

Regenerative Medicine for the Definitive Surgical Repair of Pilonidal Sinus. A New Method of Wound Reconstruction

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Abstract. *Objective: A retrospective analysis of patients undergoing surgery for complex (≥ 3 tracks) or recurrent pilonidal sinus (PS) was performed; the results of this clinical experience were compared with an original method of primary wound closure, coupling a "tension-free" technique of wound reconstruction with autologous cryoplatelet gel application, in order to improve the wound healing process and reduce the postoperative disability period. Patients and Methods: The retrospective analysis included 30 patients undergoing surgery for PS between January 2003 and May 2005: in the first group of 15 consecutive patients, the wound was left open to close secondarily while in the remaining 15 patients, primary closure by means of a "tension-free" technique of wound reconstruction was attempted. Between June 2005 and May 2006, another subset of 15 patients was prospectively recruited, coupling the "tension-free" technique of wound reconstruction with autologous cryoplatelet gel application. Results: In the first group of patients, median postoperative disability accounted for 65 days with one recurrence. In the second group, primary healing was achieved in 11 patients, with a median postoperative disability of 28 days; two recurrences did occur. In the third group of patients, primary healing was achieved in all patients within 14 to 29 days, and no recurrence has yet been detected. Conclusion: Short follow-up notwithstanding, the simplicity of the operation, the use of autologous products and the minimal postoperative disability with complete wound healing suggest that this new approach may represent a useful alternative to current surgical techniques for PS excision.*

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Pilonidal sinus (PS) is a rather common chronic and intermittent infective process occurring in the natal cleft and sacrococcygeal region, that primarily affects young adults and teenagers, with a 3:1 male predominance (1). Although PS cannot be regarded as a life-threatening condition, it may be a serious cause of morbidity, with time lost from school or work, even for some months. Patients with uncomplicated disease are usually best treated in an outpatient setting with small excision, curettage and unroofing. However, patients with more complicated conditions, such as those with long-standing disease and multiple openings with pus or with recurrent disease, should undergo more complex surgical procedures including wide excision, creation of skin flaps, and grafting, which require in-patient stay due to the risk of wound dehiscence, bleeding, or infection, as suggested by the practice parameters for the performance of ambulatory surgery reported within the Standards Task Force of the American Society of Colon and Rectal Surgeons (2).

Multiple surgical procedures have been advocated for the definitive elective treatment of PS, yet none of them has proved to be ideal. The main issues concerning the surgical treatment of PS regard its simplicity, minimal postoperative disability, and rapid return to normal activity which are by no means satisfied by those procedures which are based on excision, leaving the wound open to close secondarily, or by simple incision and curettage, due to their long healing time (3). Conversely, the healing process is more rapid after excision with primary closure alone or with grafting (Z-plasty, Limberg buttock flap, Dufourmentel technique, or Karydak's technique) although wound infection and/or dehiscence and recurrence are reported in up to 25% and 17% of patients, respectively (4-8).

Clinical experience has been gathered on the use of an autologous cryoplatelet gel which is used to improve the tissue healing process. This viscous gel couples the sealant properties of fibrin with the promoting activities of tissue

Table I. Outcome measures in the three group of patients.

	Preoperative symptoms (months)	Operative time (min)	Hospital stay (h)	Postoperative disability (days)	Wound dehiscence n. (%)	Recurrence n. (%)
Group 1	8 (3-17)	25 (20-30)	36 (24-48)	65 (45-80)	n.a.	1 6
Group 2	10 (5-22)	40 (35-50)	72 (48-96)	28 (20-47)	2 13	2 13
Group 3	11 (4-29)	45 (40-50)	72 (48-96)	15 (12-26)	– –	– –

repair due to the release of growth factors, such as platelet derived growth factor (PDGF), transforming growth factor-beta (TGF- β), insulin growth factor-I (IGF-I) and IGF-II, which are stored within platelet α -granules (9-13). This approach of regenerative medicine was coupled with an original technique of wound reconstruction that was tested in a pilot clinical study in patients with complicated PS in order to verify whether this method might improve the wound healing process and speed the recovery to normal activities.

