A Feasibility and Safety Study of a Novel Human Decellularized Dermal Matrix Used in the Treatment of Chronic Diabetic Foot Ulcers

Paul Gratzer[1,2], Mark Glazebrook[2,3], Suzanne Lu[4], Anne-Marie McLaren[4]

[1]School of Biomedical Engineering, Dalhousie University, [2]Dept. of Surgery, Dalhousie University, [3]Dept. of Orthopaedics, QEII Health Sciences Centre, [4]Dept.of Surgery, St. Michael's Hospital

DALHOUSIE UNIVERSITY
FACULTY OF MEDICINE
FACULTY OF ENGINEERING
School of Biomedical Engineering

Introduction

- The number of diabetics is projected to reach 439 million by 2030 or approximately 10% of the world's adult population.[1]
- Up to 25% of diabetics are expected to have chronic foot ulcers, with 85% of these leading to lower extremity amputations.[1,2]
- This equates to a limb being amputated somewhere in the world every 20 seconds due to diabetes.[3,4]
- The most common treatment for chronic diabetic foot ulcers (DFU's) is weekly debridement.
- The success rate for complete wound closure with standard of care is variable and takes on average 8 - 9.5 weeks.[5,6]
- Advanced wound care products are available but they are costly, many require repeated applications, and they have low efficacy (see Figure 1).

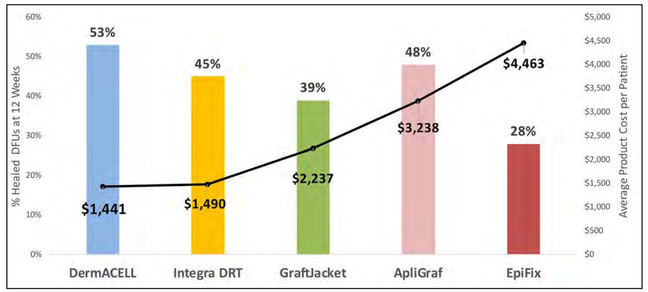


Figure 1. A comparison of recently published 12 week healing rates along with the average cost of product per patient foradvanced treatments. Expense per patient based on our cost to purchase. From Cazzell et al., Wound Repair Regen. 25(3):483-497 (2017)

Objectives

- In order to address the unmet need for a safe, consistent, and effective treatment for DFU's we have developed a sterile, highly-purified, decellularized regeneration scaffold derived from donated human skin.
- The purpose of this study was to conduct a clinical trail to perform a limited pilot study to determine the safety and effectiveness of our scaffold in the treatment of non-healing DFU's.

Methods

- 11 patients were treated with 8 located at St. Michael's Hospital in Toronto and 3 located at the QEII hospital in Halifax.
- Following standard of care procedures, each wound was debrided to provide a bleeding wound bed. A piece of decellularized human dermis was applied by sizing to approximately 2-3 mm past the margins of the ulcer with the dermal side in contact with the wound bed.
- Grafts were secured with staples for the first 6 patients, thereafter grafts were applied with only a bolstered dressing for the first week.
- A non-adherent dressing (e.g. Mepilex) was used to cover the graft, followed by dry gauze or retentive dressing.
- All patients received off-loading using a device appropriate to ulcer location.
- Follow-ups were at weeks 1,2,3,4,12, and 20 and the Leg Ulcer Management Tool (LUMT) was administered. Digital photography was utilized to capture the appearance and size of the ulcer at each visit.

Results

- Patients treated were predominantly male (10 male, 1 female), with a range of ages (32-77 years), and evenly split between Type I and Type II diabetics.
- Ulcer location, size, and time present before treatment covered a range of values as did co-morbidities and general health.

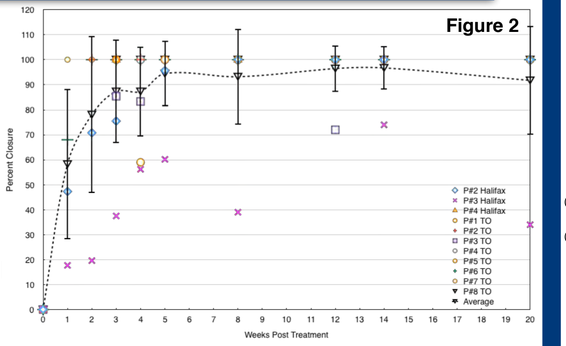
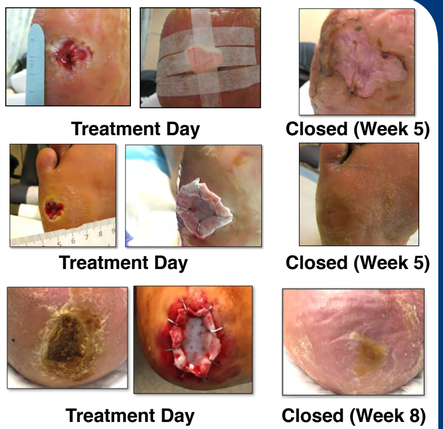


Figure 2

- Average wound size was 142 mm² (Range = 25-563 mm²). Ulcer presence prior to treatment averaged 16 weeks (range = 2 - 96 weeks)
- A total of 9 patients (82%) had achieved 100% closure between 2-8 weeks (Figure 2).
- Mean and median times to closure were 3.3 and 2.5 weeks, respectively and time to 50% closure was less than 1 week.
- One patient was non-compliant with offloading and was lost to follow-up, another completed 20 weeks without achieving 100% closure. This patient was the most severely ill of our subjects with many significant co-morbidities (coronary artery disease, myocardial infarction, moderate kidney disease, disc degeneration disease)



- All patients received only 1 application. No cases of infection or severe adverse reactions were reported. No cases of recurrence have been reported 1 year post treatment.

Conclusions

- Our decellularized scaffold has shown promising results in DFU healing occurring on average in 3.3 weeks with only one application.
- Although very encouraging, no statistically based conclusions can be drawn due to the small size of the study. Further studies are warranted.

Clinical Significance

- Our decellularized scaffold has promoted increased DFU healing.
- Clinicians noted advantages such as ease of use and one time application.

References

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Acknowledgements

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