

A new minimally invasive treatment of pilonidal sinus disease with the use of a diode laser: a prospective large series of patients

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Abstract

Aim Various surgical techniques are available for the management of pilonidal sinus, but there is still controversy concerning the optimal surgical approach. The aim of our study was to evaluate the safety, efficacy and clinical outcome of a laser procedure for the treatment of pilonidal sinus.

Method Patients suffering from pilonidal sinus were operated on with sinus laser therapy (SiLaT) in our institute. SiLaT was applied under local anaesthesia after a small skin incision of 0.5–1 cm and careful cleaning of the sinus tracts with a curette. A radial fibre connected to a diode laser set at a wavelength of 1470 nm was then introduced into the tracts. The laser energy was delivered in continuous mode.

Results Two-hundred and thirty-seven patients (183 male, median age 24 years, range 14–58) suffering from pilonidal sinus were operated on using the SiLaT laser procedure in our referral Institute and prospectively evaluated. A high healing rate was observed after the first session (90.3%, 214 of 237) with a median healing time of 47 days (range 30–70 days). A second treatment was offered for patients failing in the first session; this was successful in 78.3% (18/23). The duration of the procedure ranged between 20 and 30 min and had

limited morbidity (wound infection in 7.2%, 17 of 237).

Conclusion SiLaT proved to be a safe and effective procedure for treating patients suffering from pilonidal sinus. Clinical results showed low morbidity and recurrence rates comparable to the published literature for other modern techniques.

Keywords Pilonidal sinus, sacrococcygeal cyst, treatment, laser

What does this paper add to the literature?

Based on previous experience showing the interaction of diode lasers with human tissues in several different procedures, we used laser energy delivered by means of a specific type radial emitting fibre to ablate the epithelium of pilonidal sinuses. The aim was to promote the formation of granulation tissue with consequent healing of the sinus. We named this relatively new therapeutic approach 'SiLaT', an acronym for sinus laser therapy. The procedure had impressive results and led to a high healing rate with a minimally invasive approach and minimal morbidity. One of the major strengths of our technique is that it can be performed under local anaesthesia, sometimes combined with appropriate sedation, leading to quick recovery and cost-savings for the patient.

Introduction

Pilonidal sinus is a common disease. It has a prevalence of approximately 26 cases per 100 000 people. It is more common in young men, with a 3:1 to 4:1 male to female ratio [1–4]. Pilonidal sinus is a cavity in the subcutaneous tissue in the coccygeal area. The majority of

authors have concluded that this is an acquired disorder, while a minority believe that it is congenital [5]. Patey and Cascol, immediately after the end of World War II assumed that the disease was the result of penetration of hair into the subcutaneous tissue that led to a granulomatous inflammatory reaction [6]. According to Karydakos [7], there are three major factors that contribute to the penetration of hair into the subcutaneous tissue: (i) the substance that penetrates, which consists of loose hair; (ii) a certain force which causes the

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penetration of hair, (iii) the susceptibility of the skin in the specific area. When all these three factors apply hair infiltrate the skin and a pilonidal cyst is created.

To date, there is no treatment that can be considered a gold standard for this condition. Although acute abscesses are generally treated with incision and drainage, the chronic manifestation of the disease can be treated with wide excision. In these cases, gradual deroofting of the cavity is performed with diathermy and laser ablation and the resulting large wound is left open (or sutured, according to the personal preference of the physician), with complete healing in 2 months [8–10]. Various techniques for plastic reconstruction of larger wounds have also been used, such as the application of skin flaps, Z-plasty [11], Karydakis plasty [12], Bascom flap [13] and Limberg flap [14]. These complex techniques are often associated with increased morbidity and a high rate of recurrence [15–18]. Abramson described for the first time the simple incision and ablation of the cyst walls in patients with simple or complicated disease (abscess, chronic and relapsing conditions) with a healing rate of 93% [18].

Surgical management can be divided into two categories: excision of the diseased tissue with primary closure, using various techniques, or excision and healing with secondary intention. Both techniques have a healing rate of over 80%, but a higher complication rate has been reported with the first technique and a longer healing time with the second one [2].

In the past years, simple techniques, such as laying the sinus open, simple cavity ablation, the use of fibrin glue and chemical exposure of the tracts with phenol injection, have been more widely used in the management of pilonidal sinus, with moderate results and healing rates of 60–80% in small series of patients [19–22]. The ideal procedure should be simple, with minimal tissue loss and a low recurrence rate. Furthermore, it should require a short hospital stay and a quick return to daily activities. In this regard, there is growing evidence in small series of patients that the use of a diode laser in the treatment of pilonidal sinus may represent a good solution, being a minimally invasive procedure with minimal damage to proximal tissues and with reported success rates of 80–90% [23–27]. Failed cases usually require more aggressive surgical treatment.

