# Novel Wound Matrix Shows Significant Percent Area Reduction at 4 and 12 Weeks over Standard of Care in Clinical Study of Diabetic Foot Ulcers

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#### Introduction

Diabetic foot ulcers (DFUs) are a common type of chronic wound among patients with diabetes and are associated with an increased risk of amputation.^1,2 A novel combination therapy developed to manage chronic wounds comprises a wound therapy formulation (OCM), a wound preparation formulation, and a skin protectant formulation. One goal of this study is to demonstrate that the combination therapy with offloading moves chronic DFUs from a stalled state to a healing state in a 4-week period (NCT05417425).

## Objective

To evaluate the impact on wound chronicity from combination therapy with offloading after 4 and 12 weeks of treatment

## Endpoints

- Change in PAR at 4 weeks
- Incidence in healing after 4 weeks
- Incidence in healing by 12 weeks

## Methods

Adult (≥21-year-old) patients with Type 1 or 2 diabetes and a DFU (Wagner grade 1 or 2) of at least 1-month duration at date of signed consent were eligible for participation. During the 4-week treatment phase, patients' DFUs were managed with combination therapy and off-loading. At the end of the treatment visits, patients whose DFUs had not healed had the option of continuing therapy for up to 8 more weeks. Endpoints included 4- and 12-week change in percent area reduction (PAR). Patients with DFUs managed at the same site with standard treatment and offloading only (n=6) served as historical controls.

#### Results

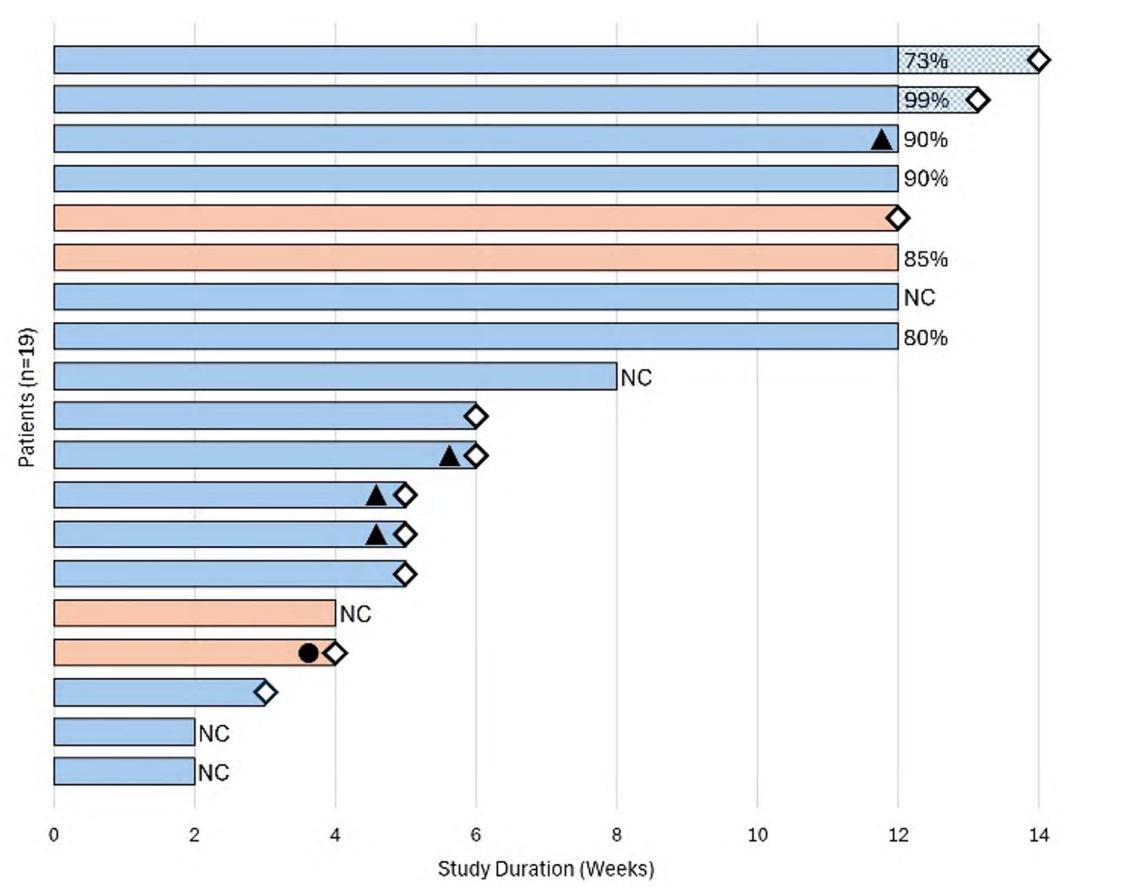
WOUND MATRIX	Patient Ages (Yrs)	Ulcer Age (Wks)	Ulcer Size(cm2)	TV5 Ulcer Size	TV12 Ulcer Size
RANGE	44 - 85	4 - 72	0.37- 25.0	1.0 -10.1	0-2.59
MEDIAN	60	36	1.7	0.63	0
AVERAGE	59.75	32.5	5.05	1.43	0.38

Table 1. Patients and ulcers treated with the wound matrix Ages listed of patients and ulcers and ulcer responses.

