

# Endoscopic pilonidal sinus treatment: a prospective multicentre trial

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## Abstract

**Background** Pilonidal disease (PD) is a common inflammatory disease of the gluteal fold, resulting in recurrent acute/chronic infection at the level of the natal cleft. In this study, endoscopic pilonidal sinus treatment (EPSiT), a new endoscopic minimally invasive procedure, was evaluated for its effectiveness in treating PD.

**Methods** Two hundred and fifty prospective patients with chronic PD were enrolled in a prospective multicentre study conducted at a secondary and tertiary colorectal surgery centre. The primary end-point of this study was wound healing, and the short-/long-term outcomes such as healing time, morbidity rate and recurrence rate were analysed. The secondary end-point of this study was quality of life (QoL).

**Results** The complete wound healing rate was 94.8%, and the mean complete wound healing time was  $26.7 \pm 10.4$  days. The incomplete healing rate (5.2%) was significantly related to the number of external openings ( $P = 0.01$ ). There was no difference in the failure rate when EPSiT was performed as the first-line

treatment for PD or when it was used after unsuccessful procedures ( $P = \text{n.s.}$ ). Recurrence occurred in 12 cases (5%). The QoL significantly increased from preoperative levels 15 days after the EPSiT procedure ( $45.3$  vs  $7.9$ ;  $P < 0.0001$ ).

**Conclusions** The EPSiT procedure is a safe and effective technique for treating PD. It provides better short- and long-term outcomes than various other techniques that are more invasive. EPSiT is a minimally invasive outpatient procedure, which is associated with a quick recovery and a good QoL outcome.

**Keywords** Pilonidal sinus, pilonidal disease, pilonidal cyst, minimally invasive treatment, endoscopic treatment, VAAFT

### What does this paper add to the literature?

The paper presents the mid- and long-term outcomes of a new minimally invasive endoscopic procedure for the treatment of pilonidal disease. Healing, healing time, morbidity rate, recurrence rate and quality of life were analysed.

## Introduction

Pilonidal sinus (PS) is a very common inflammatory disease of the buttock and gluteal fold region. It results in a subcutaneous abscess and recurrent acute and chronic infection at the level of the natal cleft [1].

The aetiology of PS is still a matter of controversy, but the three most widely accepted theories [2] (the foreign body response theory [3], the Bascom hypothesis of 'midline pits' [4,5] and the Stelzner theory of a retention dermatopathy [6]) agree that PS is characterized by follicular hair or keratin retention associated

with a follicular and peri-follicular inflammatory response.

Considering the aforementioned theories, PS could be considered a pilonidal disease (PD) that affects the whole sacrococcygeal fold and arises due to chronic retention of keratin/hair debris because of a long-lasting pressure effect in association with rubbing and rolling forces on the sacrococcygeal terminal hair follicles. Such a hypothesis could thus probably explain the origin of very late recurrence of PS described in the literature [7], and such recurrence could be considered to be new PS disease rather than relapse after primary treatment.

In accordance with the above evidence, the use of wide open/closed excision techniques [4,5,8–10] has received critical reevaluation over the past decade. These

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techniques are associated with significant postoperative discomfort and a significant recurrence rate [9,10]. Recently minimally invasive and outpatient surgical techniques have been reported. These techniques reduce the length of hospital stay and costs and result in minimal morbidity [11,12].

By building on these principles and drawing on experience acquired using the video-assisted anal fistula treatment (VAAFT) technique [13], Meinero developed the endoscopic pilonidal sinus treatment (EPSiT) procedure in 2011 [14].

The EPSiT procedure is a new minimally invasive method for treating PD. The procedure uses endoscopic treatment of the pilonidal sinus and pilonidal fistula tracts to remove and destroy follicular hair and keratin debris. After the first promising single-centre report of EPSiT in PS [14], the authors followed the IDEAL collaboration guidelines [15] to perform a multicentre study (Phase 2b, IDEAL guidelines) to ensure the results were replicated in other centres, to focus on adverse effects and potential benefits, and to verify learning curves and develop quality parameters [15].

## Materials and methods

### Study design and methods

From March 2012 to December 2014, a total of 250 consecutive patients with symptomatic PD underwent the EPSiT procedure in four different centres: Sestri Levante Hospital (Sestri Levante, Italy), Sanatrix Clinic (Rome, Italy), Madonna delle Grazie Clinic (Velletri, Italy) and the EOC Hospital of Mendrisio (Mendrisio, Switzerland). The multicentre prospective trial was approved by the hospitals' ethics committees, and specific informed patient consent was obtained prior to the operation. In addition, clinical, operative and follow-up data were recorded prospectively.

