

Surgical reconstruction of pilonidal sinus disease with concomitant extracellular matrix graft placement: a case series

Background: Pilonidal sinus disease (PSD) is a chronic inflammatory disease affecting the soft tissue of the sacrococcygeal region and remains a challenging disease for clinicians to treat. The optimal treatment for PSD remains controversial and recent reports describe several different surgical approaches offering different benefits. Approximately 40% of initial incision and drainage cases require subsequent surgery. Due to high recurrence rates and postoperative complications, a more complex revision surgery involving a flap reconstruction may be required. We hypothesised that the combination of an extracellular matrix (ECM) graft with tissue flap reconstruction may decrease the postoperative complications and recurrence rates for PSD.

Method: We report a retrospective case series using a surgical flap reconstruction with concomitant implantation of an ovine forestomach ECM graft under a fasciocutaneous flap with an off-midline closure for recurrent PSD, where previously surgical intervention had failed due to

wound dehiscence and/or recurrent disease.

Results: The case series included six patients. After three weeks, all patients except one were fully healed, and the sixth was fully healed by week 4; all wounds remained fully healed at 12 weeks. All patients achieved good cosmesis and were able to return to normal function without any residual symptoms.

Conclusion: This pilot case series explored augmenting a flap reconstruction for complex PSD with advanced ECM graft materials, demonstrating that it may improve outcomes and minimise typical complications seen in flap closure, such as inflammation, infection, haematoma/seroma and hypoperfusion. Although the study had a limited number of participants, long-term outcomes were promising and suggest that further studies are warranted.

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ADM ● acellular dermal matrix ● CTP ● dressing ● extracellular matrix ● flap ● flap reconstruction ● graft ● infection ● ovine forestomach matrix ● pilonidal ● pilonidal sinus ● reconstructive surgery ● skin substitute ● wick-assisted closure ● wound ● wound healing

Pilonidal sinus disease (PSD) is a chronic inflammatory process involving the sacrococcygeal region that is characterised by highly inflamed soft tissue, recurrent infections and significantly reduced patient quality of life. The aetiology of PSD is relatively unknown. It is believed that PSD is an acquired condition relating to the presence of hair in the natal cleft which the body recognises as a foreign object, leading to the formation of midline pits with superseding secondary infection.¹ The infected follicle extends and ruptures into the subcutaneous tissue, forming a pilonidal abscess which can form a sinus track extending to deeper subcutaneous cavities. The challenge to clinicians who manage and treat these cases stems from the high risk of recurrence due to frequent pathogenic microbes and chronically inflamed tissue. Although PSD is a benign disorder, it

can be very painful for patients, leading to absences from work or school, and may have a dramatic impact on quality of life. It is estimated that PSD has an incidence rate of 26 per 100,000¹ and affects roughly 70,000 patients annually in the US alone. Males are affected 4.1–8.1 times more frequently than females² and PSD commonly presents in the second decade of life. Risk factors include obesity, poor hygiene, familial history, repetitive irritation/trauma to the gluteal cleft and prolonged sitting.^{3–5}

Treatment can be divided into two categories, operative and non-operative, but there tends to be some overlap between these two interventions. The non-operative management can range from a primary cyst curettage with adjunctive measures, such as laser hair epilation,⁶ shaving the gluteal cleft⁷ or phenol application.⁸ Inevitably, when traditionally non-operative interventions fail, then surgical intervention is needed for the overwhelming majority of PSD cases. The mainstay of treatment for acute pilonidal disease or abscess is incision and drainage (I&D). After the acute inflammatory phase patients typically need to perform daily wound packing, dressing changes and take oral antibiotics for associated cellulitis.⁹ Unfortunately,

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simple I&D procedures are reported to have a 15–40% reoccurrence rate requiring revisional surgeries to remove residual debris, remnant sinus tracts and epithelialisation of the tissues.¹⁰

