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Exploratory Study of Minimally Invasive Therapy: Laser Ablation Combined with ADM Implantation in Recurrent Sacrococcygeal Pilonidal Disease

Zhicheng Li[#], Lei Jin[#], Jialin Qin, Zhenyi Wang[*] and Jiong Wu[*]

Abstract

Purpose: Recurrent sacrococcygeal pilonidal disease (SPD) presents considerable challenges in clinical management. In recent years, minimally invasive techniques, such as laser ablation, have emerged as promising alternatives for treatment. Furthermore, the application of acellular dermal matrix (ADM) has demonstrated potential benefits in wound healing and tissue regeneration. This clinical study aims to assess the efficacy and safety of the combined approach of laser ablation and ADM in the management of recurrent SPD.

*Correspondence:
Zhenyi Wang
drxinhuo@163.com
Department of Proctology, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai 200437, China

Jiong Wu
12491947@qq.com
Department of Proctology, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai 200437, China

Department of Proctology, Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine, Shanghai, China
[#]Contributed equally

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Basic Procedures: We retrospectively analyzed the data of our five patients who diagnosed with recurrent SPD between October 2023 and April 2024. All patients underwent laser ablation in conjunction with ADM placement. We recorded clinical outcomes, including the healing rate and recurrence rate, as well as surgical data. Postoperative pain was assessed using the visual analog scale (VAS), and we documented the time taken for patients to return to their regular work and daily activities.

Main Findings: A total of five patients underwent laser ablation combined with ADM. Patients experienced minimal postoperative pain. All patients satisfied with this surgery.

Conclusion: This pilot study suggests laser ablation with ADM may be a viable minimally invasive option for recurrent SPD, showing favorable outcomes. Larger comparative studies are needed to validate these findings.

Keywords *Recurrent sacrococcygeal pilonidal disease, laser ablation, acellular dermal matrix, surgery*

1. Introduction

Sacrococcygeal pilonidal disease (SPD) is a chronic inflammatory disorder of the sacrococcygeal region, presenting acutely with swelling and pain. In the acute phase, patients typically experience significant discomfort, which may progress to the development of a chronic sinus tract that fails to heal. This condition predominantly affects adolescents and young adults, and its incidence is continuously rising. For symptomatic individuals, the primary treatment modality is surgical excision, which may be performed with or without primary closure. However, this approach often results in extensive wounds, prolonged recovery times, and high nursing care requirements [1]. Although various minimally invasive surgical techniques are available, recurrence remains a significant concern, with reported rates as high as 68% within a decade, contingent upon the surgical method employed [2]. Currently, there is no consensus on the management of recurrent SPD, and repeated excision or suturing may elevate the risk of malignancy while adversely affecting patients' quality of life. The identification of a minimally invasive and effective surgical strategy is an urgent priority.

Since 2019, our team has been using laser ablation by 1470-nm radial diode laser fiber for the treatment of SPD, successfully treating over 300 patients, with laser ablation performed in all cases except those in the acute abscess stage. We have found it to be an effective and minimally invasive surgical technique, resulting in mild postoperative pain, small wounds, and high levels of patient satisfaction [3]. The laser emits circular energy that uniformly targets the epithelial cells within the sinus tract, destroying them and causing the sinus to naturally contract. However, some patients are prone to infection and recurrence, attributed to factors such as the large cavity within the sinus tract, the slow regeneration of new tissue, and incomplete tissue filling within the tract postoperatively.

Acellular dermal matrix (ADM), as a substitute for human dermis, not only supports the ingrowth of recipient tissue cells but also promotes wound repair and capillary regeneration. Additionally, ADM exhibits anti-infective properties and is extensively utilized in the management of skin defects resulting from burns and trauma, oral mucosa repair, plastic surgery, and soft tissue defect reconstruction [4-6]. Multiple studies have suggested that ADM can be used to treat complex anal fistulas without damaging the anal sphincter or anal shape, with cure rates ranging from 12.5% to 88% [7-10]. One study applied ADM during pilonidal sinus excision surgery for the recurrent SPD, revealing that it accelerated cellular proliferation, reduced wound healing time, and prevented recurrence in both patients [11]. Although the sample size was limited, it suggested that combining laser ablation with ADM might further shorten wound healing time, significantly reduce patient pain, and decrease the recurrence rate.