Patients and Methods

Between January 2003 and May 2005, 30 patients with complex (≥ 3 tracks) or recurrent PS underwent surgery at the Division of General Surgery, Colo-Rectal Unit, of San Martino Hospital in Genoa. They were sub-divided into two groups based on the type of surgical procedure that was adopted: the first group included 15 consecutive patients (13 male and 2 female; median age 26 years, range 18-37 years) undergoing excision of the PS leaving the wound open to close secondarily; the second group included 15 patients (14 male and one female, median age 29 years, range 19-48 years) undergoing primary closure by means of a "tension-free" wound reconstruction. Between June 2005 and May 2006, 15 consecutive patients (12 male and 3 female with a median age of 31 years; range 14-68 years) with complex or recurrent PS were prospectively recruited into a pilot clinical study; they underwent PS excision with "tension-free" wound reconstruction and regenerative medicine by means of autologous cryoplatelet gel. Institutional Ethic Committee approval and written informed consent was always obtained. All patients underwent complete medical history and full clinical examination. Antibiotic prophylaxis was performed with amoxicillin-clavulanic acid, starting with 1.2 g intravenously at induction of anaesthesia, and 1.2 g after 12 h on the operative day, followed postoperatively by 1 g orally given twice daily for four days.

For each patient, the following data were recorded: duration of symptoms, operative time, postoperative analgesia, amount of fluid collected into the suction drainage added to the discharge sampled by means of fine-needle aspiration of the wound after drainage removal, postoperative wound infection or wound dehiscence, and time to complete resumption of normal activities (work or school).

Technique for preparation of cryoplatelet gel. Patients undergoing cryoplatelet gel application were accepted two days before the operation at the Immunohematology Service where 450 mL of whole blood were collected. The blood was immediately centrifuged to obtain packed red blood cells (PRBC) and platelet-rich plasma (PRP). PRBC were reinfused to the patient. PRP was centrifuged to obtain platelet-poor plasma (PPP) and platelet-

concentrate (PC). PPP was immediately frozen at -80°C in a mechanical refrigerator, the frozen plasma (FFP) was then kept at $+4^{\circ}\text{C}$ for 18 h for spontaneous thawing. Cryodepleted plasma was removed and the residual cryoprecipitate dissolved in 30 mL of plasma. PC was kept at $+22^{\circ}\text{C}$ under continuous agitation.

As regards the quality control of the product, PC had a platelet count equal to 60×10^9 , residual leucocyte equal to 0.2×10^9 , and a maximum volume of 30 mL. The cryoprecipitate had: Factor VIII equal to 70 UI $\times 100$ mL, fibrinogen equal to 140 mg/unit, and maximum volume of 30 mL.

Technique for preparation of autologous thrombin. For the preparation of autologous thrombin 27 mL of blood were collected in three sterile tubes with 1 mL in full ACD solution. The tubes were centrifuged at 3,000 rpm for 10 min. The plasma was transferred to a second sterile tube and 1 mL of sterile CaCl was added to 5 mL of plasma. The tubes were incubated for 30 min at 37°C . The clotted plasma was then recentrifuged for 10 min at 3,000 rpm. The supernatant is thrombin and must be stored at -30°C until used. The preparation of the cryoprecipitate was as follows. One platelet aliquot was mixed with one aliquot of cryoprecipitate in a sterile plastic Petri dish. For each 10 mL of PC-cryoprecipitate solution 1 mL of autologous thrombin and 1 mL of calcium gluconate were added, then the contents of the Petri-dish were mixed in order to produce a gel-like material in 10-15 min. The cryoplatelet gel so obtained, kept at room temperature, was used within 8 hours.