CONTROL GROUP	Ulcer Age (wks)	Ulcer Size(cm2)	TV5 Ulcer Size	TV12 Ulcer Size
RANGE	2 - 30	1.32-11.25	0.12-27.14	0-16.77
MEDIAN	12	3.74	1.7	2.61
AVERAGE	n/a	4.54	7.26	4.53

Table 2. Ulcers treated with standard treatment only

At final analysis (N=19), median age was 60 years (range, 44-85), and median wound duration was 36 weeks (range, 4-72). Five patients included in the analysis did not complete the study (4 patients were terminated/withdrawn by the investigator, and 1 patient died from comorbidities before end of study). Median wound size was 1.4cm2 (range, 0.37-25.0) at treatment visit (TV) 1 and 0.68cm2 (range, 0-10.06) at TV5. Average 4-week PAR was 62%, with 3 patients experiencing 100% closure. At TV12, median wound size was 0.0cm2 (range, 0-2.59), and average PAR was 93%, with 5 additional patients experiencing 100% closure. Average 4- and 12-week PARs with SOC alone were 42% and 45%, respectively.



◆100 PAR ● African American Patient ▲ Hispanic/Latino Patient ■ Male ■ Female NC Non-Compliant

Figure 1. Plot with ulcer outcomes and treatment duration Start time denotes treatment visit 1. Length of bars show duration of treatment. Colors of bars show gender of patients. Diamonds mark 100% closure. Circle mark African American. Triangle mark Hispanic/Latino. NC – non-compliant. Hashed bars show the time after 12 weeks for ulcer to reach 100% closure.

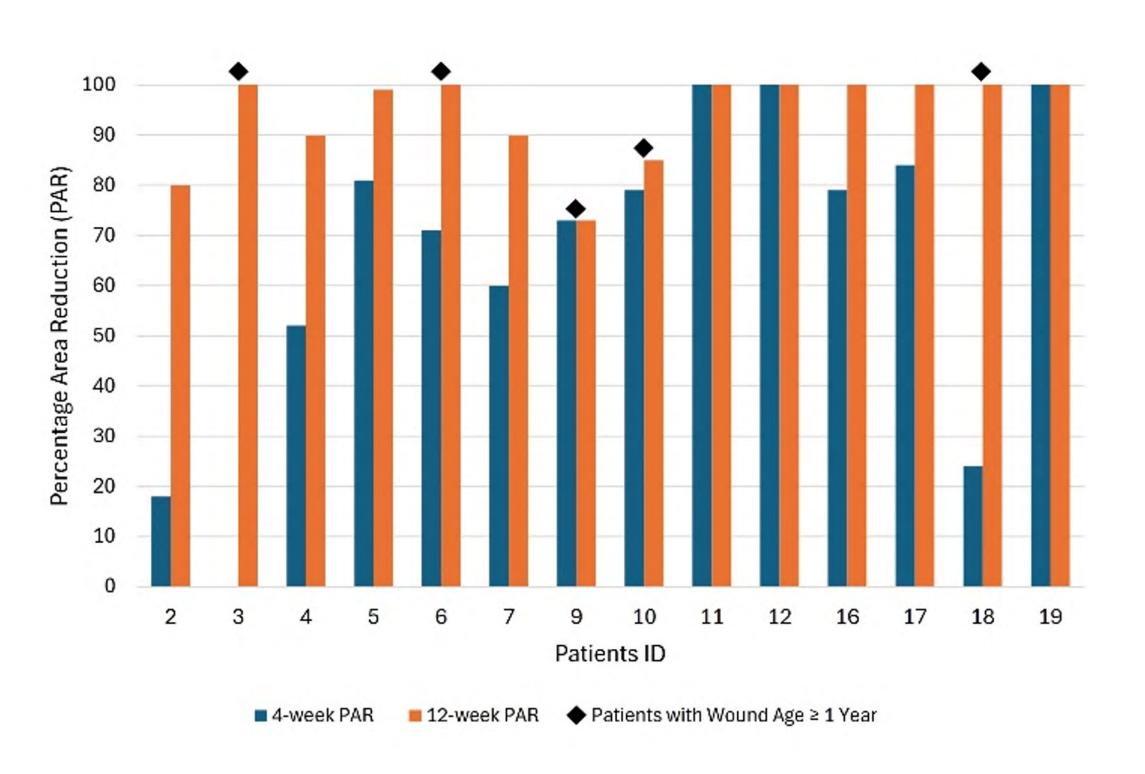


Figure 2. Plot showing PAR of Ulcers at 4 weeks and at 12 weeks PAR: Percent Area Reduction



Figure 3. Examples of patient results

1(a) TV1. 76 yr. old patient presented with 6-week-old ulcer. 1(b) TV4. DFU closed after 3 treatments. 2(a) TV1. Ulcer post-debridement of 65 yr.-old patient with a 9-week-old ulcer. Ray amputation of right foot, 2nd metatarsal. 2(b) TV6. DFU closed after 5 treatments. 3(a). TV1. Ulcer that had been open and treated with no results for more than 52 weeks. 3(b) TV12. 4(a) TV1. 3-month-old ulcer measuring 11.55cm2 post-debridement. 4(b) TV12. PAR of ulcer is 99%. 5(a) TV1. 36-week-old ulcer measuring 25cm2. 5(b) PAR of 90% at TV12.

### Conclusion

These results show encouraging healing rates (60% 4-week PAR and 93% 12-week PAR) of DFUs managed with the combination therapy and Off-loading. Clinical trials evaluating the combination therapy in VLUs (NCT05291169) and multiple wound types (NCT05921292) are underway.

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