The aim of our study was to evaluate the efficacy and safety of a new minimally invasive technique using a diode laser for the treatment of pilonidal sinus in a prospective series of patients with pilonidal sinus of varying severity.

Patients and methods

Patients

Any patient with a pilonidal sinus who presented or was referred for treatment with sinus laser therapy (SiLaT) was eligible for the study. All consecutive patients were treated with SiLaT as a first-line treatment. Patients signed an informed consent after a detailed explanation of the operative technique and any potential risks from the procedure. A complete physical examination was performed along with local evaluation of the pilonidal sinus. Patients with previous failed treatment were not excluded from SiLaT. In contrast, patients with systemic colonic disease, such as inflammatory bowel disease, were excluded from the study. Important parameters such as duration of the operation, length of hospital stay, healing time, morbidity and recurrence were reported. The postoperative follow-up included an outpatient evaluation at days 15, 30, 45 and 60. A healing time longer than 60 days was defined as delayed healing and necessitated further patient visits. Longer follow-ups were conducted via telephone interviews at 180 and 360 days. Repeat treatment was offered to the patients with persistent disease 2 months after the initial procedure.

The pain scores were calculated using a numeric rating scale (NRS) from 0 to 10 (0 no pain, 10 worst pain ever) [28]. The pain was considered mild with a score of 1–4, moderate with a score of 5–7 and severe with a score of 8–10.

In order to better define the types of patients that may mostly benefit from this procedure, we divided the disease into four stages:

Stage I: solitary cavity with a diameter < 2 cm

Stage II: solitary cavity with a diameter > 2 cm

Stage III: a sinus in the natal cleft with lateral expansion or an expansion on the medial line itself

Stage R: relapsing disease after one or more previous incisions performed elsewhere.

This classification was developed by the authors to facilitate assessment of disease severity. Patients were encouraged to come back if their symptoms relapsed, and a visit was scheduled approximately 12 months after the last treatment. If the patient did not come back at the visit a telephone call was made to ensure there had been no relapse.

Operative technique

Previous reports have shown the beneficial interaction of a diode laser with human tissues in several different

procedures [23,24,29] and its therapeutic potential for the treatment of fistulas. Wilhem *et al.* [24] used this technique for the treatment of anal fistula, while Giampundo *et al.* [23] described the FiLAC technique ('fistula-tract laser closure') for anal fistula with the same laser device. Our hypothesis was that laser energy delivered by means of a radial emitting fiber could successfully ablate the epithelium of a pilonidal sinus, promoting the production of new granulation tissue with consequent healing of the sinus. We named this relatively new therapeutic approach 'SiLaT' and refined the operative technique. We used the same laser kit as for treatment of anal fistulas [23,24,29,30] and for the treatment of pilonidal sinus in a preliminary study by Dessily *et al.* [25]. Following the subcutaneous administration of local anaesthetic (xylocaine), an incision of 0.5–1 cm is made along the medial line of the sinus or on the preexisting orifice of the sinus. Subcutaneous tracts need to be located. In selected cases, secondary incisions are deemed necessary in order to drain larger pilonidal sinuses. Hair and debris are cleaned from the sinus and the secondary tracts by means of a brush or punch biopsy forceps (Fig. 1).

The inflammatory tissue and epithelium lining the tracts are partially removed with a curette. Finally the tracts are cleaned with saline solution. A radial fibre acting at 360° connected to a diode laser set at a wavelength of 1470 nm (Biolitec Biomedical Technology, Jena, Germany) is then introduced into the tracts. The laser energy is delivered in continuous mode (Videos S1 and S2). By doing this, homogeneous ablation and total destruction of any remaining granulation tissue is achieved. Each secondary pit needs to be treated with laser energy in the same fashion (Fig. 2).

The laser energy causes progressive shrinkage of the pilonidal tracts, following the destruction of the internal



Figure 1 SiLaT: cyst after tumescent injection and during deep cleaning with a curette.



Figure 2 SiLaT: laser ablation of pits.

epithelium and the pits. The circular diffusion of the energy by the optical fibre facilitates its uniform distribution within the sinus and the tracts. The energy applied in each case depends on the extension of the tracts. An average of 200 ± 30 J of laser energy per square centimetre is usually delivered. The laser device used and the laser catheter used are shown in Fig. 3a,b, respectively.



Figure 3 (a) Biolitec device used for SiLaT. (b) Laser catheter used for the treatment.