Operative technique. In all patients, excision was always performed with regional (spinal) anaesthesia. The patient was placed in the prone jack-knife position and the buttocks were retracted with adhesive tape. The extent of the pilonidal area was defined by gentle methylene blue injection into the primary and secondary tracks in order to achieve a proper delineation of these tracks. The entire pilonidal area was then excised by scalpel blade with an elliptical incision, with *en bloc* excision of the sinus tracks, cystic wall, and fat tissue down to the postsacral fascia. The postsacral fascia was always conserved because it is rarely penetrated by the fistulous tracks, and its excision often results in considerable blood loss. Electrocoagulation was selectively used to secure vessel haemostasis and was particularly meticulous because the tissue defect should undergo primary closure. As regards the type of wound reconstruction, patients of the first group had the wound left open to close secondarily; in the second group, a "tension-free" wound reconstruction was adopted, as later described, without any application of sealant while, in the third group of patients, the "tension-free" wound reconstruction was coupled with the application of cryoplatelet gel.

"Tension-free" wound reconstruction technique. Following PS excision, both sides of the wound were undercut for a distance of at least 2-3 cm to obtain two thick fibroadipose flaps whose free

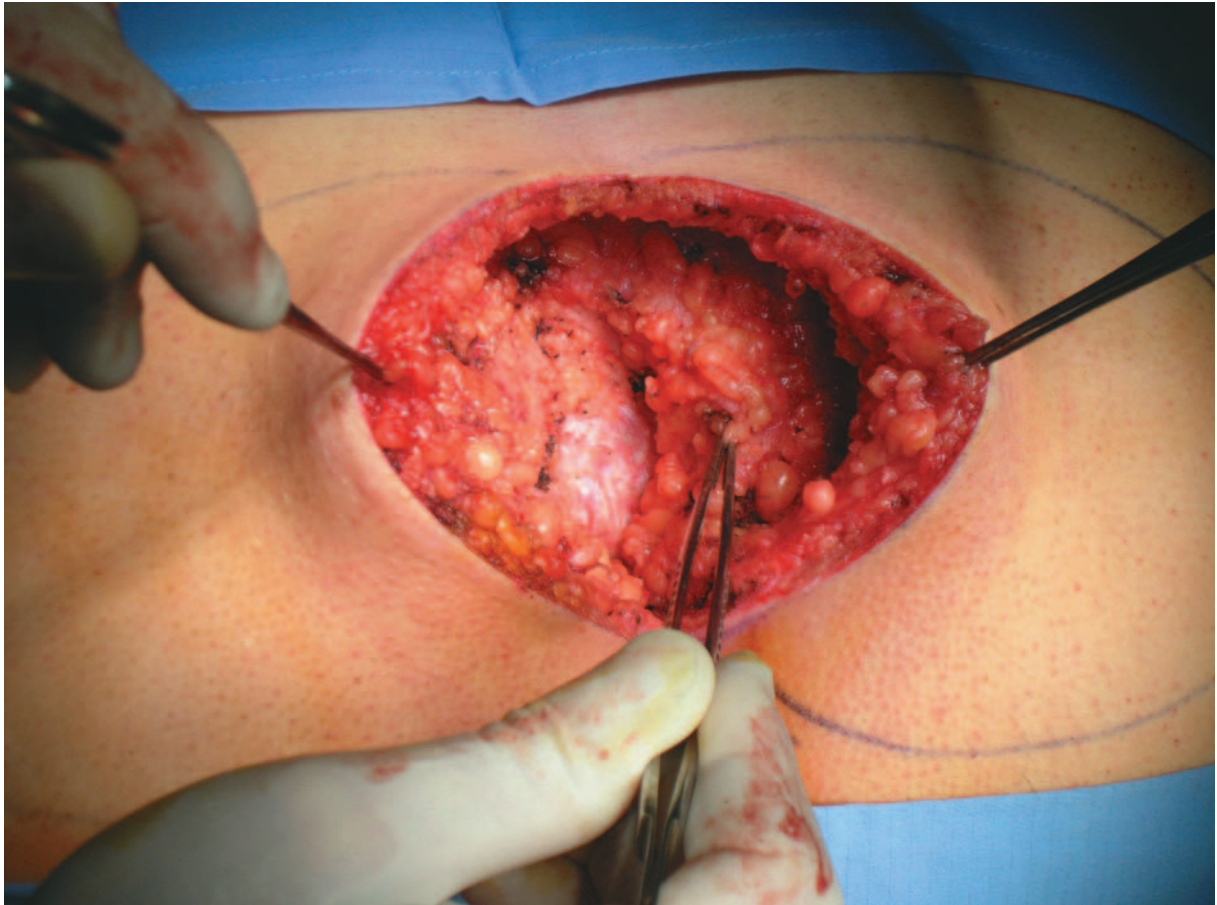


Figure 1. Following the complete excision of the pilonidal area, a thick fibroadipose flap is prepared on both sides; the flap on the right of the operative field is indicated.

margins could be easily approximated to the midline, once the adhesive tape on the buttocks had been removed; the aim was to reduce the sharing forces from the buttocks on the midline wound in the natal cleft, so as to perform a “tension free” suture line (Figure 1). Hence, the two margins of the fibroadipose flaps were sutured together by means of vertical mattress suture with n.0 polygalactin, which were held untied by means of small forceps. The space