Patients suffering from acute or chronic and primary or recurrent disease were offered surgical treatment; patients presenting with acute pilonidal abscesses were excluded from the study.

All patients were admitted on the day of the operation, and no antibiotic prophylaxis was given. The surgical technique is described below. There were no changes made to the surgical technique or anaesthetic protocol throughout the study period.

A weekly examination of each patient was performed by the operating surgeon in the outpatient clinic beginning 2 weeks after surgery. Follow-up continued until the wound had healed, or until further intervention was required. Long-term follow-up and disease recurrence were assessed by outpatient consultation.

Complete wound healing was considered to be the primary end-point; incomplete healing was considered when wound discharge or swelling persisted after postoperative day 60.

Patients were considered to have recurrence if they reported symptoms of local pain, discharge or intermittent swelling at least 4 months after the time of complete healing. If patients presented with incomplete healing or recurrence, a re-EPSiT procedure was performed.

The secondary end-point involved an assessment of quality of life (QoL). Two different questionnaires were administered: the SF-36 (validated Italian version) and an in-house QoL questionnaire specifically prepared for proctological disease, in order to perform: (1) an assessment of symptoms (pain, body temperature, wound discharge, frequency of wound dressing removal, on a scale from 0 to 20, where 0 represented an absence of fever, pain, wound discharge and no requirement to remove the wound dressing); (2) a general QoL assessment (scale from 1–6, where 1 represented 'a very good QoL'); (3) an assessment of the impact of PD on patient QoL (scale from 0 to 52, where 0 represented experiencing no significant impact of PS on QoL); (4) an assessment of QoL in the last 30 days in terms of feeling concern, despondency and depression about PD (score from 1 to 6, where 1 represented having no feelings of concern, despondency or depression related to PD). Preoperative scores from each item were then calculated and compared with the postoperative scores obtained on postoperative day 15.

### Surgical technique

The patient is placed in the prone position with their legs slightly apart. The buttocks are separated by two big plasters. The first surgeon can stand either between the patient's legs or on the patient's right side depending upon the location of the external sinus opening(s). Local anaesthesia was obtained by injecting into the area 40 ml of a solution consisting of 2% lidocaine and 7.5% naropine. The EPSiT procedure consists of two phases [12]: a diagnostic phase and an operative phase. The aim of the diagnostic phase is to identify the anatomy of the PS and any possible secondary tracts and/or abscess cavities. The midline or the lateral external opening is removed by making a 0.5-cm circular incision around the opening. The number and site of incisions varies depending on the presence of secondary fistula tracts or abscesses; therefore, in more complex cases two or three incisions may be required. The Meinero fistuloscope [12,13] (which has an 8°-angled eyepiece with an optical channel and a working channel of 3.2 × 4.8 mm diameter, and an operative length of

18 cm) (Fig. 1) is then inserted through the external opening, whilst infusion of glycine/mannitol 1% solution assists in opening the underlying tract. Hair, fistula tracts and abscess cavities appear clearly on the screen. The aim of the operative phase is to ablate and clean the infected area. Endoscopic forceps are inserted through the operative channel in order to thoroughly remove all the hair and hair follicles that are directly visible. This manoeuvre is considered to be a fundamental step in assisting healing. Once this procedure is completed, the monopolar electrode is connected to an electrosurgical knife power unit for cautery ablation of the sinus granulation tissue. This commences in the main tract, and where appropriate, then traverses secondary tracts and abscess cavities. Necrotic material is removed with an endobrush passed through the fistuloscope, or with a Volkman spoon if more superficially located. The continuous jet of glycine–mannitol solution during the procedure ensures both a clear visual field and the elimination of the cauterized waste material, which is brushed through the incision. Additional pilonidal midline pits are then treated by curettage and cauterization.

At the end of the procedure, a light dressing with no packing is applied.

### Statistics

Statistical analyses were performed using MedCalc for Windows v.10.2.0.0 (MedCalc Software, Mariakerke, Belgium). The differences in distribution were calculated using the ANOVA test for continuous variables and the chi-square test or Fisher's exact test, depending on the number of cases in each subgroup for categorical variables. A  $P$ -value  $\leq 0.05$  was considered statistically significant.

No statistical difference was noted in terms of numbers of patients enrolled from each centre ( $P = n.s.$ ).