The study protocol was approved by the local ethics committee.

Statistical analysis

Demographic data are presented using descriptive statistics. Continuous variables are described as means \pm SD when normally distributed or as median with maximal and minimal range for observations that are not normally distributed. For all calculations we used the SPSS 15.0 working package (SPSS Inc., Chicago, IL, USA).

Results

From June 2012 to December 2015, 237 patients suffering from pilonidal sinus were operated on with the SiLaT laser procedure in our referral Institute and prospectively evaluated. Of the 237 patients, 183 were male (77.2%) and 54 were female (22.8%). Seventy-six patients were diagnosed in Stage I, 49 in Stage II, 85 in Stage III and 27 in Stage R. The median age of the patients was 24 years (range 14–58 years).

The procedures were performed as day surgery. The median hospitalization was 3 h (range 2–4 h). The median duration of surgery was 24 min (range 20–

30 min). One hundred and ninety-three of 237 patients (92.8%) returned to daily activities immediately after hospital discharge. In 17 out of 237 patients (7.2%), all with multiple tracts or extended disease, the functional recovery time was 1–2 days. The various steps of the procedure and follow-up for one of our severe cases are shown in Fig. 4.

Mild pain was observed between the third and eighth days postoperatively in 45 (19.8%) patients. Fever was observed in one patient during the first hours after treatment. Wound infection with mild inflammation in the skin and subcutaneous tissue around the wound was observed in 17 (7.2%) patients. It was treated by local wound cleansing, which included mild external pressure on the surrounding tissues, careful insertion of a curette if that was possible with minimal force and washing with normal saline and antiseptic solution. No postoperative bleeding was observed. Postoperative morbidity and the ability to return to work immediately are reported in Table 1.

The median time for complete healing of pilonidal sinus was 47 days (range 30–70 days). The median follow-up time was 354 days (range 240–390 days).

All Stage-I patients (with a small cavity; 76 patients) achieved healing and showed the shortest healing time

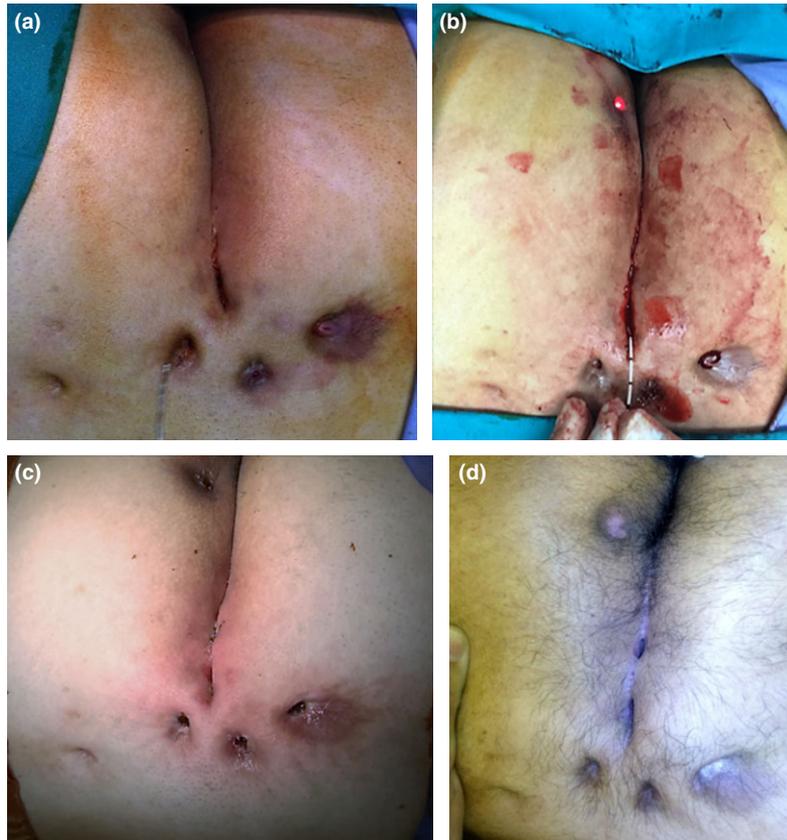


Figure 4 (a) SiLaT in a severe Stage III case with lateral expansion of the cyst. (b) During SiLaT treatment. (c) After SiLaT. (d) Follow-up after SiLaT. Gradual complete healing was achieved.

(mean 40 days, range 30–45 days). In Stage II patients (49 patients), complete healing was observed after the first treatment in 42 of them (85.7%). The mean healing time in this stage was 65 days (range 45–70 days). Of the 85 patients in Stage III, complete healing after the first treatment was observed in 69 (81.2%), with an average healing time of 60 days (range 45–65 days).