overlying the postsacral fascia was drained with suction drainage through an independent cutaneous outlet away from the wound. In patients undergoing autologous cryoplatelet gel application, this deep space was filled with the first dose of gel that was carried into the operative room in two sterile plastic Petri-dishes at the beginning of the operation and stored in sterile conditions at room temperature (Figure 2). Hence, the stitches on the midline were tied to complete the first deep suture line. The same suction drainage was adapted also to drain the superficial space that was created between the fibroadipose flap, just completed, and the cutaneous-subcutaneous layer. In patients undergoing regenerative medicine, this more superficial space was filled with the second dose of autologous cryoplatelet gel (Figure 3). Finally, subcutaneous closure with n.3/0 polygalactin suture, and cutaneous closure with n.3/0 silk or metallic stitches were performed.

Postoperative care and follow-up. All patients were observed daily up to discharge from hospital, then, weekly in the outpatient clinic until the wound had healed completely. Patients undergoing “tension-free” wound reconstruction, with or without cryoplatelet gel application, were discharged from hospital after three postoperative days, in order to closely check the wound and serous discharge as well as to guarantee adequate rest during the first postoperative days. Patients were always discharged with the suction drainage in place, which was removed on the fifth postoperative day. In patients undergoing primary wound closure, the wound was systematically aspirated during the outpatient visit in order to empty any fluid collection, even if clinically undetected. The patients were routinely checked every three months.

Results

In all patients, histopathology confirmed the clinical diagnosis of PS, with detection of hair tufts in the cavities of the PS. In the three groups of patients, the mean duration of preoperative symptoms and operative time were similar. Hospital stay was one to two days longer in patients of group 2 and 3, due to the need to closely observe their

