

Multicenter, Randomized Controlled Clinical Investigation Evaluating a Unique Micro Water Jet Technology Device Versus Standard Debridement in the Treatment of Diabetic Foot

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Introduction: The financial cost and prevalence of diabetes and neuropathic foot ulcers continues to increase dramatically in the world, and wounds that do not heal are at higher risk for infection, osteomyelitis and amputation.¹ As part of a treatment regimen for managing diabetic foot ulcers, debridement is critical. A unique Micro Water Jet device has been developed that precisely cleans acute and chronic wounds (including burns, chronic defects, and acute trauma) in a tissue-preserving manner by removing the unhealthy tissue such as fibrin, necrosis, and biofilm as well as foreign bodies efficiently while performing a precise mechanical debridement and stimulation of the wound base to enhance granulation and healing. In this trial the device was used to treat non healing diabetic foot wounds which carry the highest risk of complication. Proper debridement of the wound base is critical to facilitate wound granulation and closure in non healing DFU's.

Objectives:. The goal of this study was to compare healing rates and wound area reduction in wounds debrided weekly with the Micro Water Jet technology and standard of care (SOC) wound dressing versus those debrided with standard sharp debridement and SOC alone.

Methods: 85 patients were screened, and 50 patients were enrolled for the preliminary analysis, in a two arm IRB approved randomized controlled trial; registration number NCT04564443. Diabetic foot wounds that were non-healing for at least 4 weeks, with adequate blood flow and were void of clinical infection or osteomyelitis were entered into 2 weeks of screening. Those that met all the qualifications were randomized to receive either weekly Micro Water Jet wound debridement or standard sharp debridement along with SOC wound dressing and offloading. Both groups were followed for 16 weeks with those patients healing undergoing a two week durable wound healing follow up with blinded plastic surgeon review to confirm healing confirmation

Primary endpoint: Complete wound closure at 16 weeks

Secondary endpoints:

