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Using amniotic allograft in diabetes-related foot ulcers: A case series

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Background and aims
Placental derived dressings promote healing, as an adjunct to best available standard of care for non-healing diabetes-related foot ulcers (DFU)[1]. When and how often to apply these new products are important unanswered questions, given the high unit cost. This case series presents our experience using a TGA approved cryopreserved human amniotic allograft (AA) in the management of DFU that failed to achieve 50% percent wound closure (PWC) at 4 weeks, despite optimal care within an accredited interdisciplinary High Risk Foot Service (iHRFS).

Methods
This prospective case series was conducted at the Royal Prince Alfred Diabetes Centre (iHRFS) from August 2023 to December 2024. Three serial patients with DFU ≥ 0.5 cm² who failed to achieve 50% PWC at 4 weeks and exhibited continued healing failure despite receiving best available standard care were offered AA treatment. After obtaining informed consent, each received a single AA application following sharp debridement and saline irrigation. The AA was cut to wound size, placed in the wound bed and covered with a secondary dressing to manage exudate. AA was left in-situ and secondary dressings were changed every 2–3 days at home. At fortnightly iHRFS visits, the wound edges (not base) was sharp debrided. Wound size was measured using planimetry and a 3D camera during the fortnightly visits prior to AA application, at the time of application (baseline), and at weeks 4, 8, and 12 to show healing trajectory post application.

Results
Three patients were offered and accepted AA treatment. DFU1 was 14 weeks treatment duration, 4.5 cm^1, clinically infected with tendon exposed, no peripheral arterial disease (PAD) and a SINBAD Score 4. DFU2 was 14 weeks treatment duration, 1.3cm^2, clinically infected with tendon exposed with mild PAD (WIFI 1) and a SINBAD Score 5. DFU3 was 4 weeks treatment duration, 0.5cm^2 no infection or PAD and a SINBAD Score 1. All wounds were granulating at the time of application. The dressing was fully absorbed by week two. Application was comparable in complexity and time to routine dressings. Healing improved in all cases, from PWC less than 50% at 4 weeks to an average PWC of 68% between weeks 4 and 8 post application. All patients achieved complete healing by 12 weeks with two healing by 6 weeks post application. No adverse events related to AA were observed.

Conclusions
This small case series suggests AA is an adjunct for DFU unresponsive after 4 weeks of optimal care. The findings support AA as a targeted, second-line treatment rather than first line. Our iHRFS is currently running a larger trial to strengthen evidence on AA and healing outcomes[2].