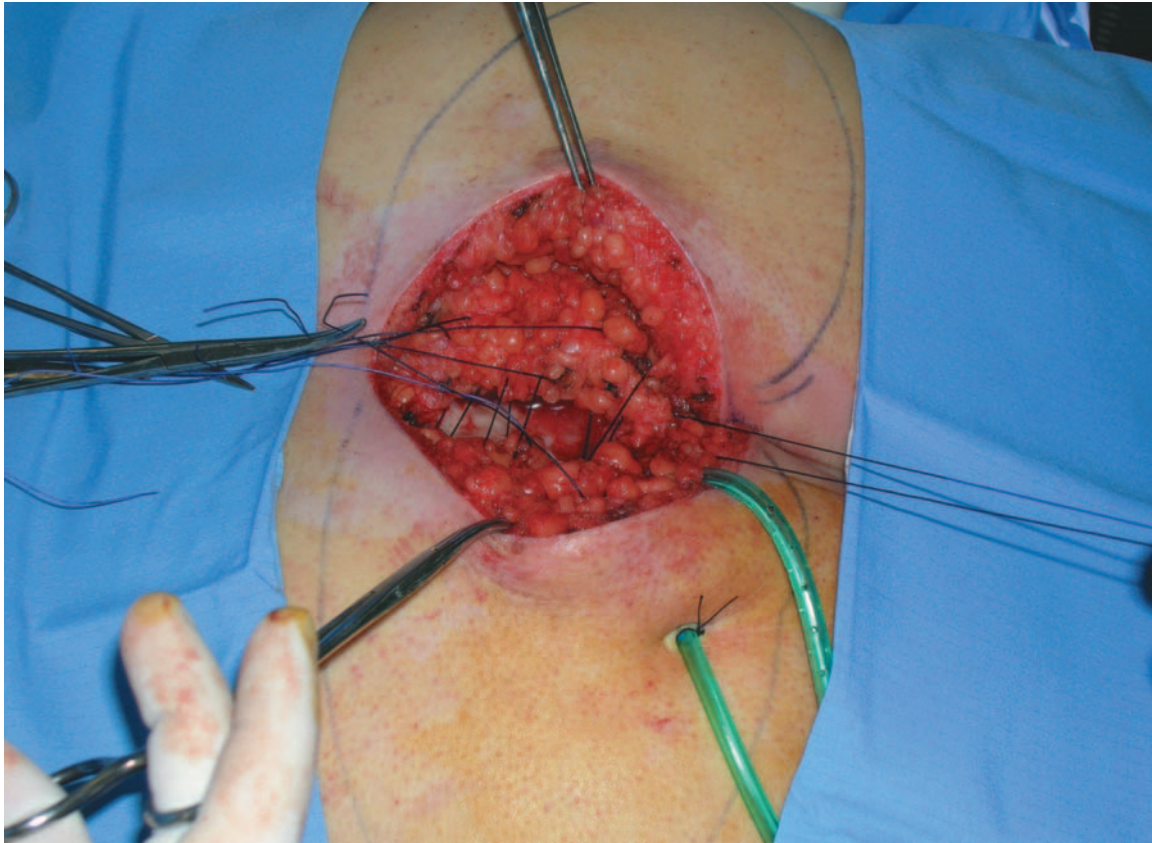


Figure 2. Once the first row of stitches on the midline has been performed, the autologous cryoplatelet gel is applied to the bottom of the operative field, to fill the deep space overlying the postsacral fascia.

clinical course in this pilot phase of study. Patients in group 1 complained of postoperative pain, requiring analgesic medications for one to three days but, mostly, their postoperative disability was remarkably longer, accounting for a median period of 65 days (range: 45-80 days) as compared to 28 days (range: 20-47) and 15 days (range: 12-26 days) in patients of group 2 and 3, respectively.

As regards the mean total amount of fluid collected in the wound (suction drainage plus fine-needle aspiration after drainage removal) this was higher (280 mL: range: 200-380 mL) in patients of group 2 as compared to group 3 (150 mL: range: 120-190 mL). Moreover, primary healing was also more satisfying in patients of group 3 as compared to group 2 because, in the former, it was achieved in all patients within 14 to 29 days (median = 18 days) and only one patient had wound infection with a delayed healing while, in the latter, it was achieved in 11 patients within 17 to 32 days (median = 25 days), while four patients had wound infection with wound dehiscence in two of them (13%) (Table I). Finally, recurrence was only detected in one patient of group 1 (6%) and in two patients in group 2 (13%).