### Results

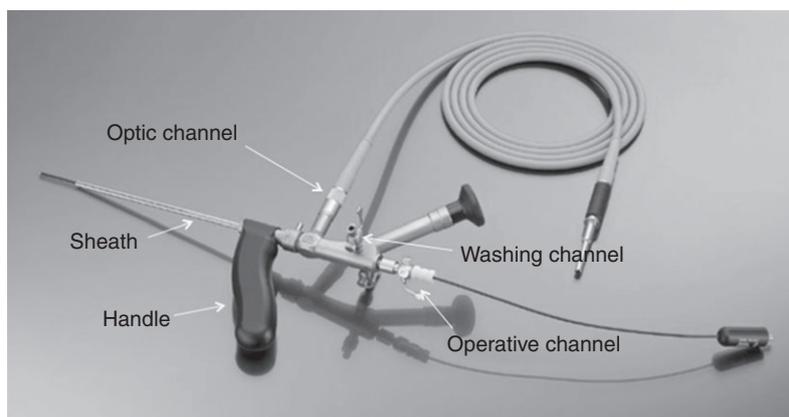
There were 250 patients recruited to the study. Patient characteristics and clinical findings are presented in Table 1. The patient sample was primarily male (74%) with a mean age of  $24.3 \pm 3.6$  years.

The EPSiT procedure was performed as a first treatment for PD in 141 cases (56.4%), and after one or more than one other surgical procedures in 76 (30.4%) and 33 cases (13.2%), respectively. The mean number of pilonidal openings per patient was  $1.56 \pm 0.56$ . In 181 cases (72.4%) the openings were localized in the midline, in 29 cases (11.6%) there were openings in the midline and one or more lateral additional openings and in 40 cases (16%) there were only lateral openings (Table 1).

All patients returned to normal daily activities unimpeded by pain on the first postoperative day. The mean time until return to work was  $2 \pm 0.5$  days; and only 9.7% of patients required analgesics. No patient experienced early wound complications (e.g. haematoma, seroma or necrosis) necessitating hospitalization.

After a mean (minimum) follow-up time of 12 (6) months, complete wound healing was seen in 237 patients (94.8%), all of whom had healed within two postoperative months. The mean complete wound healing time was  $26.7 \pm 10.4$  days (Table 2).

Thirteen patients presented with incomplete healing (5.2%). The failed healing was related to the number of external openings ( $P = 0.01$ ): when PD was associated with one opening healing failure occurred in 3.9% of patients (5 out of 133 patients); when PD was associated with two openings healing failure occurred in 4.4% of patients (4 out of 95 patients); and when PD was associated with three or more openings healing failure occurred in 22.2% of patients (4 out of 22 patients). It was determined that healing time was also significantly related to the number of openings ( $P = 0.002$ ) (Fig. 2):



**Figure 1** The Meirero fistuloscope.

**Table 1** Patient characteristics.

Factor	No. of patients (%)
Age (years)	24.3 ± 3.6
Sex	
Male	185 (74)
Female	65 (26)
Number of openings and fistulae	
1	133 (53.2)
2	95 (38)
≥3	22 (8.8)
Location of openings and fistulae	
Midline	181 (72.4)
Midline and lateral opening	29 (11.6)
Lateral opening	40 (16)
Previous operative management	
0	141 (56.4)
1	76 (30.4)
≥2	33 (13.2)

**Table 2** Postoperative outcomes.

Outcome	No. of patients (%)
Complete wound healing	237 (94.8)
Incomplete wound healing (failed healing)	13 (5.2)
Healing time (days)	26.7 ± 10.4
Healing rate within 2 weeks	29.6%
Healing rate within 4 weeks	48.8%
Healing rate within 6 weeks	90.4%
Healing rate within 60 days	94.8%
Recurrence	13 (5)
Healing not verified (lost at follow-up)	4 (1.6)

