



The SiLaC procedure for pilonidal sinus disease: long-term outcomes of a single institution prospective study

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Abstract

Background In 2014, we started to treat pilonidal sinus disease in our institution with sinus laser-assisted closure (SiLaC) procedure. The aim of the present study was to evaluate the safety and efficacy of the SiLaC procedure in a single institution prospective study on a large cohort of patients and with a long follow-up period, and try to determine what factors that could influence healing and recurrence.

Methods A prospective study was conducted on consecutive patients with primary pilonidal sinus disease operated on with the SiLaC procedure at our institution from March 2015 to August 2017. Demographic and surgical data, outcomes, and complications were prospectively recorded and compared between the healed and not healed/recurrence groups to find factors influencing healing. Postoperative follow-up was performed in the outpatient clinic every 2 weeks for 2 months. In March 2018, patients were questioned by mail or phone to assess long-term recurrences.

Results There were 200 patients. The healing rate was high (94%) with a mean healing time of 19.5 ± 14.4 days. Mean operative time (9.4 ± 2.6 min) and mean duration of postoperative analgesic therapy (4.72 ± 5.64 days) were short. Postoperative complications (15%) were mainly infection (9.5%). There was a response rate of 77.5% to mail/phone questionnaires about recurrence. The recurrence rate was 14.9%. Mean time until recurrence was 193.5 ± 87.19 days. The incidence of secondary openings, complications, and infection in the healing vs not healed or recurrence groups, was 24.8% vs 56.6%, 19.2% vs 40%, and 8.8% vs 30%, respectively.

Conclusions SiLaC is an effective, easy to perform, reproducible, and almost painless procedure. Factors influencing healing seem to be the presence of secondary openings, postoperative complications, and, especially, infection. The SiLaC procedure could become one of the treatments of choice for pilonidal sinus disease.

Keywords SiLaC · Pilonidal disease · Pilonidal sinus · Laser · Surgery · Technique

Introduction

Pilonidal sinus disease (PSD) is a benign disease occurring in adolescents or young adults, especially males, generally between 15 and 30 years old, and characterized by the presence of primary pits and subcutaneous tracts in the natal cleft which may be asymptomatic or become infected leading to a painful acute abscess or a chronic swelling and recurrent discharge from the primary or secondary openings

off midline with repetitive periods out of school or work [1–6].

Sacroccygeal PSD is generally considered to be an acquired, not a congenital disease [5, 7]. Two theories have been proposed for the appearance of a pilonidal sinus. Bascom suggested that pits developed from midline hair follicles that became obstructed and distended with keratin and entry of hair and debris are a secondary phenomenon [8, 9]. Karidakis considered hair as the primary cause of PSD. Small shafts of hair coming from the buttocks or other regions of the body, sometimes hair from animals, enter into the skin of the natal cleft creating a foreign body reaction and the progressive development of a tract filled with granulation tissue and partially lined with an epithelium [3, 4, 10].

Risk factors for PSD include familial history, obesity, male sex, an occupation requiring prolonged sitting, and

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sometimes poor hygiene, but the most important factor is excessive body hair/hair in the natal cleft [1, 2, 7]. There are many surgical options for treating PSD, but none of them is considered a gold standard. The ideal procedure should have the characteristics of minimally invasive surgery: easy to perform, reproducible with a short learning curve, a short operative time and hospital stay, easy postoperative care, a rapid recovery with minimal pain, and few complications [1, 11, 12].

In 2011, Wilhelm described for the first time a new technique using a radial diode laser probe for the treatment of anal fistula [fistula–tract laser closure (FiLaC™), biolitec, Germany]. The probe destroys the epithelium lining the fistula and simultaneously obliterates the tract by a shrinkage effect [13].

In 2014, we were the first in Belgium to use the sinus laser-assisted closure (SiLaC™, biolitec, Germany) procedure for the treatment of PSD based on the same principles as FiLaC™ [1]. Our good results published in a preliminary retrospective study on a small group of patients were more recently confirmed by different publications [1, 11, 14–16].

