fistula was made clinically in all patients. Patients' continence was assessed using the Jorge and Wexner incontinence score (SIW) [28]. This study was approved by the ethics committee of the Faculty of Medicine and Biomedical Sciences of the University of Yaoundé I. Written informed consent was obtained from all patients after a full explanation of the procedure. They agreed to participate in regular follow-up assessments.

Information regarding patient demographics, history, fistula characteristics, operative data and follow-up results was collected using a data sheet. Each patient had a minimum of six months of follow-up and the last patient was to be recruited by 30th November 2020. Treatment failure was defined as persistence of discharge beyond four weeks after the surgery and recurrence was defined as recurrence of discharge or air leakage through the external opening and/or inter-sphincter incision after healing (healing of the external opening and inter-sphincter wound).

2.2. Surgical Technique

All patients were admitted the day before surgery without prior colonic preparation. Preoperative fasting was observed and a dose of Ceftriaxone 2 g antibiotic was administered intravenous at the time of anaesthetic induction. After general or locoregional anesthesia was administered according to the findings of the pre-anesthetic consultation, patients were placed in the gynecological position. The internal ostia was identified by injecting methylene blue or povidone-iodine from an external opening and the fistulous path was marked with a metal stylet from the external ostia to the internal ostia. A curvilinear incision parallel to the anal margin of approximately 1.5 to 2 cm was made in the inter-sphincter groove overlooking the fistula path previously marked by the stylet. A blunt dissection was performed in the inter-sphincter space to expose the fistula path (**Figure 1**). The dissected path was encircled and the stylet removed. It was then ligated near the internal sphincter with absorbable suture Vicryl* 3/0 (polyglactine) before being sectioned. The inter-sphincter tract was opened, curetted and washed with 0.9% saline. A piece of Ventralight st® (a two-sided prosthesis made of a medium

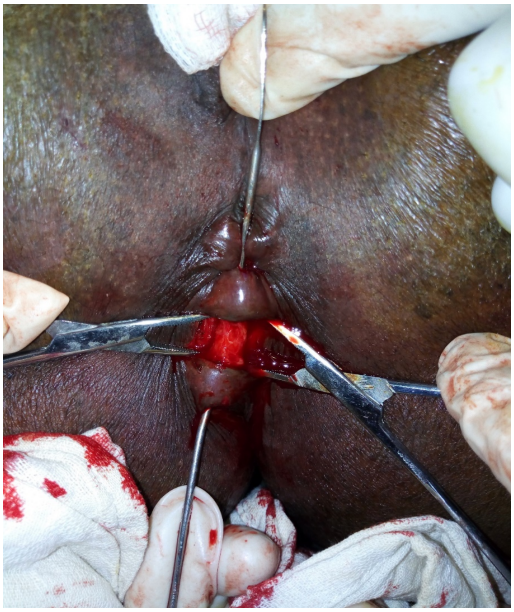

Figure 1. Dissection of the inter-sphincter pathway.

weight uncoated polypropylene monofilament on one side and an absorbable hydrogel barrier on the other side), 3 × 5 cm in size, was soaked in saline and then rolled up into a cone shape to serve as an anal plug (**Figure 2**). It was inserted into the fistula path from the external orifice and secured with 3/0 polyglactin at the external sphincter. The excess of the prosthesis was resected and the inter-sphincter wound was sutured. The external orifice was left open to facilitate drainage (**Figure 3**).

2.3. Postoperative Follow-up

All patients received antibiotics (Ceftriaxone and metronidazole) and analgesics (paracetamol, tramadol and diclofenac) intravenously for 24 hours. They were all discharged the next day with analgesia and faecal stool softeners. Sitz baths were routinely prescribed.

Patients were regularly reviewed weekly after surgery until healing, then monthly until the sixth month of surgery. At each visit, the patient's clinical continence status was assessed using the SIW. An examination of the surgical wound, internal and external orifices were performed and other complications were investigated.