In this study, we retrospectively analyzed the cases of 5 patients who underwent treatment, and the results are reported as follows.

2. Material and Methods

2.1. Inclusion Criteria

Patients with recurrent sacrococcygeal pilonidal disease (SPD) who had previously undergone surgical treatment (excluding abscess drainage).

2.2. Exclusion Criteria

Patients in the acute abscess stage and first-time surgical candidates (no prior definitive SPD surgery.

2.3. Outcome Measures

2.3.1. Primary Outcomes

i) Wound healing rate and time. Healing was characterized by complete epithelization with absence of swelling, redness or discharge.
ii) Recurrence rate at 12 months. Recurrence was characterized by the reappearance of suppurative manifestations (abscess formation or purulent discharge) following complete wound healing.

2.3.2. Secondary Outcomes

i) Postoperative pain is assessed using VAS scores (patient-reported) on operation day, postoperative days 1, 3, and 7, assessed during wound dressing changes.
ii) The occurrence of complications within one week (wound infection and bleeding).
iii) Time to return to work.
iv) Patient satisfaction.

We retrospectively analyzed the data of our five patients who diagnosed with recurrent SPD between October 2023 and April 2024. Specifically, two patients had previously undergone flap techniques, while three patients had undergone excision with primary closure. All patients signed informed consent forms prior to surgery. The surgeries were performed by the same physician. This retrospective study was approved by the institutional ethics board of Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine (No. 2017-033). Postoperative follow-up was conducted weekly in the clinical setting under the supervision of the operating surgeon, with continuation until either complete wound healing was achieved or additional surgical intervention became necessary.

2.4. Surgical Technique

All patients underwent preoperative preparation of the sacrococcygeal area. Patients were placed in the left lateral position and intravenous anesthesia was induced and maintained using Propofol Medium/Long Chain Fat Emulsion Injection (Propofol was infused via Target-Controlled Infusion (TCI) after setting the patient's age, height, and weight parameters, inducing at 3 μg/mL and maintaining at 2 μg/mL). A circular or elliptical incision was made at the top of the sinus tract, based on the extent of infection. A mosquito clamp was inserted through the incision to clear hair within the sinus tract. A probe was then inserted reversely from the incision to ascertain the course of the sinus tract, and an incision was made at the protruding end of the probe. A fiber-optic catheter (from the German Biolitec Leonardo DUAL 45 laser device, Biolitec AG, Germany, featuring a single-loop laser catheter) was inserted into the sinus tract and guided by a light indicator to reach the end of the tract. The laser, with a power of 10 W and a wavelength of 1470 nm, was used to completely ablate and close the sinus tract by pulling the fiber-optic catheter bidirectionally at a speed of 1 mm/s. The acellular dermal matrix (ADM) was provided by Beijing Jayya Life Biotechnology Co., Ltd. (NMPA Certificate: 20223130785). The 10 cm × 10 cm ADM graft was rehydrated in sterile saline (5 minutes), trimmed to size, then placed into the base of the defect. The graft was anchored to the wound edges using interrupted 2-0 sutures. Images showing the condition before and after surgery are provided (Figures 1-5).

FIGURE 1: The ADM was provided by Beijing Jayyalife Biological Technology Co., Ltd (NMPA Certificate: 20223130785).

FIGURE 2: Biolitec device used for sinus laser treatment.

FIGURE 3: Preoperative picture.

FIGURE 4: After the operation.

FIGURE 5: Successful healing at 30 days.

2.5. Data Analysis

Data analysis was conducted using SPSS 26.0 statistical software. Quantitative data that conform to a skewed distribution are expressed as M (Q1, Q3). Categorical data are presented as (n).

3. Results

A total of five patients underwent laser ablation combined with ADM, comprising four males, with an age range of 29 (25, 32) years. The surgical time was 23 (19, 26) minutes, and the length of the sinus tract

was 6 (5, 8) cm. The VAS score on the day of operation was 1 (1, 2), on the first postoperative day was 1 (1, 3), on the third postoperative day was 1 (1, 2), on the seventh postoperative day was 0 (0,0). The laser energy values were 374.7 (269.2-594.8) J, and the median follow-up time was 14.5 (13, 16) months. Notably, all five patients achieved successful resolution of their condition without any recurrence. As are shown in (Tables 1 & 2).