The aim of the present study was to evaluate the safety and efficacy of the SiLaC procedure in a single institution prospective study on a large cohort of patients and with a long follow-up period and to determine what factors influence healing and recurrence. We also give some tips and tricks.

This prospective study was approved by the local institutional review board and faculty ethics committee.

Materials and methods

A prospective study was conducted on all consecutive patients with primary PSDs who were operated on with the SiLaC technique in our institution from March 2015 to August 2017. In case of acute abscess, definitive SiLaC surgery was delayed for 6–8 weeks after the onset of infection.

The diagnosis was confirmed by local clinical examination. Only in case of doubt was magnetic resonance imaging or a computed tomography scan performed. The operative technique and potential risks and complications of the procedure were explained to the patients and they were informed of the prospective study. Written informed consent was obtained from all patients.

A persistent secondary opening off midline was not a counter indication for the procedure. SiLaC was offered to patients already operated on with a classical or laser technique, but they were excluded from the study.

Postoperative follow-up was performed in the outpatient clinic every 2 weeks for 2 months. After healing, patients were asked to come back in case of recurrence or any

complications. Patients with soiling for more than 2 months were considered not healed.

Parameters entered into the database were patient age and sex, the number of primary pits, the presence of secondary orifices at the time of the operation, operative time, total amount of joules delivered as is displayed on the screen of the generator, duration of analgesic therapy, and duration of soiling and complications.

In March 2018, a questionnaire was sent to the patients to assess any further complications or recurrences and to evaluate satisfaction with a numeric rate scale satisfaction score from 0 to 10 (0: not satisfied at all; 10: fully satisfied). Those who did not respond were contacted by phone and completed the questionnaire in a phone interview.

Technique

The SiLaC technique is the same as described in our previous retrospective study published in 2016 [1].

The probe used is the smooth radial diode laser at 1470 nm wavelength. Energy used is 10 W.

Patients were operated on as day cases, usually under loco-regional (spinal) anesthesia in the prone position with no antibiotic prophylaxis.

The procedure begins with enlargement of the different primary pits or reopening those completely sealed and removal of hair with a Mosquito clamp (Fig. 1). The subcutaneous tissue around the tract is infiltrated with saline to avoid skin burning by a cooling and a bulging effect. Injection of water increases



