

# Extracellular Matrix for the Treatment of Anal Fistula: A Single Center Retrospective Review

## Background

- Anal fistula – inflammatory tract between anal canal and perianal skin
- Caused by crypto-glandular infection, Crohn's
- Surgical management is centered around healing and clearing infections, while preserving sphincter function
- Ovine forestomach matrix (OFM) - decellularized extracellular matrix – derived from ovine (sheep) forestomach: being investigated for treatment of anal fistulae
- Easily absorbed into regenerating tissue
- Has been investigated in soft tissue repair and wound healing applications
- Recent pilot studies have investigated its use for anal fistula, with promising results
- **Aim** – to perform a larger single-center retrospective case series to validate pilot study. Primary outcome was wound healing at 12 weeks.

## Methods

- Data collected from anal fistula patients undergoing surgery at our institution between July 2021 and October 2023
- Excluded patients with Crohn's or acute perianal infection
- Preoperative MRI to anatomically categorize the fistulae
- Standardized surgical technique, slightly different than pilot study
- Patients followed in clinic postoperatively – 1 week, 1 month, 3 months, 6 months
- Assessed time to healing, recurrence, complications (infection, bleeding).
- Descriptive statistics calculated

## Technique

- General / MAC
- Lidocaine for pudendal/perianal block
- Fistula tract debrided/curetted
- Aroa BioSurgery Myriad Matrix Soft Tissue Bioscaffold™ OFM hydrated with saline, rolled and cut to length for fistula tract
- Remainder of tract filled with Aroa BioSurgery Myriad Morcells™ product
- Secured internally and externally with 3-0 PDS
- Xeroform gauze applied as dressing, stitched in place
- Exparel® injected at end of case

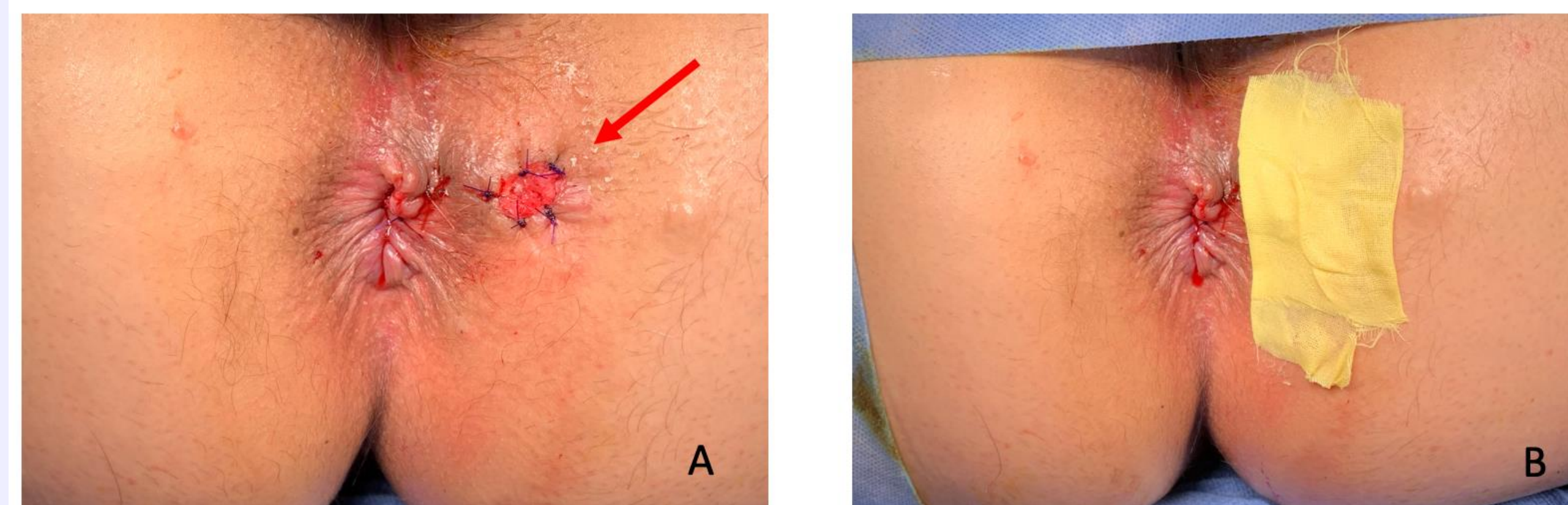


Figure 1. (A) OFM graft sewn in place with interrupted PDS. (B) Xeroform® dressing over surgical site.