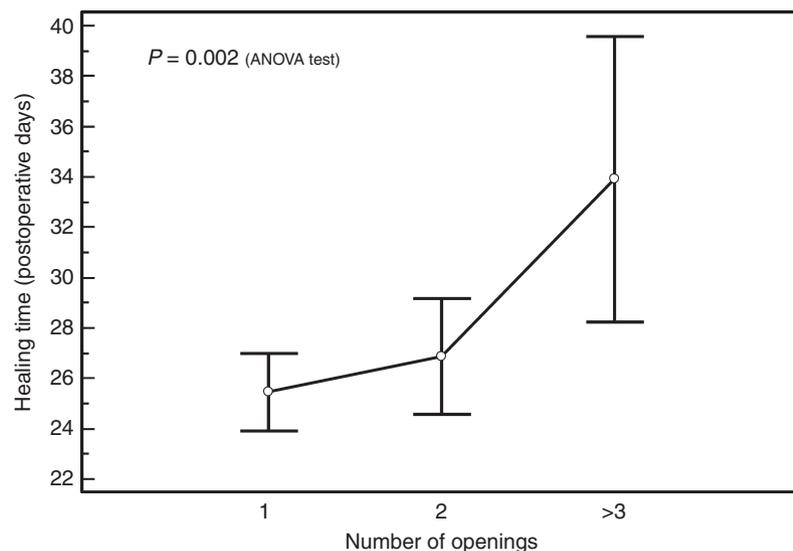
patients with one opening healed within a mean period of 25 days; patients with two openings healed within a mean period of 27 days; and patients with three or more openings healed within a mean period of 33.9 days (Fig. 2).

There were no significant variations between the failure rate when the EPSiT procedure was performed as a first treatment for PD and when it was performed following unsuccessful procedures performed with different techniques [7 healing failures out of 141 patients (4.9%), and 6 healing failures out of 109 patients (5.5%), respectively; *P* = n.s.] (Table 3).

Recurrence after complete and successful wound healing (>4 months) was observed in 12 cases of 237 (5%) completely healed patients. There were no variations between the recurrence rate when the EPSiT procedure was performed as a first treatment for PD or when it was performed after unsuccessful treatment using different techniques [6 healing failures out of 128 patients (3.1%), and 6 healing failures out of 97 patients (6.1%), respectively; *P* = n.s.] (Table 3).

Four patients (1.6%) who presented with healing failure or recurrence were lost to follow-up. All remaining 21 patients who presented with incomplete healing, or recurrence, underwent a re-EPSiT procedure, and definitive and complete healing occurred within 30 postoperative days.

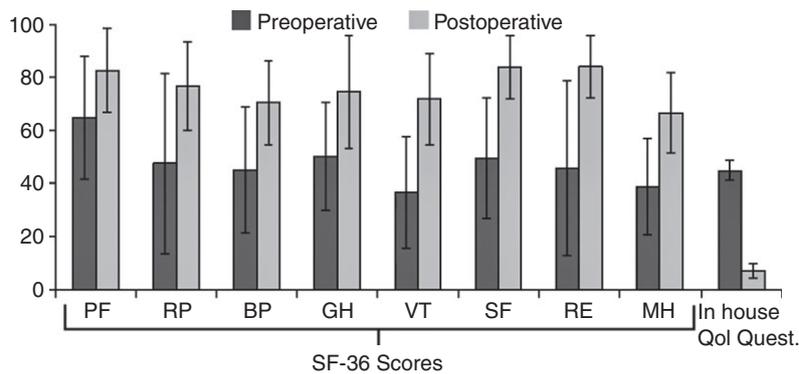
The QoL of 45 patients was studied. SF-36 scores improved significantly for all the items studied: physical function (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social function (SF), role-emotional (RE) and mental health (MH) (*P* < 0.001, *t*-test) (Fig. 3). When the in-house QoL



**Figure 2** Healing time related to the number of openings.

**Table 3** Wound healing and the number of surgical procedures performed.

	No. of procedures before EPSiT				$P$ ( $\chi^2$ )
	0 ( $n = 141$ )	1 ( $n = 76$ )	2 ( $n = 26$ )	3 ( $n = 7$ )	
Incomplete healing	7 (4.9%)	3 (3.9%)	2 (7.6%)	1 (33%)	0.624
Recurrence	6 (4.2%)	5 (6.5%)	1 (3.8%)	0 (0%)	0.795

**Figure 3** Preoperative and postoperative (15 days) quality of life (QoL): SF-36 questionnaire and in-house QoL questionnaire.

score questionnaire was analysed, the preoperative mean QoL score was  $45.3 \pm 3.2$ , while on the 15th postoperative day, the mean score was found to be  $7.9 \pm 1.3$ , with a statistically significant difference between the two scores ( $P < 0.0001$ ,  $t$ -test) (Fig. 3).

## Discussion

The acquired foreign body theory of the pathogenesis of PS disease (PSD) is now widely accepted. The aetiology of PSD is described in the literature as being a foreign body response associated with retention dermatopathy due to the inclusion of keratin plugs, hair and debris at the level of follicular hair units in the natal cleft [2,3,14,16]. Søndena and Pollard [17] demonstrated that PSD is caused by keratin plugs and debris, and in agreement with their findings von Laffert [2] recently demonstrated that dislocated hair was visible in the majority of cases (74%) and was usually disseminated in multiple foci.