Surgical excision of chronic PSD is the current standard of care and the two techniques include surgical excision of diseased tissue with primary closure (including various flap techniques), versus excision with healing by secondary intention. There is a significant trend towards faster median healing times and decreased time for returning to work with the primary closure techniques.^{11,12} Closure techniques have an impact on healing and recurrence rates. An off-midline closure seems to provide a clear benefit when compared to a midline closure, providing faster healing times, lower recurrence and lower rates of wound morbidity.¹³ In complex chronic PSD where previous surgical treatment has failed, several flap-based treatment strategies have been described to provide healthy tissue coverage over the surgical defect. However, a potentially unfavourable outcome from this procedure is haematoma/seroma formation and wound dehiscence.¹⁴

A proposed solution to complications associated with flap reconstruction is the placement of an extracellular matrix (ECM) graft to augment the surgical flap and underlying tissues.^{15,16} ECM grafts have been used in a

variety of plastic and reconstructive surgery soft tissue repair given their innate ability to provide a scaffold for cellular infiltration and capillary formation.¹⁷ There are many different ECM grafts clinically available that differ in their source (e.g., human, porcine, bovine, equine) and processing technique to decellularise the tissue to remove nuclear and cellular materials while preserving the structure and composition of the tissue ECM.

Ovine forestomach matrix (OFM) graft has shown promise in reducing complication rates when used during the surgical reconstruction of chronic soft tissues resulting from hidradenitis suppurativa (HS),¹⁵ complex hard-to-heal wounds,¹⁶ skin grafting¹⁸ and abdominal wall repair.^{19,20} OFM is a decellularised ECM graft that is a biomimetic of tissue ECM that has been shown to be anti-inflammatory through modulating protease activity,^{21,22} stimulating angiogenesis, promoting cellular infiltration, and undergoing complete remodelling.²³

The ability of the OFM graft to achieve these biological functions can be attributed to the 151 different matrisomal proteins that have been identified to date.²⁴ These include a wide variety of collagens, such as collagen I, III and IV, adhesion proteins and signalling molecules including, but not limited to, platelet-derived growth factor (PDGF), fibroblast growth factor 2 (FGF2), epidermal growth factor (EGF) and

Table 1. Participant summary including demographic, surgical defect size and outcomes

Gender/age	Comorbidities	History	Area of diseased tissue	Outcomes
F, 21	Smoker Resumed smoking at <3 weeks post-operative	5 year history Prior I/D	~7×11cm	Minor dehiscence at 3 weeks Debrided and primarily reclosed No complication or recurrence at 40 weeks
M, 20 (Case 1)	None	2 year history Prior I/D Prior (12 month) excision and primary closure; dehiscid	~12×6cm	Healed at 3 weeks No complication or recurrence at 40 weeks
M, 19	None	4 year history Prior I/D Prior (12 month) excision and primary closure; dehiscid	~12×3cm	Healed at 3 weeks No complication or recurrence at 35 weeks
F, 52	Obesity Hidradenitis suppurativa	5 year history Prior I/D Prior (10 year) excision and primary closure; dehiscid	~10×4cm	Minor complication at 1 week Closed without intervention Healed at 3 weeks No complication or recurrence at 12 weeks
M, 19 (Case 2)	Severe asthma Splenomegaly Gout	7 year history Prior I/D Prior (6 months) excision and primary closure; dehiscid	~11×4cm	Healed at 3 weeks No complication or recurrence at 12 weeks
M, 15 (Case 3)	None	8 month history Prior I/D (2 months); NPWT resulting in severe pain at dressing change	~12×5cm	Healed at 3 weeks No complication or recurrence at 12 weeks

I/D—incision and drainage; F—female; M—male; NPWT—negative pressure wound therapy

connective tissue growth factor (CTGF).^{18, 24} When used during the reconstruction of chronic soft tissues, the aim of the OFM graft is to reduce surgical complications by suppressing tissue inflammation, filling surgical dead space and rapidly forming well-vascularised new tissue within the defect.