TABLE 1: Baseline patients' characteristics and postoperative outcome.

Characteristic	Value
Gender	5
Male (%)	4(83%)
Female (%)	1(17%)
Age (years)	
median (Q1, Q3)	29(25,32)
BMI (kg/m2)	
median (Q1, Q3)	23(22,27)
Sinus tract length (cm),	
median (Q1, Q3)	6(5,8)
Current smoker (%)	33.3%
Number of pits	
median (Q1, Q3)	1(0,1)
Number of previous operations	
median (Q1, Q3)	1(0,2)
Family history of pilonidal sinus disease (%)	0
Natal cleft hairiness (%)	
None/mild	1(33.3%)
Intermediate	4(6.7%)
Significant hairiness	0
Operative time (min)	
median (Q1, Q3)	23(19,26)
Energy (J), median (Q1, Q3)	374.7(269.2- 594.8)
VAS score, median (Q1, Q3)	
Operation day	1(1,2)
Postoperative (1 Day)	1(1,3)
Postoperative (3 Day)	1(1,2)
Postoperative (7 Day)	0(0,0)
Patient satisfaction index n (%)	
Very satisfied	5(100)
Satisfied	0
Neutral	0

Dissatisfied	0
Very dissatisfied	0
Follow up(days)	
median (Q1, Q3)	7(6,7)
Complications, n (%)	0
Time(days)median (Q1, Q3)	
To complete healing	34(30,35)
To return to work	10(9,11)
Recurrence (n)	0
Follow up (month)	
median (Q1, Q3)	14.5(13, 16)

TABLE 2: Baseline demographics and result.

Patient number	Age (years)	Sex	BMI	Duration of illness (months)	Results	Time to healing (days)
1	25	F	30.47	48	Healed	30
2	21	M	27.76	12	Healed	34
3	32	M	22.40	108	Healed	31
4	29	M	21.60	12	Healed	34
5	32	M	23.51	5	Healed	35

4. Discussion

Despite the multitude of surgical methods for SPD, the long-term recurrence rates range from 40.2% to 67.9%, depending on the operative strategy [2]. Currently, there are no guidelines for recurrent SPD. High recurrence rates and chronic disease can impact self-esteem, personality development. An ideal method should be characterized by minimal invasiveness, a high cure rate, and elevated patient satisfaction.

Dr. Megha Shalini performed the Limberg procedure on 14 patients with recurrent SPD, with no recurrences observed postoperatively, and all patients returned to work within three weeks [12]. Postoperative pain was reported as mild, but this approach causes significant appearance damage and requires surgeon experience. Pronk treated 57 patients with recurrent SPD using phenolization, 51 patients resumed their normal daily activities two weeks later, with 90% of patients achieving complete wound healing after three months [13]. Despite its minimally invasive nature, phenolization is associated with a relatively low cure rate. The toxicity of phenol has led to its prohibition in certain countries [14]. Repeated surgical interventions carry the risk of further complications for the patient. Therefore, the optimal surgical approach should be characterized by minimal invasiveness, a high cure rate, and a high level of patient satisfaction.

Laser ablation for the treatment of SPD was first proposed by Dessily, who reported an impressive success rate of 87.5% alongside a low recurrence rate of 2.9% [15]. This technique operates on the principle of uniformly applying circular energy emitted by a laser catheter to the epithelial cells lining the sinus tract, resulting in cellular damage and subsequent

natural contraction of the sinus. Increasing numbers of clinical studies have confirmed the advantages of laser treatment [16-19]. The latest meta-analysis suggests that laser ablation is an effective and safe short-term treatment for recurrent sacrococcygeal pilonidal sinus [20]. However, with extended follow-up, most patients experienced recurrence within six months postoperatively, demonstrating a 15% recurrence rate [21]. Our previous research also indicated that laser treatment is an ideal option for patients with primary pilonidal sinus, as it results in minimal postoperative pain and significantly reduced recovery time for patients [3]. Conversely, as the number of patients increased and follow-up durations extended, the recurrence rate also demonstrated a relative upward trend. The rationale behind this is that, while laser treatment can damage the sinus wall tissue, it exhibits poor closure efficacy for sinus tracts with larger cavities. Inadequate postoperative care may result in delayed healing or recurrence. Nevertheless, laser surgery remains a viable option for recurrent patients without affecting the success rate of the surgery [22].

