

Prospective Registry Study Evaluating Ovine Forestomach Matrix Graft As Part Of Pilonidal Sinus Flap Reconstruction – Interim Analysis

Yosef Nasser, MD; Kimberly Oka; Kristina La; Andrea Solis; Jason Cohen; Moshe Barnajian, MD

Surgical Group of LA Research Foundation – Los Angeles, CA, USA

PURPOSE/BACKGROUND

Flap procedures following excision of recurrent or complex pilonidal sinus disease (PSD) are associated with relatively high wound complication rate^{1,2}.

AIM/HYPOTHESIS

Given the inflammation and contamination associated with PSD, we hypothesized that the addition of an ovine forestomach matrix graft to our existing bilateral gluteal fasciocutaneous advancement flaps may help to reduce wound complications.

METHODS

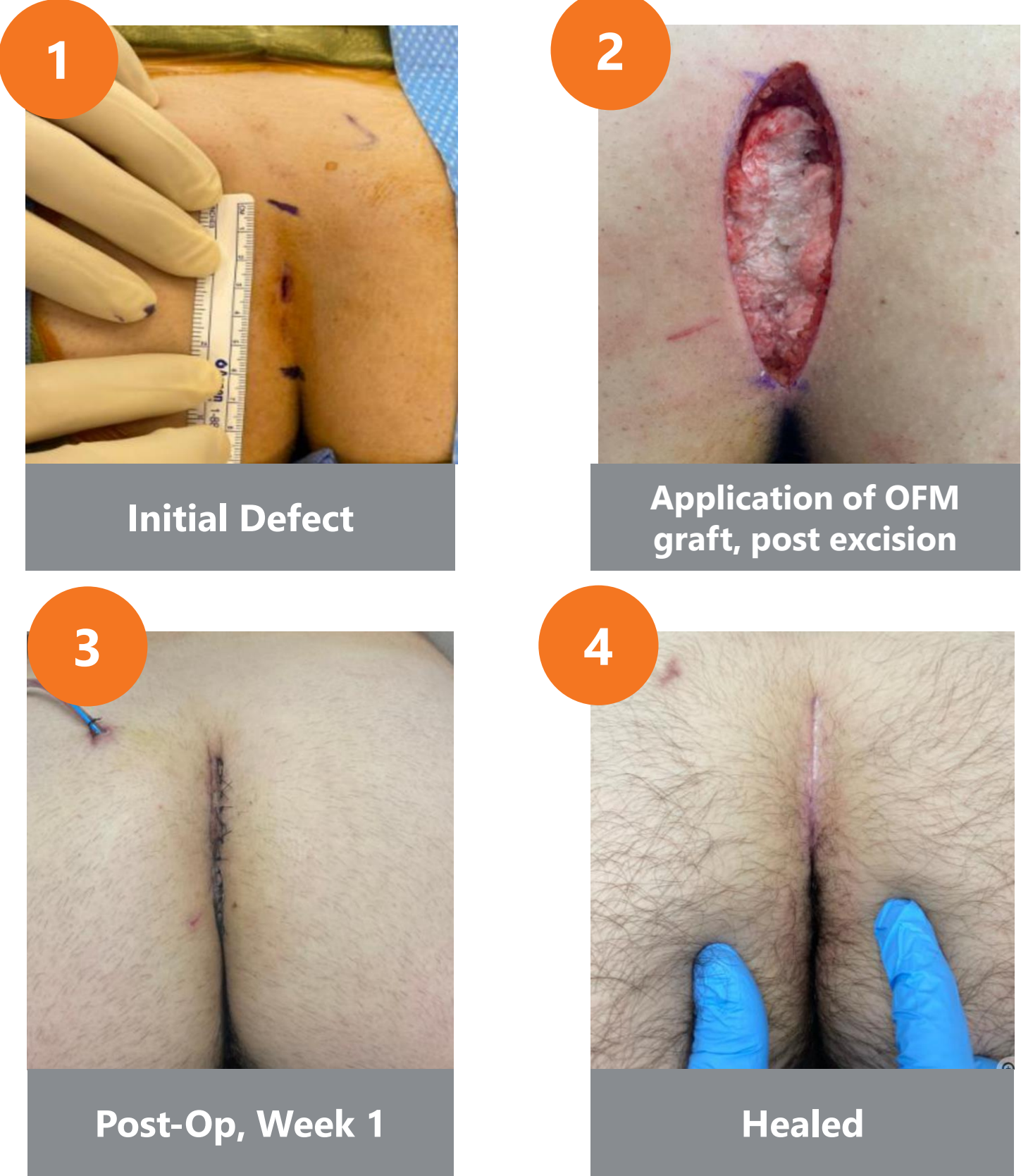
This is an interim analysis of a single site in an ongoing prospective registry study evaluating the safety and efficacy of an ovine forestomach matrix (OFM) graft across a range of surgical procedures (ClinicalTrials.gov Identifier: NCT05243966). The OFM graft* (Myriad Matrix™) is an FDA-cleared biologic implant, which provides a scaffold for cell re-population³ and rapidly forms well vascularized tissue and is remodeled over time⁴. Following elliptical excision of pilonidal disease, gluteal fasciocutaneous advancement flaps were elevated circumferentially. Prior to closure, a hydrated OFM graft was placed in the surgical dead space above the pre-coccygeal fascia. The flap was then approximated with interrupted sutures incorporating the OFM graft. A surgical drain was then placed in the subcutaneous space followed by midline closure of the dermal layer with interrupted absorbable sutures. Two full thickness retention sutures tied over a rolled-up gauze were placed at the inferior portion of the midline incision. The primary outcome for the study were device related adverse events, wound complications, and time (weeks) to complete healing.