In this retrospective case series, we present a novel use of an OFM graft to aid in the soft tissue flap reconstruction of complex chronic PSD. We employed a wide excision of the chronically inflamed tissue, OFM graft placement at the base of the defect, perforator

artery-sparing gluteal fasciocutaneous flap advancement, wick-assisted off-midline closure and incisional negative pressure wound therapy (NPWT).

Methods

Ethical approval

All patients provided written informed consent for their photographs and data to be used for research and publication purposes. The study was conducted in accordance with World Medical Association Declaration of Helsinki ethical guidelines.

Data collection

Retrospective data were collected from operative notes, clinical follow-up notes and clinical photography. All patients were taken to the operating room and the surgical site was prepared with chlorhexidine gluconate (CHG), and all patients received a single dose of appropriate prophylactic antibiotics. Through an off-midline approach, all the chronically inflamed tissue was removed via a wide excision down to the sacral fascia. A combination of manual palpation of indurated tissue and the injection of methylene blue into sinus tissues was used to help delineate the area of resection. A 10cm×10cm OFM ECM graft (Myriad Soft Tissue Matrix, Aroa Biosurgery Limited, New Zealand) was rehydrated in sterile saline (~5 minutes), trimmed to size, then placed into the base of the defect. The graft was anchored to the deep sacral fascia and medial gluteal fascia using interrupted 2-0 Vicryl (Ethicon, US) sutures. A gluteal fasciocutaneous advancement flap was raised, sparing the inferior and/or superior gluteal artery perforating blood vessels, and advanced over the graft. Deep quilting 0 PDS II (Ethicon, US) sutures were secured in a progressive tension fashion to immobilise and advance the flap. A size 15FR Blake drain was placed with a tunnelled exit point in the lateral aspect of the wound and secured using nylon suture (3-0) and connected to a bulb suction device. The dermal layer was closed using interrupted 3-0 Monocryl suture (Ethicon, US) and the skin was closed using 2-0 nylon suture, using a vertical mattress technique. Two patients had half-inch Iodoform (Integrity Medical Devices Inc., US) wicks placed at a depth of ~1cm, between the vertical mattress sutures (e.g. Fig 3d). All patients received closed incision NPWT (Prevena, 3M+KCI, US) which remained in place for one week.

Patients were followed up at a one-week postoperative visit for NPWT and drain removal and then were followed for at least 12 weeks to monitor for dehiscence, infection or recurrence.

Results

A total of six patients were included in this case series (Table 1). The median age of patients was 25 years old. All patients had previously undergone I&D procedures and four patients had previously undergone a primary closure that had failed/dehiscd at an outside institution. There was a variety of chronicity to the

Fig 1. Representative images of Case 1. Initial defect (a); post wide excision, defect measuring 12×6×5cm (b); placement of the ovine forestomach matrix (OFM) graft at the base of the defect (arrow) (c); fasciocutaneous flap advancement and closure (d); incisional negative pressure wound therapy (NPWT) device (e); postoperative at week 1 (f); fully healed at postoperative week 3 (g); postoperative at week 10 (h)