Repeat laser treatment was offered and performed in 23 patients (7 Stage II and 16 Stage III) 2 or more months after the first treatment. Complete healing was observed in 18 of them. In five patients healing was unsuccessful, even after the second treatment. These patients underwent repeated surgery with a different technique. In these cases, gradual deroofting of the cavity was performed with diathermy and laser ablation and the wound was left open, with complete healing in 2 months. A summary of the results is reported in Table 2.

Since the patients did not undergo large surgical excision of the pilonidal sinus, the wound openings were small and limited to the site of the sinus opening. In addition, cases of wound infection were few and easily controlled.

An impressive outcome was achieved in the 27 patients with Stage R (relapsing disease after one or more incisions performed elsewhere). All patients with Stage R achieved complete healing after SiLaT treatment, with a mean healing time of 45 days (range 32–55 days), and morbidity was minimal, including only

three cases of delayed healing and five cases of mild postoperative pain.

Discussion

Herein we report the largest series with the new minimally invasive SiLaT procedure. With this technique, healing of pilonidal sinus is achieved by the thermal effect of a laser beam emitted by a diode laser. The penetration of the laser energy is controlled and limited to 2–3 mm around the fibre. As a result of the destruction of the epithelial lining and the granulation tissue, a shrinking and sealing effect on the sinus is elicited [24]. The procedure can be easily applied to all patients regardless of the stage of their disease. A high healing rate was observed after the first session (90.3%, 214 of 237) with a median healing time of 47 days (range 30–70 days). A second treatment was offered to patients who failed in the first session and was successful in 78.3% (18/23). The duration of the procedure ranged from 20 to 30 min and it had limited morbidity (wound infection in 7.2%, 17 of 237). One of the strengths of our technique is that it can be carried out under local anaesthesia and in complex cases with the additional use of intravenous sedation.

In our study the most impressive results were obtained in the complicated cases where the main sinus was longer and with multiple side tracts. In this case

Table 1 Summary of postoperative morbidity and immediate return to work in patients treated with SiLaT treatment for pilonidal cysts of Stages I to III.

	Stage I patients (<i>n</i> = 76; 32.1%)	Stage II patients (<i>n</i> = 49; 20.7%)	Stage III patients (<i>n</i> = 85; 35.8%)	Stage R patients (<i>n</i> = 27; 11.4%)	All patients (237)
Postoperative pain	3 (4.0%)	23 (46.9%)	16 (18.8%)	5 (18.5%)	42 (19.8%)
Wound infection	0 (0%)	12 (24.5%)	5 (5.9%)	0 (0%)	17 (7.2%)
Postoperative haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Delayed healing (> 60 days)	0 (0%)	7 (14.2%)	16 (18.8%)	3 (11.1%)	23 (9.7%)
Immediate return to work	76 (100%)	46 (93.9%)	71 (83.5%)	22 (81.5%)	193 (92.8%)

Table 2 Results of SiLaT treatment for the various stages of pilonidal cysts.

	Patients	Median time (days) to complete healing (range)	Patients subjected to second treatment	Patients subjected to third treatment (open)	Recurrences
Stage I	76 (32%)	40 (30–45)	0	0	0
Stage II	49 (20%)	65 (45–70)	7 (14.2%)	3	2
Stage III	85 (36%)	60 (45–65)	16 (18.8%)	2	5
Stage R	27 (11.4%)	45 (35–65)	0	0	0
Total	237	47 (30–70)	23 (9.7%)	5 (2.1%)	7 (2.9%)

the minimally invasive nature of the procedure is more evident as it does not require the excision of large amounts of tissue. In the case of incomplete closure or recurrence a second session of laser treatment can be applied. The procedure does not prohibit surgery if there is an unsuccessful outcome. In addition, SiLaT treatment can also be applied after another failed procedure with a very high success rate and without increased postoperative morbidity. This excellent result in that group was attributed to the fact that previous treatment had probably achieved significant improvement of the disease, so final SiLaT treatment with a high-energy laser was highly effective. It could also be speculated that patients with relapsing extensive disease treated elsewhere were not referred for SiLaT and were instructed to follow other more invasive therapeutic approaches.