Fig. 1 Enlargement of the pits and removal of hair with the mosquito clamp

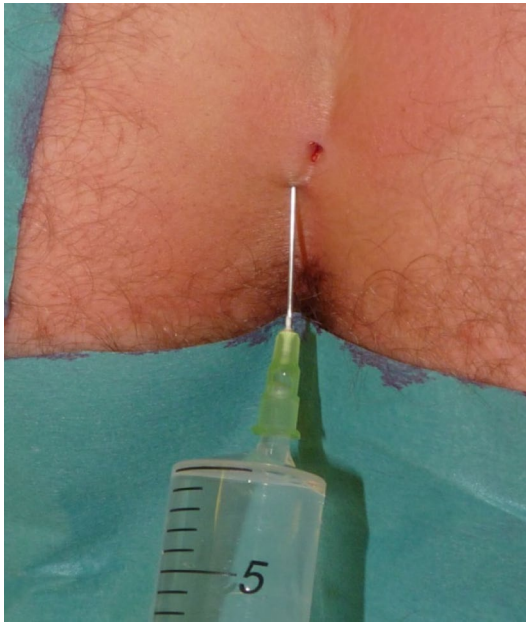


Fig. 2 Subcutaneous infiltration with saline water

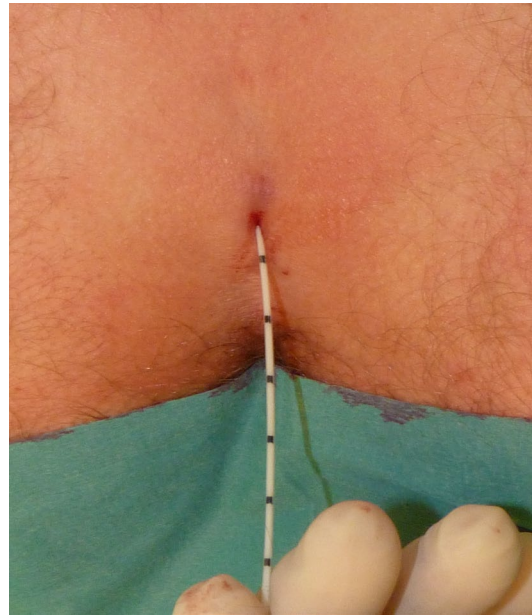


Fig. 4 Destruction of the tract with the laser

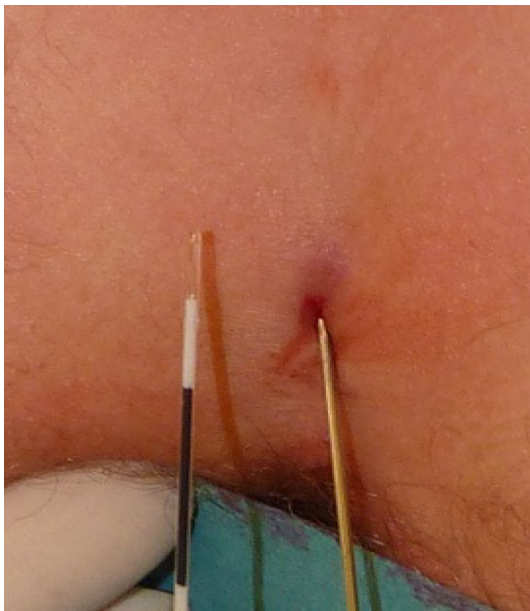


Fig. 3 The tract is found with a metallic stylet which is then replaced by a probe

the distance between the skin and the probe as the laser interacts with cells in a 2–3 mm radius (Fig. 2). A metallic stylet is used to determine the length and direction of the different tracts (Fig. 3). The probe is pushed up to the top of the tract and removed slowly (about half a centimeter per second), while the laser is activated. Application of the laser causes destruction of the epithelium lining the tract and a shrinkage

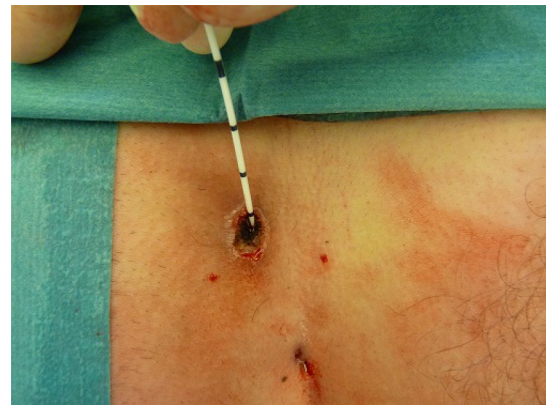


Fig. 5 Destruction of the sinus wall through the secondary opening

effect (Fig. 4). If shrinkage is not complete (i.e., if there is no blocking or resistance when reinserting the probe), a second procedure is performed. If there is a secondary opening at the site of the previous abscess, the procedure is performed through that opening after a first procedure from the primary pit (Fig. 5).

At discharge, the patient is instructed to take a shower twice a day, push on the skin of the natal cleft to bring out secretions, and cover the pits with an antiseptic cream on a compress.

Statistical analysis

Prospective data were collected using Microsoft® Excel 2016 and expressed as mean \pm standard deviation (SD) and minimal and maximal range.

Student's *T* test was used to compare the continuous variables and the test of comparison of two proportions or Fisher's exact test was used for categorical variables. The program used for the comparison was also Microsoft® Excel 2016.