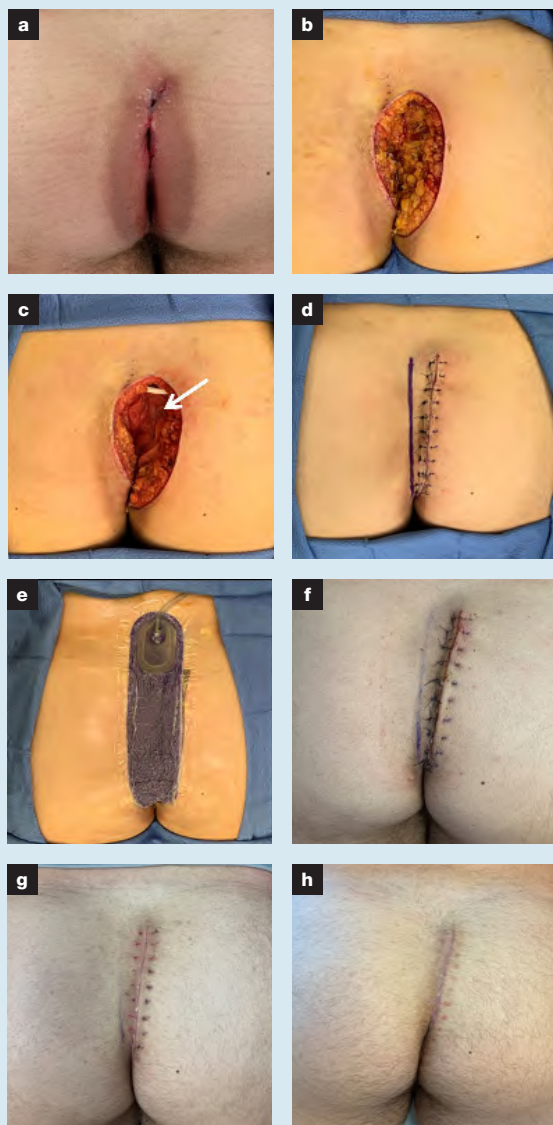


Fig 2. Representative images of Case 2. Initial defect (a); indicating the off-midline excision (b); post wide excision, defect measuring 11×5×6cm (c); placement of the ovine forestomach matrix (OFM) graft at the base of the defect (arrow) (d); fasciocutaneous flap advancement and off-midline closure (e); incisional negative pressure wound therapy (NPWT) device (f); postoperative at week 1 (g); fully healed at postoperative week 4 (h)

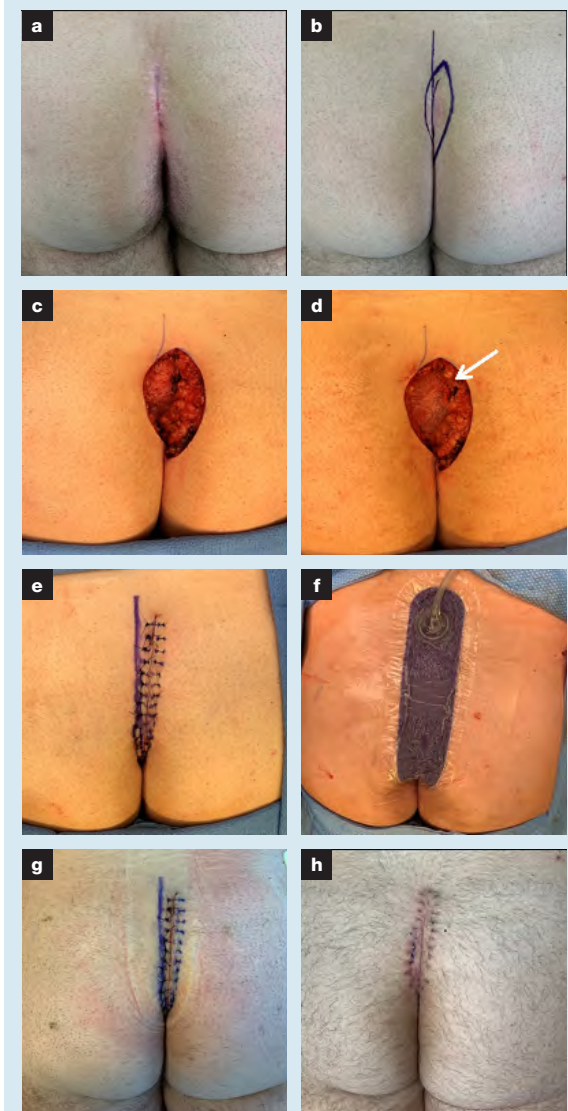
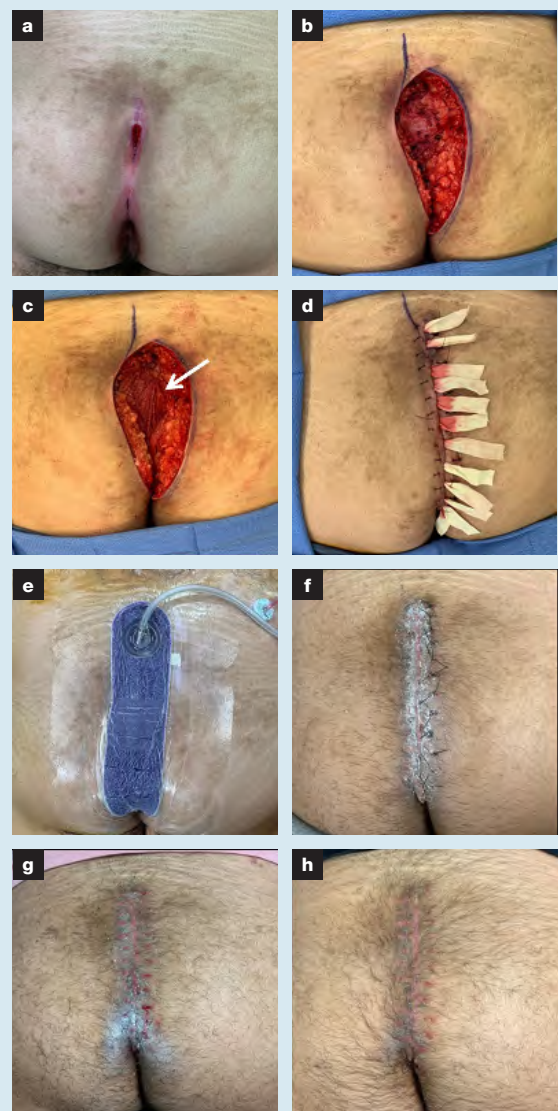