Despite the increasing number of procedures proposed, there is still uncertainty about the best type of surgical technique for the management of pilonidal sinus. Traditional surgical techniques include excision of the pilonidal sinus after removal of debris, hair and necrotic tissue from the sinus cavity. Ensuring a healthy tissue margin increases the healing rate. The wound can be left open for secondary closure with granulation or sutured closed. Primary wound closure shortens the healing time but is associated with an increased complication rate, such as infection, abscess formation and recurrence of the disease. On the whole, no clear benefit has been demonstrated for open or closed technique. The success rate of surgical techniques has been reported to reach 80–90% in most series [31–35]. Some surgeons recommend wound closure by the construction of a flap in complicated cases, with the most common methods being Limberg flap, Karydakias flap, V-Y plasty and Z-plasty. The reported recurrence rate was < 5% with these methods and the complication rate < 10% [36–38].

In recent years there has been a strong effort towards the introduction of minimally invasive techniques for the treatment of pilonidal sinus [21–23]. Conservative methods used in the past include thermal destruction, local radiation, phenol injection and cryosurgery [39–41]. These techniques are no longer recommended due to high complication rates. Some authors proposed the cleaning of the sinus with a Farrell applicator, thorough removal of hair and debris from the cyst and application of 3% peroxide solution to achieve haemostasis and promote the granulation process [42].

Another interesting minimally invasive method is endoscopic pilonidal sinus treatment (the EPSiT technique) popularized by Meneiro *et al.* [43,44] and

published as a multicentre trial. In this method, a fistuloscope is introduced endoscopically into the pilonidal sinus under spinal anaesthesia and then necrotic material, granulation tissue and hairs are removed under direct vision. Good clearance of the cavity is the strongest point of this method and it is followed by widening of the external opening to achieve optimal wound drainage and secondary healing. Meneiro *et al.*'s [44] complete wound healing rate was high at 94.8%, with a short mean complete wound healing time of 26.7 ± 10.4 days and a recurrence rate of 5%.

Currently, the objectives of the ideal treatment are a simple treatment requiring local anaesthesia, minimum hospitalization, quick recovery and return to everyday life activities, less postoperative pain, a high success rate and low cost [22,45]. Some surgeons have introduced lasers for the treatment of pilonidal sinus based on the initial encouraging results for epilation of the sacrococcygeal region performed by dermatologists [32,46–49]. The idea was that the high laser energy could destroy the deep tract systems of the sinus without affecting the overlying skin. Initial reports with Nd-YAG lasers gave encouraging results, with success rates over 70%, shorter duration of treatment, shorter hospital stay, low need for additional surgery (about 7%), minimal discomfort and a low complication rate [26,27]. Other authors have used a newer type of laser treatment for closure of fistula-in-ano, with a primary healing rate of about 70% [30,50]. Primary closure of the tract was achieved by a radial laser fibre connected to a diode laser. The laser energy caused shrinkage of the tissue around the fibre, resulting in healing and preservation of continence for such a complex situation. The diode laser delivers energy at 1470 nm, providing an optimal absorption curve in water which is considered to achieve effective protein denaturation and tissue shrinkage. Dessily *et al.* [25] treated 40 patients with a pilonidal sinus using a radial diode laser probe in order to destroy the sinus epithelium by the delivered energy and achieve obliteration of the tract. The success rate was 87.5%, the recurrence rate 2.9% and the complication rate 10% (two cases of haematoma and two abscesses, all medically treated).

The weakness of the procedure is the blind control of the tracts that may still contain foreign bodies or untreated epithelium. For this reason, in order to reduce the risk of recurrence, careful cleaning of the cavity is deemed mandatory prior to laser treatment [51]. The limitations of our study were the absence of a control arm with a traditional surgical treatment and the variability of the treated cases, which was due to the wide range of manifestations of pilonidal sinus. We even included cases that had failed by other methods and were successfully treated with SiLaT.

Conclusion

SiLaT proved to be a safe and effective procedure to treat patients suffering from pilonidal sinus. Clinical results showed low morbidity and reasonable recurrence rates.

The procedure was proven to be quick, minimally invasive and easy to perform. It can be performed under local anaesthesia and does not require postoperative packing of wounds. In addition, it is associated with a quick return to normal daily activities.

Further randomized studies are needed in order to better define the future role of this procedure in comparison with other procedures in the treatment of pilonidal sinus disease.

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Supporting Information

The video may be found in the online version of this article and also on the Colorectal Disease Journal YouTube and Vimeo channels:

Video S1. ‘Video SiLaT Treatment’. A short video demonstrating the sinus laser treatment in a pilonidal sinus. The effective delivery of laser energy in continuous mode and at the predefined settings as described in the manuscript is very important for the efficacy of treatment.

Video S2. ‘Video Setting’ A short video demonstrating the setting of the device in the operating theatre, along with the fiber. Getting everything ready and the knowledge of the unit is very important.