RESULTS/OUTCOMES

A total of 11 (10 male: 1 female) patients underwent PSD reconstruction the OFM graft during the study interval, with a mean age of 26.1 (range: 21-36) years and three patient are tobacco smokers. There was a mean follow up of 4.6 months (range:1-11 months). In follow-up, 9 (81.8%) patients had complete healing at their 1 month follow up. Of that subset, the mean time to complete healing was 3.6 weeks (range:2-4 weeks). There were two superficial wound dehiscences that occurred at or before the 1-month post op visit. Both healed without any need for subsequent surgery. There were no post-procedural infections, hematoma/seroma formation, nor device related adverse events. 8 patients (72.3%) achieved at least a 3-month follow-up with an average patient satisfaction score of 4.8 on a 1-5 scale, with 5 being highly satisfied. Limitation of this study is that it is an interim analysis of an ongoing long term registry study with a limited sample size.

Sex/Age	History	Outcomes
M, 21	<ul style="list-style-type: none"> >2-year history of PSD 	<ul style="list-style-type: none"> Fully healed at 4 weeks No recurrence, last follow-up 6 months No complications
M, 30	<ul style="list-style-type: none"> >5-year history of PSD 	<ul style="list-style-type: none"> Mild Dehiscence, fully healed with local wound care No recurrence, last follow-up 7 months No further complications
M, 28	<ul style="list-style-type: none"> >5-year history of PSD Smoker 	<ul style="list-style-type: none"> Fully healed at 4 weeks No recurrence, last follow-up 11 months No complications
M, 21	<ul style="list-style-type: none"> <6-month history of PSD 	<ul style="list-style-type: none"> Fully healed at 3 weeks No recurrence, last follow-up 8 months No complications
F, 36	<ul style="list-style-type: none"> 6-12-month history of PSD Abscess 	<ul style="list-style-type: none"> Mild Dehiscence, fully healed with local wound care No recurrence, last follow-up 5 months No further complications
M, 21	<ul style="list-style-type: none"> <6-month history of PSD 	<ul style="list-style-type: none"> Fully healed at 4 weeks No recurrence, last follow-up 5 months No complications
M, 21	<ul style="list-style-type: none"> 2-year history of PSD 	<ul style="list-style-type: none"> Fully healed at 4 weeks No recurrence, last follow-up 3 months No complications
M, 21	<ul style="list-style-type: none"> >2-year history of PSD 	<ul style="list-style-type: none"> Fully healed at 3 weeks No recurrence, last follow-up 3 months No complications
M, 36	<ul style="list-style-type: none"> >2-year history of PSD 	<ul style="list-style-type: none"> Fully healed at 4 weeks No recurrence, last follow-up 1 month No complications
M, 25	<ul style="list-style-type: none"> 6-12-month history of PSD Smoker 	<ul style="list-style-type: none"> Fully healed at 2 weeks No recurrence, last follow-up 1 month No complications
M, 28	<ul style="list-style-type: none"> >5-year history of PSD 	<ul style="list-style-type: none"> Fully healed at 4 weeks No recurrence, last follow-up 1 month No complications

Case Example



DISCUSSION/CONCLUSION

This is an interim analysis of a registry study evaluating the use of OFM graft as an implant in a fasciocutaneous midline closure technique in treatment of PSD. The addition of the OFM graft was safe and effective at achieving an improved cosmetic outcome with a high patient satisfaction scar score. . Limitation of this study is that it is an interim analysis of an ongoing long-term registry study with a limited sample size and limited long-term follow-up interval. A larger analysis will be complete at the conclusion of the study.

REFERENCES AND DISCLOSURES
 YN has received honoraria from Aroa Biosurgery Ltd [1]Nasser Y, Oka K, Soliman J, Kasher E, Zhu R, Cohen J, Barnajian M. Bilateral Gluteal Fasciocutaneous Advancement Flaps With and Without Tie-Over Sutures in Treatment of Chronic Pilonidal Disease: A Prospective Case Series. Am Surg. 2022 May 17;31348221075731. doi: 10.1177/00031348221075731. Epub ahead of print. PMID: 35580246.[2] "Surgical reconstruction of pilonidal sinus disease with concomitant extracellular matrix graft placement: a case series." J Wound Care. [3]Ovine Forestomach Matrix (OFM) Stimulates Angiogenesis In Vitro and In Vivo. SAWC, Dallas, Texas, USA. [5] Chaffin, A. E. and M. C. Buckley (2020). "Extracellular matrix graft for the surgical management of Hurley stage III hidradenitis suppurativa: a pilot case series." J Wound Care 29(11): 624-630. [6] Chaffin, A. E., S. G. Dowling, M. S. Kosyk and B. A. Bosque (2021). [3]Ovine Forestomach Matrix (OFM) Stimulates Angiogenesis In Vitro and In Vivo. SAWC, Dallas, Texas, USA. [4] Lun S, Irvine SM, Johnson KD, Fisher NJ, Floden EW, Negron L, Dempsey SG, McLaughlin RJ, Vasudevaramurthy M, Ward BR, May BC. A functional extracellular matrix biomaterial derived from ovine forestomach. Biomaterials. 2010 Jun;31(16):4517-29. doi: 10.1016/j.biomaterials.2010.02.025. Epub 2010 Mar 11. PMID: 20226520.