

# Healing Hard to Heal Diabetic Foot Ulcers Using an Advanced Regenerative Matrix\*: A Large Multi-Site Case Series

Bishop, R.<sup>1</sup> Roche-Nagle, G.<sup>2</sup>, Saleh, A.<sup>3</sup>, Costa, I.G.<sup>4</sup>, Glazebrook, M.<sup>5</sup>, Langile, M.<sup>6</sup>, Labbie, M.<sup>7</sup>, De Jagger, L.<sup>8</sup>, Smith, C.<sup>8</sup>, Stoesz, S.<sup>9</sup>, Wolfli, J.<sup>10</sup> and Gratzner, P.F.<sup>11</sup>

1. Halton Healthcare Services, Oakville-Trafalgar Hospital, Oakville, ON. 2. Dept. of Vascular Surgery, Toronto General Hospital, Toronto, ON. 3. Division of Vascular Surgery, Humber River Hospital, Toronto, ON. 4. School of Nursing, Lakehead University, Thunder Bay, ON. 5. Dept. of Orthopaedic Surgery, QEII Hospital, Halifax, NS. 6. Ambulatory Care Centre, QEH, Charlottetown, PEI. 7. Ambulatory Wound & IV Clinic, West View Health Centre, Stony Plain, AB. 8. QEII Ambulatory Care Center, Grande Prairie, AB. 9. Red Deer Community Health, Red Deer, AB. 10. Dept. of Plastic Surgery, Grey Nuns Hospital, Edmonton, AB. 11. School of Biomedical Engineering, Dalhousie University, Halifax, NS

## Introduction

Current Standard of Care (SOC) for DFU's represents a growing cost to healthcare and produces sub-optimal clinical outcomes resulting in avoidable complications including amputation and significant quality of life implications for people with diabetes.

Here we present a large case series involving 80 hard to heal Diabetic Foot Ulcers (DFUs) in patients from clinics and hospitals located in Alberta, Ontario, Nova Scotia and PEI. All patients had received SOC with some also receiving adjuvant therapies (e.g. negative pressure, oxygen exposure) without successful healing. An alternative Advanced Regenerative Matrix\* was then utilized to treat these hard to heal DFUs and the results of this therapy are summarized here. This product is decellularized human skin that maintains the structural matrix through a unique cell extraction and non-gamma sterilization process.<sup>1</sup> This preserves the biochemistry of the skin's healing environment and provides a scaffold for tissue regeneration.

## Patient Data

Patients ranged in age from 32-95 years old, were predominantly male, either type I or type II diabetic, had a broad range of co-morbidities, with wounds present unhealed from 4 weeks to 3 years, and in various locations of the foot and/or leg.

| Patient Demographics    |                                            |
|-------------------------|--------------------------------------------|
| Age Range               | 32-95 years                                |
| Sex (M:F)               | 75:25                                      |
| Diabetes Type           | Type I & II                                |
| Wound Duration          | 4 weeks to 3 years                         |
| Wound Size (Max., Min.) | 20.7 cm <sup>2</sup> – 2.5 cm <sup>2</sup> |
| Wound Locations         |                                            |
| Top of Foot             | 5%                                         |
| Bottom of Foot          | 47%                                        |
| Side of Foot            | 24%                                        |
| Heel                    | 12%                                        |
| Toe                     | 8%                                         |
| Shin                    | 4%                                         |

## Actions Taken

A total of 80 patients were treated between Feb. 2021 and Nov. 2024. The size of DFUs treated ranged from 2.5 cm<sup>2</sup> to 20.7 cm<sup>2</sup>. All patients met the criteria for treatment that included Wagner Grade 1 or 2 wound, adequate blood flow demonstrated by bleeding at wound site during debridement and a willingness to be involved in self-care.

All patients underwent a similar general application procedure for the Advanced Regenerative Matrix\* (Fig. 1) that included conservative sharp debridement, placing of the matrix onto the wound, covering the matrix with a non-adherent moisture controlling dressing, and appropriate offloading when necessary. In general, dressings were replaced and healing progress monitored weekly.