2.4. Statistical Analysis

The data were analysed using SPSS 19 software. Qualitative data are expressed as frequency and quantitative data as mean and standard deviation.

3. Results

During the study period, 28 patients met our criteria and were included in the study. There were 15 men (53.6%) and 13 women (46.4%), giving a sex ratio of

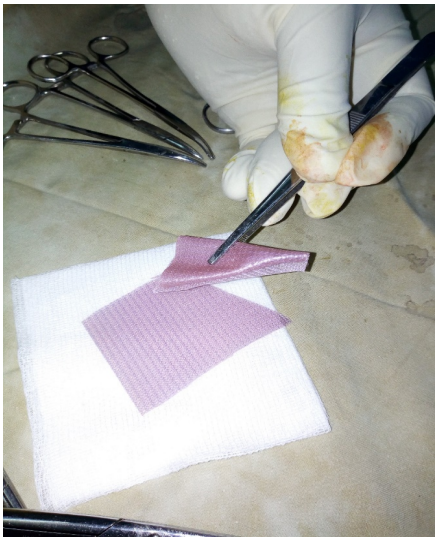

Figure 2. Preparation of the cone-shaped anal plug.

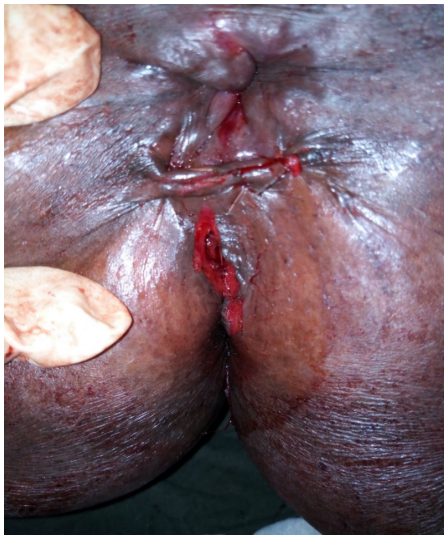

Figure 3. Postoperative appearance (inter-sphincter wound closed and external orifice left open).

1.15. Their mean age was 42 years ± 24 - 68 years. The 35 - 45 age group was the most represented (11 cases, 39.3%). The majority of patients were hypertensive (17 cases, 60.7%), one patient (3.6%) had a recurrent anal fistula and one patient (3.6%) had a history of anal trauma. The average body mass index (BMI) of our patients was 26.19 kg/m^2 (17.5 to 32.2 kg/m^2). Twenty patients (71.4%) had a BMI ≥ 25 Kg/m^2 and 5 (17.9%) were obese. All patients (28 cases, 100%) had consulted for chronic perianal discharge, most often purulent (16 cases, 57.1%), evolving for a mean of 7.93 months with extremes of 3.5 and 19 months. None of the patients had a continence disorder preoperatively. Inspection of the anal margin revealed a single external orifice in 26 cases (92.9%). It was double in the other 2 cases (7.1%). All patients had prior drainage of the discharge with a mean time to dryness of 4.46 months (2.75 to 7.5 months). In the majority of

cases (64.3%), the discharge had dried up between 3 and 6 months. No additional morphological examination was performed. Nineteen patients (67.9%) were classified as ASA 1. The clinical epidemiology of the study population is summarised in Table 1.

All patients were installed in the waist position, under locoregional anaesthesia in the majority of cases (21, 75%). The internal orifice was identified in all cases and was most often posterior (15 cases, 53.6%). The fistula tract was high trans-sphincter in 25 cases (89.3%). We recorded 2 cases (7.1%) of Y-shaped fistula and one case (3.6%) of horseshoe-shaped fistula. The average duration of the surgery was 55.2 minutes with extremes ranging from 45 to 66 minute. No intraoperative complications were noted. Twenty-seven patients (96.4%) were

Table 1. Clinical epidemiology of the study population.