Fig 3. Representative images of Case 3. Initial defect (a); post wide excision, defect measuring 15×6×5cm (b); placement of the ovine forestomach matrix (OFM) graft at the base of the defect (arrow) (c); fasciocutaneous flap advancement and wick-assisted off-midline closure (d); incisional negative pressure wound therapy (NPWT) device (e); postoperative at week 2 (f); fully healed at postoperative week 5 (g); postoperative at week 8 (h)



wounds, with the longest being seven years old. Post wide excision, defects ranged in size from 36–77cm². Using this flap strategy, a fully healed incision was achieved for all but one patient by the three-week point. The one minor dehiscence at week 3 was resolved without further surgical intervention. All wounds remained fully healed at week 12. All surgical wounds demonstrated good cosmesis compared to adjacent tissue. The healed incisions demonstrated excellent functionality and all patients were satisfied with their respective outcomes.

Case 1

A 20-year-old male athlete with no significant comorbidities who had a 2-year history of PSD and had undergone multiple prior I&D procedures with the most recent being 12 months prior to presentation. At that time, a primary midline closure was attempted that dehisced early in the postoperative period and was being managed by NPWT. The chronic sinus was draining purulent material prior to surgery (Fig 1a). The patient had significant discomfort with any sitting and was not able to compete in athletics due to the wound.

Wide excision gave a defect measuring 12×6×5cm (Fig 1b). The deep wound was irrigated with a dilute chlorhexidine solution (Irrisept, Innovation Technologies, Inc., US) followed by a 50/50 povidone-iodine (Betadine, Alcon Laboratories Inc., US) and saline solution soak. The OFM graft was rehydrated, trimmed and secured in the defect (Fig 1c) as described above, followed by advancement of a fasciocutaneous flap (12×10cm) elevated from the right buttock, sparing the superior gluteal artery perforator, and an off-midline closure (Fig 1d). The wound was then dressed with a silver dressing (Mepitel Ag, Mölnlycke Health Care AB, US) and an incisional NPWT was placed (Fig 1e). The patient was followed up one-week post-operation for NPWT and drain removal. There was minimal erythema, no dehiscence and the patient reported no pain (Fig 1f). Sutures were removed at week 3 (Fig 1g) and the wound remained healed at week 10 (Fig 1h). At 40-week long-term follow-up there were no complications or recurrence.