Discussion

PS is a rather frequent disease that primarily affects male patients in their second to third decade of life. Although this condition is by no means life-threatening, it may cause prolonged pre- and postoperative morbidity, and may represent a special challenge to the surgeon and the patient.

From the clinical standpoint, three categories may be differentiated: first, that of acute pilonidal abscess which are usually treated merely by drainage with local anaesthesia, in compliant patients. In the clinical experience of Jensen and Harling (14), this policy achieved healing in 58% of patients and only 27% required definitive treatment of the underlying PS.

Second, that of chronic PS, managed by many methods, such as excision and healing by granulation, excision and marsupialisation, excision and primary closure, excision and flap closure, or sinus extraction (Lord-Bascom procedure) (1). Basically, primary closure has the potential to produce early wound healing as compared to open excision if infection or wound dehiscence do not occur, although it

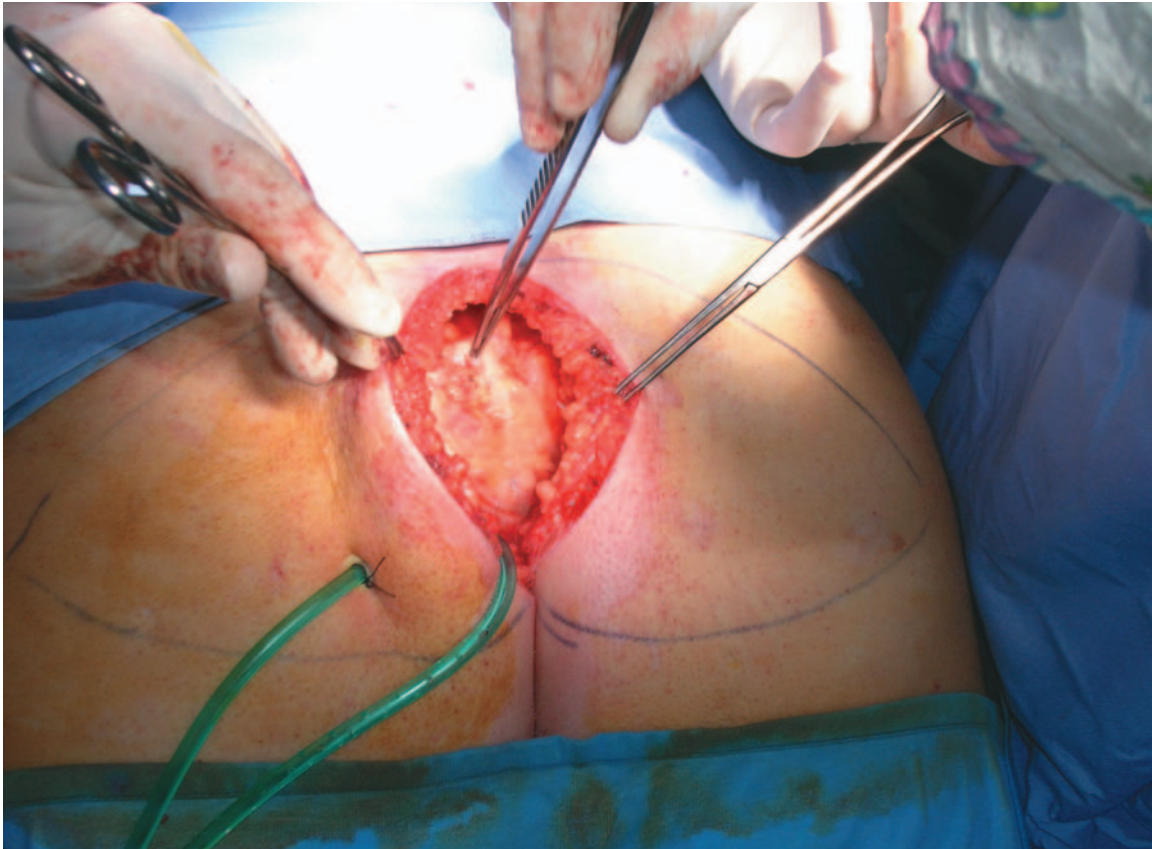


Figure 3. The stitches on the midline have been tied and a second dose of autologous cryoplatelet gel is applied in the more superficial space underlying the subcutaneous tissue.