A *p* value ≤ 0.05 was considered statistically significant.

Results

Two hundred consecutive patients with a primary pilonidal sinus were prospectively studied. One hundred and forty-four patients were men (72%) and 56 women (28%). The mean age was 24.5 ± 7.2 years (range 15–45 years). Demographic data and operative characteristics are presented in Table 1.

In March 2018, 45 patients were lost to follow-up at the end of the study and 155 (77.5%) patients were fully evaluated.

The mean duration of follow-up was 525 ± 266 days (range 182–1114 days).

All the patients were operated on day case surgery and only one patient was re-hospitalized within a month for a postoperative abscess.

The mean operative time was 9.4 ± 2.6 min (range 6–16 min). The mean number of primary pits was 1.57 ± 0.82 (range 1–5 pits). Sixty patients had a secondary orifice opening off midline at the site of a previous abscess (30%). The mean amount of joules delivered per pit was 352.6 ± 268.34 (range 135–570 joules).

The mean duration of analgesic therapy (paracetamol) was 4.72 ± 5.64 days (range 0–30 days). One hundred and seventy-one (85.5%) of the 200 patients took pain killers for less than 7 days and 47 (23.5%) patients took no pain killers at all postoperatively.

The mean satisfaction score was 8.66 ± 1.98 (range 0–10).

Thirty (15%) patients developed postoperative complications. Nineteen (9.5%) patients developed postoperative infection: 17 (8.5%) had infected soiling needing antibiotics in addition to the local care and 2 (1%) developed an abscess drained by gently reopening the primary pits in the

office without analgesia. Eight (4%) patients developed a fibrin membrane obstructing the primary pits and preventing evacuation of secretions. The membrane was easily removed with a curette during outpatient appointments. No antibiotic treatment was proposed to those patients and all of them had an uneventful recovery. Three (1.5%) patients developed a hematoma: one hematoma was punctured and the other was evacuated by a gentle pressure. Postoperative outcomes are summarized in Table 2.

One hundred and eighty-eight (94%) of the 200 patients followed healed within 2 months. Of these 188 patients, 176 (94%) had no soiling at 2 months and were considered healed. The mean time for healing was 19.5 ± 14.4 days (range 2–60 days).

Of the 155 patients answering the questionnaire in March 2018, 144 patients had healed and 22 (15.2%) of them had recurrence of symptoms. The mean time for recurrence was 193.5 ± 87.19 days (range 30–360 days).

A second laser treatment was proposed to the patients who did not heal or recurred. Healing and recurrences are summarized in Table 3.

In an attempt to find factors that could influence healing, we compared different parameters in the groups healed and not healed or recurrence among the 155 patients fully followed. The comparison is summarized in Table 4.

There was no statistically significant difference between the two groups by sex (healed: 91/125, 72.8%, not healed: 22/30, 73.3%, $p = 0.635$), age (healed 26.3 years, not healed 24.6 years, $p = 0.755$) or mean number of joules per pit (healed 351.4, not healed 354.9, $p = 0.0851$).

However, the presence of a secondary orifice at the time of the operation (healed: 31/125, 24.8%, not healed: 17/30, 56.6%, $p = 1.8 \times 10^{-11}$), postoperative complications (healed:

Table 1 Patients and operative characteristics

Age (years) ^a	24.5 ± 7.2 (15–40)
Sex (M/F)	72/28
Follow-up (days) ^a	525 ± 266 (182–1114)
Operative time (min) ^a	9.4 ± 2.6 (6–16)
Primary pits ^a	1.57 ± 0.82 (1–5)
Number of secondary orifices (%)	60 (30)
Amount of Joules/pit ^a	352.6 ± 268.34 (135–570)