Case 2

A 19-year-old male with a past medical history significant for severe asthma, currently on dupilumab (Dupixent, Sanofi, France), with a history of gout, splenomegaly, and PSD for 7 years. The patient had undergone multiple rounds of oral antibiotics and had undergone surgical excision of the cyst followed by a midline closure six months prior to presentation. When sutures were removed at week 2 post-operation, the wound had dehisced within the first 24 hours, and since this time the wound was being managed with wet to dry dressings and oral antibiotics. The wound continued to drain, and a culture was positive for methicillin-resistant *Staphylococcus aureus* (MRSA) (Fig 2a). The patient had severe pain and elected to proceed with a re-excision of the PSD and flap reconstruction with an off-midline closure (Fig 2b). A wide excision of the cysts extending down the sacral fascia was completed and the resulting wound measured 11×5×6cm (Fig 2c). The OFM graft was rehydrated, trimmed, and secured in the defect (Fig 2d) as described above, followed by advancement of a fasciocutaneous flap (12×10cm) elevated from the left buttock, sparing the inferior gluteal artery perforator, and an off-midline closure (Fig 2e), and dressed with a non-adherent and incisional NPWT (Fig 2f). The patient was followed up one week post-operation for NPWT and drain removal with minimal erythema, no wound dehiscence and reported no pain. At week 4 post-operation, sutures were removed (Fig 2h) and the wound remained healed at week 12 without any reoccurrence.

Case 3

A 19-year-old male with no significant past medical history presenting with an 8-month history of a draining PSD abscess after an I&D (Fig 3a). Due to the persistent drainage the patient underwent an attempted cyst excision two months prior to presentation with a

plan to heal the wound by secondary intention through NPWT. The patient admitted to severe pain requiring anaesthesia at NPWT dressing changes. Due to these factors the patient elected to proceed with a wide excision and closure. During the wide excision of the cyst, another sinus tract was found that tunnelled an additional 4.5cm cephalad to the anal verge leading to a 15×6×5cm defect (Fig 3b). The OFM graft was rehydrated, trimmed and secured in the defect (Fig 3c) as described above, followed by advancement of a fasciocutaneous flap (12×10cm) elevated from the left buttock, sparing the inferior gluteal artery perforator, and an off-midline closure with the addition of Iodoform wicks (Fig 3d). The wound was dressed with an incisional NPWT and the patient was placed on Bactrim DS (Sun Pharmaceutical Industries Inc. India) twice daily for seven days. One-week post-operation, there was mild erythema present. Sutures were removed at week 3 and the patient was placing zinc ointment on the incision daily. The incision remained closed at a 12-week follow-up visit.

Discussion

PSD mainly affects the young male patient population with a rate of 4.1 to 8.1 times greater for males than females.² There is no current consensus on the incidence of PSD, with reported incidences ranging from 26 per 100,000¹ to as high as 700 per 100,000.²⁵

PSD presents a challenge to clinicians due to its high rates of recurrence and surgical wound complications.¹⁰ These complications have been attributed to risk factors such as obesity, smoking, family history, poor hygiene, sinus size and previous surgical excisions.^{3-5,25} Although I&D of a pilonidal abscess helps alleviate pain and avoid a septic infection, it does not address the underlying problem and can lead to a chronically inflamed soft tissue envelope.²⁶ For these reasons, a more complex soft tissue reconstructive approach has been suggested to mitigate these problems and is an attempt to remove all the diseased tissue to prevent reoccurrence.