- Percent area reduction
- Proportion of wounds with at least one infection

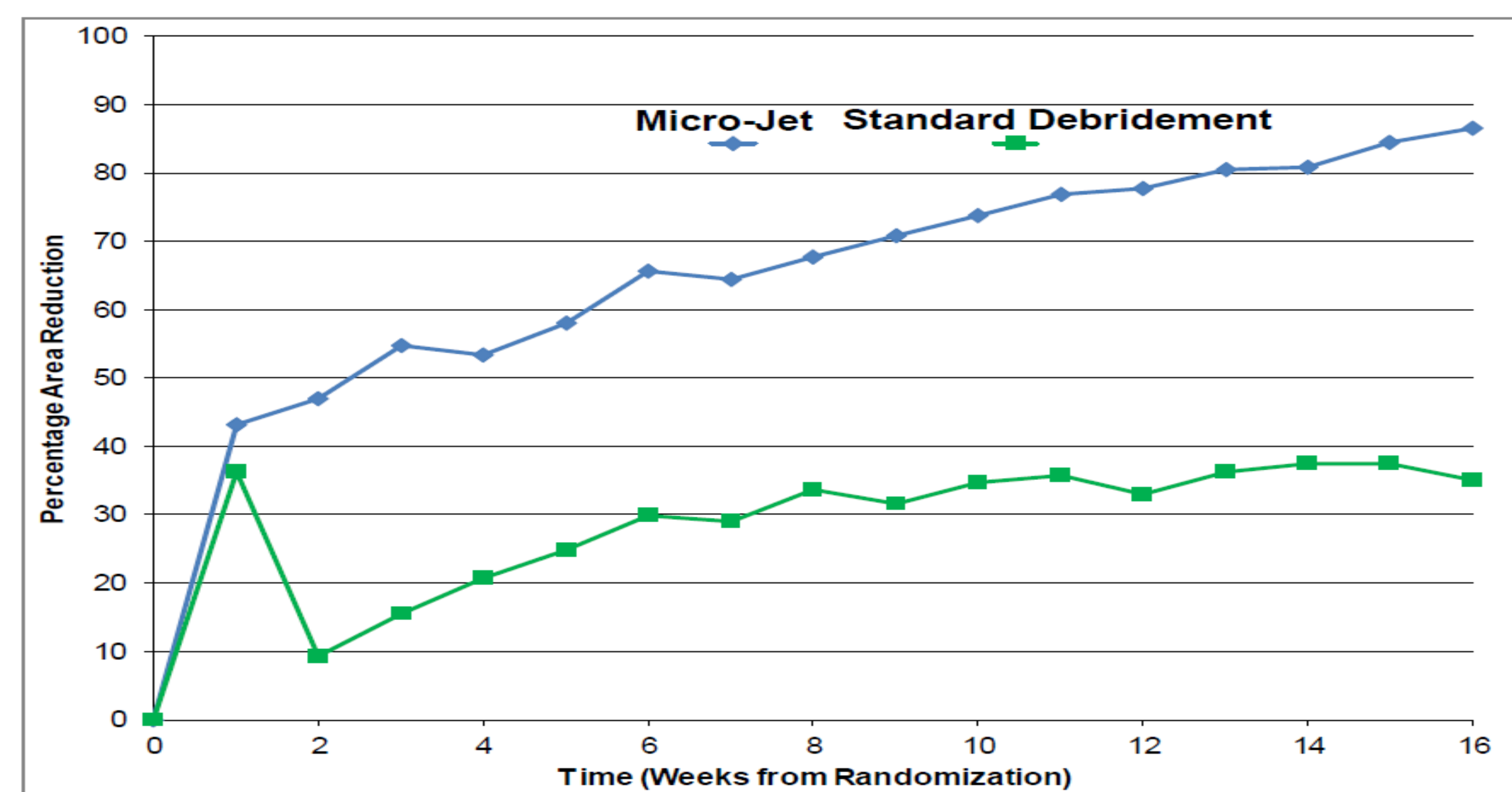


Provides precision
in debridement

Removes
devitalized tissue
while leaving
healthy tissue intact

Statistics

Percent wound area reduction



Results

- 72% (18/25) of the Micro Water Jet treated DFUs healed compared with 40% (10/25) treated with standard sharp debridement (p=0.023)
- Percent area reduction (PAR) was 86.5% (SD: 25.60) for the wounds treated with the Micro Water Jet versus 35.1% (SD: 164.47) with standard of care, sharp wound debridement (p=0.021)
- The safety analysis with regard to wound related adverse events (AE) and serious adverse events (SAE) showed; 1 AE and 1 SAE occurring in the Micro Water Jet group versus 9 AEs and 4 SAEs in the standard of care, sharp debridement group
- Proportion of wounds having at least one infection or cellulitis episode by 16 weeks 1/25 (4%) in the Micro Water Jet cohort versus 6/25 (24%) in the standard of care, wound debridement group.

Case examples - Clinical trial patients treated with Micro-jet Technology

Patient 1



Baseline wound



Treatment visit 3 wound size
60% improved



Wound closure at Treatment visit 5

Patient 2



Baseline wound



Treatment visit 4
50% improved



Wound closure at Treatment visit 9

Conclusions: The Micro Water Jet device was able to close statistically significantly more refractory DFUs over 16 weeks, with a significant difference in wound area reduction that should also be noted. This early data shows great promise that better debridement tools can improve wound closure and decrease diabetic foot related complications and infections. Further evaluation with larger randomized controlled trials are warranted to validate these findings.

Key Message: This study supports that **improved micro debridement methods** combined with standard of care dressings and offloading is likely **beneficial and even synergistic to achieve wound healing in non-healing DFU's.**

References

1. Armstrong DG, Boulton AJM, Bus SA. Diabetic Foot Ulcers and Their Recurrence. N Engl J Med. 2017 Jun 15;376(24):2367-2375.