^aExpressed as mean \pm SD and range

Table 2 Postoperative outcomes

Patients not doing usual activities, <i>n</i> (%)	
For 4 days	151 (97.4)
For 11 days	4 (2.6)
Duration of analgesic therapy, days ^a	4.72 ± 5.64 (0–30)
Patients taking PK ≤ 7 days (%)	171 (85.5)
Patients not taking PK (%)	47 (23.5)
Satisfaction score/10 ^a	8.66 ± 1.98 (0–10)
Complications/200 patients (%)	
Overall	30 (15)
Infection	19 (9.5)
1. Abscess	2 (1)
2. Infected soiling	17 (8.5)
Fibrin membrane	8 (4)
Hematoma	3 (1.5)

n number, PK pain killers

^aExpressed as mean \pm SD and range

Table 3 Healing and recurrence

Primary healing/200p (%)	188 (94)
Healing time (days) ^a	19.5 ± 14.4 (2–60)
Recurrence/144p (%)	22 (15.2)
Time for recurrence (days) ^a	193.5 ± 87.19 (30–360)
Second treatment/30p	
Laser (%)	12 (40)
Open (%)	12 (40)
None (%)	6 (20)
Healing rate/12p (%) after second laser treatment	9 (75)

p patients

^aExpressed as mean ± SD and range

24/125, 19.2%, not healed: 12/30, 40%, $p = 9.4 \times 10^{-10}$), and particularly postoperative infection (healed: 11/125, 8.8%, not healed: 9/30, 30%, $p = 2.4 \times 10^{-12}$) were associated with higher non healing and more recurrence.

Discussion

PSD is a benign but disabling disease occurring in adolescents and young adults. Although conservative approaches may sometimes control the disease, only surgery can definitively solve the problem [1, 2, 4, 5, 7].

Many surgical techniques can be used, and there is no consensus about the ideal treatment. The most frequently used technique is wide excision in healthy tissue creating a large wound, with secondary healing, and disabling and generally painful postoperative care for more than 2 months [7, 12, 14, 17]. For simple cases, curettage or pit picking can be used with 85% healing rates and 20–25% recurrence rates [11, 12, 18].

To reduce healing time, different types of closure can be performed. Midline closure is easy and quick to perform, but no longer recommended by some national guidelines because of high rates of infection and wound dehiscence and recurrence rates as high as 38% [3, 7, 17, 19].

Off midline techniques (Z plasties, V–Y flaps, Limberg, Karidakis or Bascom flap...) are generally used for more complex or recurrent cases, but they involve longer hospitalization, drains, intravenous antibiotics, and are also more painful. Results are variable and wound dehiscence ranges from 3 to 15% [3, 7, 17–20].

In 2014, we decided to radically change our approach to pilonidal sinus treatment and begun to use the SiLaC procedure based on the FiLaC procedure for the treatment of anal fistula described for the first time by Wilhelm in 2013 [13].

Our preliminary good results were confirmed by different studies using the same laser procedure [1, 11, 14–16]. Herein, we report the results of a prospective study on 200 patients and those of a survey on 155 patients with long-term follow-up (mean duration of follow-up: about 1 year and 5 months).

The operative time is very short (about 9 min) and the technique is very easy to perform. The learning curve is very short and a maximum of 20 cases could be considered enough for proficiency. In our institution, all the patients are operated on under loco-regional anesthesia (spinal anesthesia) as 1-day surgery cases with no antibiotic prophylaxis, but other surgeons operate under local anesthesia sometimes with an additional sedation [11, 14, 15]. One of the greatest advantages of the technique is that it can be applied to all stages of pilonidal disease, from a simple primary pit, multiple primary pits, patients with multiple secondary openings off midline, tracks going up or down with the same simplicity, and no need to choose between different techniques. Nevertheless, the recurrence rate (14.9%) should be kept in mind especially when treating patients with chronic secondary opening, since we have shown a recurrence rate which is double of the one of patients presenting without secondary opening. Therefore, the best indications of SiLaC are for an advanced disease with multiple primary pits and secondary openings, since it prevents these patients from having large excisions and long-lasting postoperative home care.