Based on these findings, the EPSiT procedure was developed to allow direct endoscopic vision of the PS from the inside. During the procedure, debris and hair can be easily identified and removed. There is no agreement about which procedure is best for managing chronic and recurrent PD. Wide excision with the wound left open or directly closed remain the most common surgical procedures performed for PSD. The disadvantage of healing by secondary intention is that it involves a lengthy healing time [14], but it is associated with significantly lower recurrence rates than closed

healing. Primary closure is associated with faster healing and fewer days off work [1,15,18–21]. However, this potential benefit is offset by the increased risk of wound complications, recurrence and costs, particularly if associated with a reconstructive flap [22]. Wide extended tissue excision is not guaranteed to avoid sinus recurrence, which is thought to be due to the persistence of debris and hair retention at the level of the natal cleft. Several studies have demonstrated high recurrence rates. Allen-Mersh [23] described an average recurrence rate of 13% at 1 year following the use of open methods, and 15% after excision and closure. In a recent multi-center study, Doll *et al.* [24] found a 17% recurrence rate following excision with the resulting wound left open, and 30% following excision and the use of a primary suture.

Wide excision techniques have become less popular with patients and surgeons, and minimally invasive surgical techniques to treat PD are now more frequently used to allow the patient to leave hospital sooner and result in minimal morbidity. In 1993, Bascom presented the outcome of his technique, which consisted in follicle removal. In 2000 a modification with a laterally placed incision that served for open exploration of the pilonidal cavity was reported [6]. The recurrence rates after Bascom's procedures are 10% after 1 year, and 13% and 16% after 3–5 years [6].

The EPSiT procedure offers the potential advantages of Bascom's procedure together with a minimally invasive technique. In addition the fistuloscope allows complete endoscopic exploration of the pilonidal cavity and

the pilonidal secondary tracts without the need for a draining lateral suture. This reduces postoperative pain, discomfort and discharge from the wound, causes only minimal modification of daily activities, and significantly reduces work limitations. EPSiT should guarantee a painless procedure, with only 9.7% of the patients in this study requiring analgesics. It also allows a return to normal daily activities unlimited by pain on the first postoperative day, with a mean time until return to work of 2 days (range 1–4 days).

Gips *et al.* (2008) [11] reported a minimally invasive technique to treat PSD. This consisted of elimination of the skin openings and removal of underlying hair and debris using trephines. They reported the trephine procedure on 1358 patients with follow-up duration of  $6.9 \pm 1.8$  years (median 6.6 years), and reported that nonhealing operative wounds (considered as early failure) were observed in 58 patients (4.4%) during the early postoperative period. The trephine procedure was associated with a 1-year recurrence rate of 6.5%, but follow-up was incomplete in 13.8% of the cases, leading to the possibility of a higher overall recurrence rate [11].

Although the present study has the limitation of the absence of a very-long follow-up period, the EPSiT technique appears to offer adequate and effective outcomes with a 5% recurrence rate at a mean follow-up duration of 12 months, and incomplete wound healing of in only 5.2% of patients. In addition, when PD was persistent or recurrent, re-EPSiT was able to efficiently treat the disease with a success rate of 100% (21/21 cases).

The direct vision achieved with the Meinero fistuloscope [14] in the EPSiT procedure allows the surgeon: (1) to see not only the PS but also any possible fistula tracts or abscess cavities, (2) to guarantee the complete destruction of the granulation tissue, (3) to completely remove the hair follicles that are often located not only in the PS but also in the surrounding tissue, as previously described, and (4) to achieve effective haemostasis.

## Conclusion

In this multicentre trial EPSiT appears to offer an effective healing rate in association with a low recurrence rate and good aesthetic outcomes. EPSiT guarantees a short postoperative course with a early return to normal daily activities and work. In addition, patients do not need oral analgesic drugs, and can leave the hospital a few hours after the procedure. Furthermore, only outpatient clinical review is required. It therefore appears that re-EPSiT is safe to perform, and can offer a high definitive success rate. However, further studies involv-

ing long-term follow-up are required to confirm these results.

## Conflict of interest

Professor Piercarlo Meinero receives financial grants from Karl Storz. The remaining authors declare that they have no conflict of interest.

## Author contributions

Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data: PM, AS, AC, FF, LR, MLaT. Drafting the article or revising it critically for important intellectual content: PM, AS, AC, FF, LR, MLaT. Final approval of the version to be published: PM, AS, AC, FF, LR, MLaT.

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