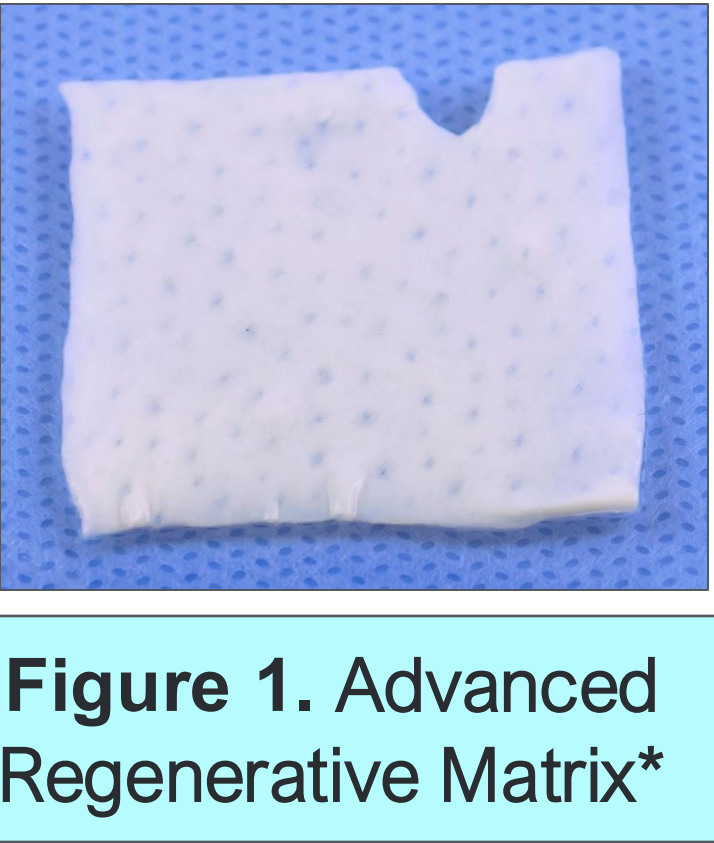
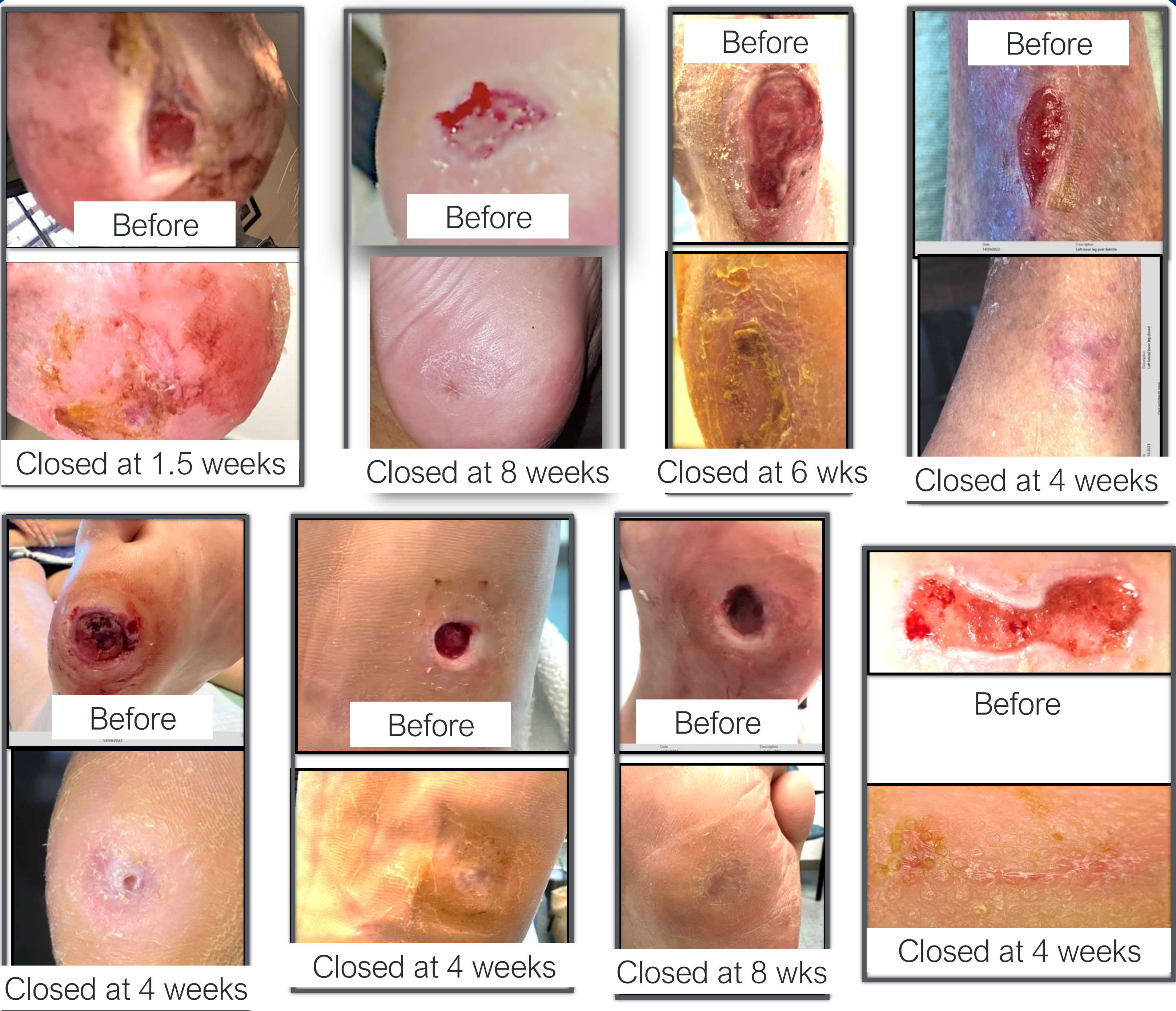


Figure 1. Advanced Regenerative Matrix\*

## Results

Patients did not have any complications during treatment. An 85% success rate for healing the treated DFUs was obtained with healing occurring between 2 to 10 weeks and with a median time of 4 weeks. In almost all cases, only 1 application of the Advanced Regenerative Matrix\* was required. Causes of failures were mainly attributed to failure to offload and maceration of the matrix due to excessive moisture in the wound site.

### Open Wounds Before and Then Closed After Treatment



## Implications for Practice

The new Advanced Regenerative Matrix\* provided the needed environment and stimulation for cells to mount effective healing of hard to heal DFUs. This approach provides one-and-done application aimed at improving healing outcomes, improving the patient and clinician experience and lowering health care costs.

## References

(1) Costa, I.G. et al. A Feasibility and Safety Study of a Novel Human Decellularized Dermal Matrix to Accelerate Healing of Neuropathic Diabetic Foot Ulcers in People With Type 1 and Type 2 Diabetes Can J Diabetes (2022) 46: 671-677. DOI: 10.1016/j.jcjd.2022.03.010

## Acknowledgements

\* DermGEN™ for the study was supplied by RegenMed under license from DeCell Technologies Inc.