Variables	N	Percent
Sex		
Male	15	53.6
Female	13	46.4
Age		
<25	1	3.6
[25 - 35[	5	17.9
[35 - 45[	11	39.3
[45 - 55[	7	25
[55 - 65[	2	7.1
≥65	2	7.1
History/Comorbidities		
HBP	17	60.7
Alcohol	22	78.6
Tobacco	13	46.4
BMI		
<18.5	1	3.6
[18.5 - 25[	7	25
[25 - 30[	15	53.6
>30	5	17.9
Fistulectomy	1	3.6
Anal trauma	1	3.6
HIV infection	1	3.6
Preoperative SIW		
0	28	100
External Orifice		
Unique	26	92.9
Double	2	7.1
ASA Classification		
1	19	67.9
2	9	32.1

HBP: High Blood Pressure; BMI: Body Mass Index; HIV: Human Immunodeficiency Virus; SIW: Jorge and Wexner Incontinence Score; ASA: American Society of Anaesthesiologists.

discharged within 24 hours of the procedure and one patient (3.6%) stayed two days after surgery due to severe postoperative pain and acute urine retention requiring trans-urethral catheterisation. The postoperative course was generally simple. However, seventeen patients (60.7%) had experienced tingling that did not require any specific medication. Three patients (10.7%) had experienced transitory gas incontinence (SIW of 4) which had completely regressed after one month. The average healing time was 63.21 days (25 - 95 days). The majority of patients (60.7%) had healed by the third month. All patients had a 6-month follow-up and at the end of this follow-up, none of them had continence problems and no recurrence had been recorded. The operative and evolutionary data of the patients are reported in Table 2.

Table 2. Operative and evolutionary data of patients.

Variables	N	Percent
Type of anaesthesia		
General	7	25
Local	21	75
Topography of the internal orifice		
Anterior	2	7.1
Posterior	15	53.6
Right lateral	4	14.3
Left lateral	7	25
Type of fistula		
High trans-sphincter	25	89.3
Y-shaped	2	7.1
Horseshoe	1	3.6
Post-operative hospital stay		
24 hours	27	96.4
>24 hours	1	3.6
Postoperative SIW		
At 1 week		
0	25	89.3
4	3	10.7
At 1 month		
0	28	100
At 6 months		
0	28	100
Healing Time in day		
0 - 30	1	3.6
31 - 60	6	21.4
61 - 90	17	60.7
>90	4	14.3
Recurrences		
Yes	0	0
No	28	100

SIW: Jorge and Wexner incontinence score.

4. Discussion

LIFT-Plug is a surgical technique in the treatment of fistula introduced by Han *et al.* in 2011 [23]. In the original description, the authors used an acellular dermal matrix (ADM) which a soft connective tissue graft generated by a decellularisation process preserving the intact extracellular skin matrix. During implantation, this structure serves as a scaffold facilitating subsequent cell repopulation and revascularisation by providing resistance to infection or contamination [29] [30]. Subsequently, other authors have used the Cook Surgisis AFP™ device which is a collagen-rich extracellular matrix made from freeze-dried porcine small intestinal submucosa. It contains growth factors and cytokines. It is designed in the shape of a cone to be placed in the fistula tract. These materials are not marketed in our country. Our team has adapted an anal plug by folding it into a cone shape, a two-sided piece of prosthesis made of a non-resorbable polypropylene monofilament on one side and an absorbable hydrogel barrier on the other side. It is therefore a non-absorbable material introduced into an infected and inflammatory environment. The aim of our work was to evaluate the therapeutic results and medium-term safety of this device.