Acellular dermal matrix (ADM) is an innovative biocompatible material derived from allogeneic or xenogeneic skin tissue, which facilitates the repair and reconstruction of defective tissues. It can be utilized as a filler in sinus tracts, promptly inducing connective tissue and neovascularization upon integration with the wound. The basement membrane side provides a natural substrate for the migration and colonization of epithelial cells, promoting epithelialization of the decellularized dermis, while the dermal side favors the ingrowth of host cells and rapid vascularization. Following transplantation, ADM can guide the infiltration of recipient cells and neovascularization, forming a new extracellular matrix [23, 24]. It endows the tissue with toughness, elasticity, hydration, and shock absorption against mechanical forces, providing a microenvironment for cell survival and various activities [25]. Eventually, it will degrade and be replaced by newly formed tissue. Its excellent biocompatibility and biodegradability render it effective in repairing dermal defect wounds, minimizing scar hyperplasia post-healing, and exhibiting certain anti-infective properties. It has been widely applied in various clinical departments. For complex anal fistula surgery with significant anal wound defects, ADM has also demonstrated effective reparative capabilities, they suggest that ADM is a reasonable new option for closure of anal fistulas [26-28]. ADM has shown promise in reducing postoperative complications in complex hard-to-heal wounds and large cavity with inflammation through its ability to modulate the inflammatory response in these chronically inflamed soft tissues, fill surgical dead space and rapidly regenerate soft tissues.

Several studies have investigated the use of this material as an auxiliary filler in resection and other surgical methods of patients with recurrent SPD [11, 29]. Notably, no recurrences were observed postoperatively in these studies, but the patient's postoperative experience was not as good as laser ablation. Our preliminary research indicates that a surgical approach combining laser ablation with ADM achieved a 100% cure rate. Median postoperative VAS decreased from 1 (1, 2) to 0 (0, 0) and no recurrences during the follow-up period, significantly reducing the time required for patients to resume their normal lives. Consequently, for complex sinus tract diseases with chronic wounds following repeated surgeries and the combination of laser ablation with ADM may not only enhance the inpatient experience but also potentially reduce the recurrence rate.

TABLE 3: Participant summary including demographic, surgical methods and outcome.

Case (ID)	Gender/ age (y)	Past surgical history	Surgical method	Area of diseased tissue	Recurrence
Patient 1	M,21	Excision and primary closure, and excision and NPWT	Excision with placement of Integra and NPWT	No mention	No
Patient 2	F,19	Primary closure, healing by secondary intention, and NPWT	Excision with placement of Integra and NPWT	No mention	No
Patient 3	F, 21	Incision and drainage	Flap reconstruction with ECM + NPWT	7×11cm	No
Patient 4	M, 20	Incision and drainage, excision and primary closure	Flap reconstruction with ECM+ NPWT	12×6cm	No
Patient 5	M, 19	Incision and drainage, excision and primary closure	Flap reconstruction with ECM+ NPWT	12×3cm	No
Patient 6	F, 52	Incision and drainage, excision and primary closure	Flap reconstruction with ECM+ NPWT	10×4cm	No
Patient 7	M, 19	Incision and drainage, excision and primary closure	Flap reconstruction with ECM+ NPWT	11×4cm	No
Patient 8	M, 15	Incision and drainage, excision and primary closure	Flap reconstruction with ECM+ NPWT	12×5cm	No

5. Conclusion

The concept of combining ADM with laser ablation for recurrent SPD demonstrates innovation and potential clinical impact. However, given the extremely limited sample size and absence of comparative data, the findings need for additional long-term, multicenter, randomized controlled trials to rigorously evaluate the efficacy of this combined modality in the treatment of recurrent SPD.

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Conflicts of Interest

None.

Ethical Approval

Not applicable.

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