The immediate healing rate in the present study was very good (188/200, 94%) and comparable to that found by Pappas et al. (90.3%) and Georgiou (92%) in two recent prospective studies [11, 14].

Table 4 Factors influencing healing

	Healed	Not healed-recurrences	Statistics (exact p)
Male sex (%)	72.8	73.3	NS ($p = 0.635$)
Age (years) ^a	26.3 ± 8.2	24.6 ± 4.8	NS ($p = 0.755$)
Joules/pit ^a	351.4 ± 169.6	354.9 ± 240.6	NS ($p = 0.0851$)
Secondary orifice (%)	31/125 (24.8)	17/30 (56.6)	$p < 0.05$ ($p = 1.8 \times 10^{-11}$)
Complications (%)	24/125 (19.2)	12/30 (40)	$p < 0.05$ ($p = 9.4 \times 10^{-10}$)
Infection (%)	11/125 (8.8)	9/30 (30)	$p < 0.05$ ($p = 2.4 \times 10^{-12}$)

NS not significant ($p \geq 0.05$)

^aExpressed as mean ± SD

This study concerned only patients with primary disease. Patients already operated on with another technique or with the SiLaC procedure were excluded from the study. After an SiLaC procedure, a second laser procedure is always possible and was proposed to the 30 patients in our study who either did not heal or had recurrence. But of the 30 patients in that situation, 12 patients (40%) did not want any further operation, because their pain and soiling were minimal and 12 underwent redo SiLaC with a success rate of 75% (9/12) which is comparable to Pappas (78.3) [11]. Georgiou had 100% success rate with redo SiLaC on a very small number of patients ($n=4$) [14]. After a lay open or suture procedure, some patients were unsuitable for laser. The ideal patient should not have a big cavity, so that the laser can destroy the entire lining of the cavity and give the patient the best chances to heal. Pappas, on the contrary, included all the patients with PSD with or without a previous intervention with the same results for the two groups [11].

We never give antibiotics preoperatively or postoperatively, in contrast to Georgiou [14, 15]. The use of perioperative antibiotics for the SiLaC may be the subject of future investigations.

Postoperative complications were mainly infections (19/200, 9.5%) needing only oral antibiotics and local wound care but no reoperations. Another complication observed was the presence of a fibrin membrane at the site of the primary orifice which was easily removed with a curette with no further consequences on healing. The appearance of that membrane is probably due to the fear of the patients to clean the skin of the natal cleft during showering to remove secretions and debris. To avoid this, patients should try to clean the pits with a Q-tip, but it is not possible to perform this without help. One of the great advantages of the technique is the short duration and low level of postoperative pain: this permits a rapid return to work or school. Mean duration of analgesic therapy was only 5 days (range 0–30 days). An important finding was that 47/200 (23.5%) patients took no pain killers at all postoperatively.

Trying to find factors that could influence healing, we compared the group of patients who healed and the group of patients who did not heal or had recurrence. The presence of secondary off midline open orifices, postoperative complications, and, particularly, infection were significantly higher in group of patients who experienced a recurrence. Although a secondary opening increases the risk of recurrence after SiLaC, the benefits of the procedure outweigh the risks, because in patients with advanced disease, it prevents the need for morbid wide excisions of tissue. In patients with a secondary off midline opening, after a first passage of the laser probe through the different primary pits, the probe may be inserted and activated from the secondary orifice to allow a better destruction of the lining of the sinus. When a tract turns towards the anus, secretions cannot easily drain out the

primary pit. In these cases, a secondary orifice at the lower end of the tract can be created with electrocautery to allow a better evacuation of secretions and debris (Fig. 6).