Anal fistula is an abnormal communication between the anal canal and the surrounding perineal skin, most often originating from an infected anal gland. It is a chronic infection and inflammation with no tendency for spontaneous healing. Treatment is based on surgery, the aim of which is to remove the infection while preserving the patient's continence. It should therefore spare as much as possible the sphincter, crossed at variable height by the fistulous path. Traditional treatment by fistulotomy or fistulectomy, which is effective and safe in low fistulas, is not recommended in the case of high fistulas, due to a high rate of continence disorders [1] [2] [3] [4] [5]. Several treatment alternatives have been developed. Fibrin sealant injection, anal plug and LIFT are procedures that have been widely used in recent decades. They are simple to perform and preserve the sphincters, thus limiting the risk of postoperative incontinence. However, they have a low cure rate with frequent recurrences, requiring repeat procedures or other techniques [7] [9]-[22] [31].

Since its initial description by Han *et al.*, the LIFT-Plug has been evaluated several times. This method has shown better healing results than either of the two techniques alone. Indeed, success rates after anal plug placement or LIFT vary from 20% to 86.7% [7] [9] [10] [11] [12] and 40% to 95% [13]-[18] respectively, depending on the study. High recurrence rates are high and range from 0% to 26.3% [11] [12] and 6.4% to 28% [19] [20] [21] [22] for anal plug and LIFT respectively. Moreover, these results seem to deteriorate over time [32]. The LIFT-Plug gives better results with cure rates of 94% - 96.5% and minimal recurrence [17] [18] [24] [25]. However, Tan *et al.* found a success rate of 68.8% with an average delay of 3 weeks between surgery and diagnosis of failure [26]. In our study, the LIFT-Plug has a 100% cure rate and no recurrence at 6 months follow-up. However, this follow-up time is much shorter than that of many au-

thors [11] [14] [16] [18] [24], and when we know that the results fade with time [32]. Indeed, Eduardo and al found a median time to recurrence of 24.8 weeks after inter-sphincter ligation [16]. In addition, patients with specific fistulas, other anal lesions, or defects that could impede the healing process were excluded. Two studies comparing LIFT with LIFT-Plug found a statistically significant higher success rate with the LIFT-Plug technique and a shorter healing time, despite a longer operative time [17] [18]. The average operating time in our series was 55.2 minutes, which is longer than the 17 to 28.5 minutes of other authors [17] [23] [24] [25]. The LIFT-Plug is a new technique in our therapeutic arsenal and therefore requires more learning. The average time to healing was 63.2 days. It was 4 weeks for Cianci *et al.* after LIFT [13]. It is much shorter after LIFT-Plug [17] [18] [23] [24] [25]. This high healing time in our study could be explained by the material used, which does not have the cell repopulation and revascularisation properties of conventional materials. In addition, it has an anti-adherent face which would delay its incorporation into the host tissue.

Preservation of continence remains a major goal in the treatment of anal fistula. While conventional techniques may result in unacceptable levels of incontinence in some cases [1] [2] [3] [4] [5], sphincter-sparing techniques, by preserving the sphincters, have minimal impact on continence. For example, fibrin sealant injection, anal plug and LIFT have very little impact on continence [12] [14] [20] [21] [33]. The LIFT-Plug, as well as the LIFT and anal plug, preserve the sphincters and thus the continence of the patients. Three of our patients presented with transient gas incontinence and none of the patients presented with continence problems at the end of the 6-month follow-up. Compared with LIFT and LIFT-Plug, these results are similar [14] [17] [20] [21] [23] [24] [26].

No major adverse events were noted. However, a significant proportion of our patients (60.7%) presented with tingling that regressed spontaneously. No cases of intolerance or infection of the plug were recorded, apart from the delay in healing already mentioned. In contrast to our series, several authors have reported cases of spontaneous expulsion of the plug, often signifying failure of the procedure [11] [24] [33]. However, these promising results need to be followed up for a long time in order to consolidate the effectiveness of our procedure and to confirm the safety of our anal plug.

5. Conclusion

The LIFT-Plug is a simple, and effective technique for the treatment of high anal fistula without major impairment of continence despite delayed healing. The adapted two-sided prosthesis is a good alternative to the conventional anal plug. It is very well tolerated but a significant amount of time is needed to validate these results.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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