There are a multitude of surgical techniques that are suggested to reduce postoperative complication rates following surgical reconstruction of PSD.¹ In this case series, we investigated the benefit of a modified flap technique previously described for hidradenitis suppurativa (HS) and complex hard-to-heal wound reconstruction.^{15,16} We have chosen this technique due to the chronic inflammatory response and bacterial contamination seen in HS and PSD. Both disease processes lead to the creation of 'pits' in the subcutaneous space which, when contaminated by bacteria, become painful abscesses that are challenging to manage with standard wound care. OFM has shown promise in reducing postoperative complications in HS and complex hard-to-heal wounds through its ability to modulate the inflammatory response in these chronically inflamed soft tissues, fill surgical dead space and rapidly regenerate soft tissues.^{15,16,21}

OFM is known to contain a number of naturally

occurring anti-inflammatory proteins²⁴ and has been shown to balance soft tissue proteases through broad spectrum modulation of matrix metalloproteinases and neutrophil elastase.²¹ The biology and structure of OFM, including residual vascular channels, may establish increased perfusion within the fasciocutaneous flap at an earlier time point.²³ Additionally, the placement of the ECM graft material may lead to a decrease in the dead space that can occur after a wide excision, therefore decreasing the risk of seroma/haematoma formation.¹⁶

The recurrence rates for PSD after lay open and primary closure techniques are 17% and 30%, respectively.²⁷ There are two different techniques to achieve closure for PSD, a lateralised off-midline closure with flattening of the natal cleft and a midline incision that falls in line with the native cleft. When comparing the recurrence rates of these two approaches, the latter has a significantly higher rate of 7–40% compared to 0–3% seen with the off-midline approach.²⁷

A large meta-analysis of RCT and non RCT studies, which included 89,583 patients who underwent either a Karydakos or Bascom flap procedure, had a recurrence rate of 0.2% at 12 months, 0.6% at 24 months and 2.7% at 120 months.²⁹ In the same paper, Stauffer et al.²⁸ evaluated the recurrence rate for a primary midline closure to be 3.4% at 12 months, 7% at 24 months, 32% at 120 months and more than doubling to 67.9% at 240 months.²⁸ In our case series presented here we had a 0% recurrence rate at 12 weeks postoperatively.

The two patients whose incisions were closed using wick-assisted closure both achieved complete closure and remained closed at the 12-week mark. The purpose of the wick, to remove excess fluid accumulation and optimise the wound healing environment, has been demonstrated in a similar chronically inflamed tissue pathology, HS, with successful wide excision and subsequent wick-assisted closure technique.¹⁵

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Study limitations

Although results from this pilot case series are promising, a long-term follow-up is needed to assess the overall recurrence rate compared to the current literature. Ideally, follow-up would occur at 12, 24 and 60 months. One other limitation is the small sample size in our case series. The concurrent use of closed incisional NPWT was employed on all patients, upon which we cannot draw a conclusion given the limited sample size. Some of the desired benefits of NPWT were to have a sterile dressing to cover the incision for seven days, therefore providing a barrier to any faecal contamination in the early postoperative period while also being able to improve the blood flow to the incision site. While NPWT has been shown to decrease surgical site infections, there has been no benefit in preventing wound dehiscence when compared to standard wound dressing.²⁹

Conclusions

Flap reconstruction of PSD and recurrent PSD has demonstrated the ability to lower the its recurrence rate. This present case series demonstrates the first known use of an ECM graft to augment flap reconstruction in PSD. Our initial findings using the OFM graft as part of our surgical flap reconstruction of these affected patients is very encouraging. A larger case study with long-term follow-up of patients treated with OFM graft would be a valuable tool to access improvements in the rate of recurrence of the disease and complications after surgical intervention with OFM. **JWC**

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Reflective questions

- Pilonidal sinus disease (PSD) has a significant impact on patients' quality of life, especially at a young age, and often PSD patients require frequent surgical procedures to cure the disease. Should surgical flap reconstruction be considered earlier in the treatment course for recurrent PSD?
- Does the addition of a wick-assisted closure lead to a higher rate of wound closure in the acute postoperative phase?
- Surgical reconstruction involving inflamed tissue like that seen in PSD often suffers from increased complication rates (e.g., infection, dehiscence or seroma). Should the inclusion of advanced extracellular matrix (ECM) technology to counteract tissue inflammation be considered more often for these types of surgeries?

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