## Results

- 25 patients underwent the fistula plug procedure at our institution
- Mean – 48.3 years old (SD=14.9)
- Mean depth of tract – 3.34 cm (SD=1.58)
- Mean time to heal – 4.68 weeks (SD = 1.13)
- 18/25 trans-sphincteric, 3/25 extra-sphincteric, 4/25 inter-sphincteric
- No patients lost to follow-up (mean follow-up 14 weeks)
- 88% (22/25) healed within the study period, 12% (3/25) did not
- 4% (1/25) with recurrence - (already recurrent, had previous seton, trans-sphincteric)
- No adverse effects reported

## Discussion

- Our recurrence rate in this series was 4%, as compared to 7% in the previous pilot study
- Previous data on endorectal flaps with recurrence rates reported between 12.5 and 38%
- Previously reported fistula plugs (other biologic materials) with 12 month recurrence rates between 66-80%
- Extrusion has been seen with premade plug products
- OFM inhibits tissue proteases and recruits stem cells, may be helpful with anal fistulae given the extensive associated inflammation
- Compared to other plugs, each OFM plug was tailored to fit the fistula tract during case
- Our lower recurrence rate may be due to using PDS as opposed to Vicryl to secure the graft (main difference) – longer absorption time for internal opening

## Conclusion / Future Directions

- OFM graft appears to be an efficacious method of treating anal fistula in non Crohn's patients, with low recurrence rates and high closure rates based on our data and previous pilot study
- At a mean of 14 week follow up, 88% of patients healed with 4% recurrence rate
- As compared with previously used products, OFM has anti-inflammatory properties and is custom fit to the fistula tract
- Will need to continue follow-up to determine if failure rates rise over time as seen with other products
- Ongoing prospective observational study (multicenter) to further investigate use of OFM in anal fistula treatment

## Acknowledgements / References

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Bondl J, Avdagic J, Karlboom U, Hallböök O, Kalman D, Šaltyté Benth J, Nairny N, Øresland T. Randomized clinical trial comparing collagen plug and advancement flap for trans-sphincteric anal fistula. *Br J Surg*. 2017 Aug;104(9):1160-1166. doi: 10.1002/bjs.10549. Epub 2017 May 10. PMID: 28489253.

Buchberg B, Masoomi H, Choi J, Bergman H, Mills S, Stamos MJ. A Tale of Two (Anal Fistula) Plugs: Is there a Difference in Short-Term Outcomes? *The American Surgeon*. 2010;76(10):1150-1153. doi:10.1177/000313481007601030

Herold, A., Ommer, A., Fürst, A., Pakravan, F., Hahnloser, D., Strittmatter, B., ... Vershenya, S. (2016). Results of the Gore Bio-A fistula plug implantation in the treatment of anal fistula: a multicentre study. *Techniques in Coloproctology*, 20(8), 585–590. doi:10.1007/s10151-016-1505-8

Hsu A, Schildt K, D'Adamo CR, Bosque BA, Dowling SG, Wolf JH. Surgical management of perianal fistula using an ovine forestomach matrix implant. *Tech Coloproctol*. 2023 Sep;27(9):769-774. doi: 10.1007/s10151-023-02809-y. Epub 2023 May 3. PMID: 37133736; PMCID: PMC10404168.

Ky AJ, Sylla P, Steinhagen R, Steinhagen E, Khaikov S, Ky EK. Collagen fistula plug for the treatment of anal fistulas. *Dis Colon Rectum*. 2008;51(6):838-843. doi: 10.1007/s10350-007-9191-2.