does require some restriction of activity due to tissue tension. Notably, complete primary healing is achieved in only 51% to 92% of patients at 1 to 6 month postoperatively, and when the wound breaks down, healing rates are even longer than with excision alone (1,15). Moreover, recurrence rates after primary closure vary between 1% and 46%; two randomized trials comparing leaving wounds open with primary suture suggested lower recurrence rates in the open management group (0% vs. 4.4%) respectively coupled with a lower rate of infection (1.8% vs. 3.6%) although patients with primary closure returned to work significantly earlier ($p < 0.05$) (1, 16-17).

Finally the category of complex or recurrent PS, which usually require wide excision of the pilonidal area due to the extent of fistulous tracks and the presence of bacteria in the excised specimen. Moreover, in recurrent cases, the risk of wound dehiscence is even higher due to previous pilonidal excision that increases suture line tension. Like chronic PS, the ideal operation should be simple, require a short hospitalization time with minimal postoperative disability and have a low recurrence rate (18).

The clinical experience derived from our clinical study suggests that the optimization of the operation is related to several aspects, each of them requiring special care. Certainly, the surgical preparation of a fibroadipose flap may be helpful in preventing wound dehiscence by reducing the suture line tension, according to a “tension-free” principle. However, this plastic reconstruction is hampered by the increased risk of serous discharge, which may predispose to wound infection and dehiscence. Hence, this “tension-free” technique cannot be regarded in itself as the final answer to the prevention of wound dehiscence because, in our view, the primary goal is the complete obliteration of the cavity after the excision of a wide pilonidal area, as was required in this set of patients with complex or recurrent disease. Suction drainage may help in preventing fluid collection in the wound, although it was kept no longer than five days. Thus, the true innovation is represented by the use of an autologous cryoplatelet gel, which couples the sealant properties of fibrin gel to the regenerative potential of growth factors (PDGF, TGF- β , IGF-I and IGF-II) released by platelet α -granules and

which promote the process of tissue repair (9-13). Interestingly, preliminary results have also been obtained in other clinical applications, such as neurosurgery, oral and maxillofacial, orthopaedic, ophthalmologic, hepatic, plastic and cosmetic surgery, and they deserve further study in order to optimize the methodology (13).

A careful surgical technique should be adopted, avoiding an extensive use of electrocoagulation, to reduce the postoperative serous drainage and pain, while preferably using a cold scalpel for the excision of the pilonidal area. The five-day antibiotic prophylaxis with amoxicillin-clavulanic acid should be recommended because of its activity against the most likely pathogens of these kind of postoperative wound infections (*Staphylococcus epidermidis*, *Staphylococcus aureus*, *Streptococcus* spp., *Enterococcus*, *Escherichia coli*, and mixed anaerobic flora) (1, 19). Some apparently less relevant aspects deserve further consideration, such as the wound dressing with the incorporation of an elastic adhesive tape, the position of the patient in the bed (preferably in the prone or lateral position) in order to minimize suture line tension during the early postoperative days, and the systematic fine-needle aspiration of the wound after drainage removal to avoid fluid collection deep in the wound which may be a source of infection or, possibly, wound dehiscence or even recurrence.

The rather short follow-up of patients undergoing regenerative medicine cannot give us any information regarding the actual recurrence rate of this original surgical procedure for the definitive surgical repair of PS. However, the simplicity of the operation, the use of autologous products, the short hospitalization – easily transformed into a day-surgery procedure – and minimal postoperative disability with complete wound healing are appealing and deserve further analysis in a well-designed clinical trial that could be extended to include less complicated cases of chronic PS.

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