Recognition and cleaning of the tracts are essential for good healing. A small Mosquito clamp, a curette, or a brush can be used. Nevertheless, SiLaC is a blind procedure which can miss some trapped hair or lateral tracts. To avoid those problems, Meinero et al. developed, in 2013, endoscopic pilonidal sinus treatment (EPSIT) based on a similar minimally invasive technique, video-assisted anal fistula treatment (VAAFT). Under direct vision, hair and debris are removed. Then, the sinus lining is destroyed by monopolar electrocoagulation. However, the procedure requires much more expensive instrumentation and is more complicated to perform than SiLaC and healing rates are similar ranging from 88 to 94.8% [6, 12, 21, 22]. A minimally invasive technique not requiring expensive equipment, but with similar results to this series is treatment with fibrin glue [23].

As hair is the key factor in the development of the disease, hair removal from the natal cleft can help healing and prevent recurrence. Razor, cream, and laser depilation are possible methods. Comparing these methods, Pronk et al. in 2017 showed that laser was better than no removal at all which was better than razor or cream depilation in term of recurrence after surgical treatment of pilonidal sinus. Razor particularly creates small shafts of hair which can enter the skin of the natal cleft and create a new pilonidal sinus. Therefore, razor depilation should be avoided in this area [24–26]. On the contrary, laser depilation has been used as

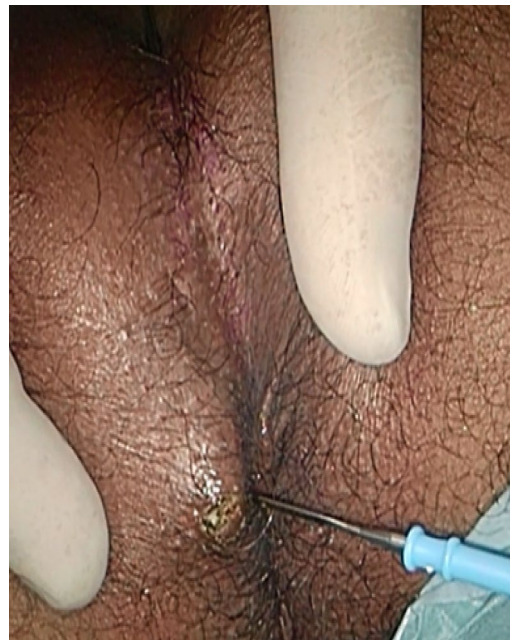


Fig. 6 Creation of a secondary opening when the tract turns downward for a better evacuation of soiling

the first-line treatment in small series with good results as high as 75% [16, 19, 26–29], and we have used it occasionally in very hairy patients prior to a first surgical treatment or prior to a second surgery in case of a recurrence.

Cost is one of the drawbacks of the SiLaC procedure as it needs a generator and a disposable probe. But that additional cost is largely balanced by the advantages of this technique: short hospital stay, short duration of postoperative pain, short period out of school or work, and no need of a nurse for postoperative care. Moreover, the laser technique and the generator can also be used to treat hemorrhoids, fistula, and varicose veins. In Belgium, the probe costs about 220 euros but for the moment, the cost of the probe is not covered by the national social security, and in our center, it was paid by the hospital and provided free of charge to the patient [14].

Our results as well as those of other prospective studies have several weaknesses; first, the lack of comparison with a more classical procedure in a randomized-controlled trial; second, the long-term follow-up was not complete. Third, pain killer intake is not the best way to measure pain and using a visual analog scale or numeric rating scale would be preferable. Finally, follow-up conducted through a questionnaire may not always reflect actual results.

Conclusions

SiLaC is easy to perform and reproducible with a short learning curve and good results in terms of healing and complications allowing a rapid recovery and rapid return to work or school. SiLaC could become one of the treatments of choice for PSD, especially for more complex cases.

Compliance with ethical standards

Conflict of interest Dr Dessily received grants From Biolitec to perform workshops on the SiLaC procedure for European Surgeons in 2018. The other authors declare that they have no conflict of interest.

Ethical approval This prospective study was approved by the local institutional review board and faculty ethics committee.

Informed consent Written informed consent was obtained from all patients.

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