

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 cleaning 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 treated weekly with the Micro Water Jet technology and standard of care (SOC) wound dressing versus those treated with standard sharp debridement and SOC alone.

Methods: 170 patients were screened, and 96 patients were enrolled for this interim 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 jet therapy 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:

Incidence of Adverse and Serious Adverse Events

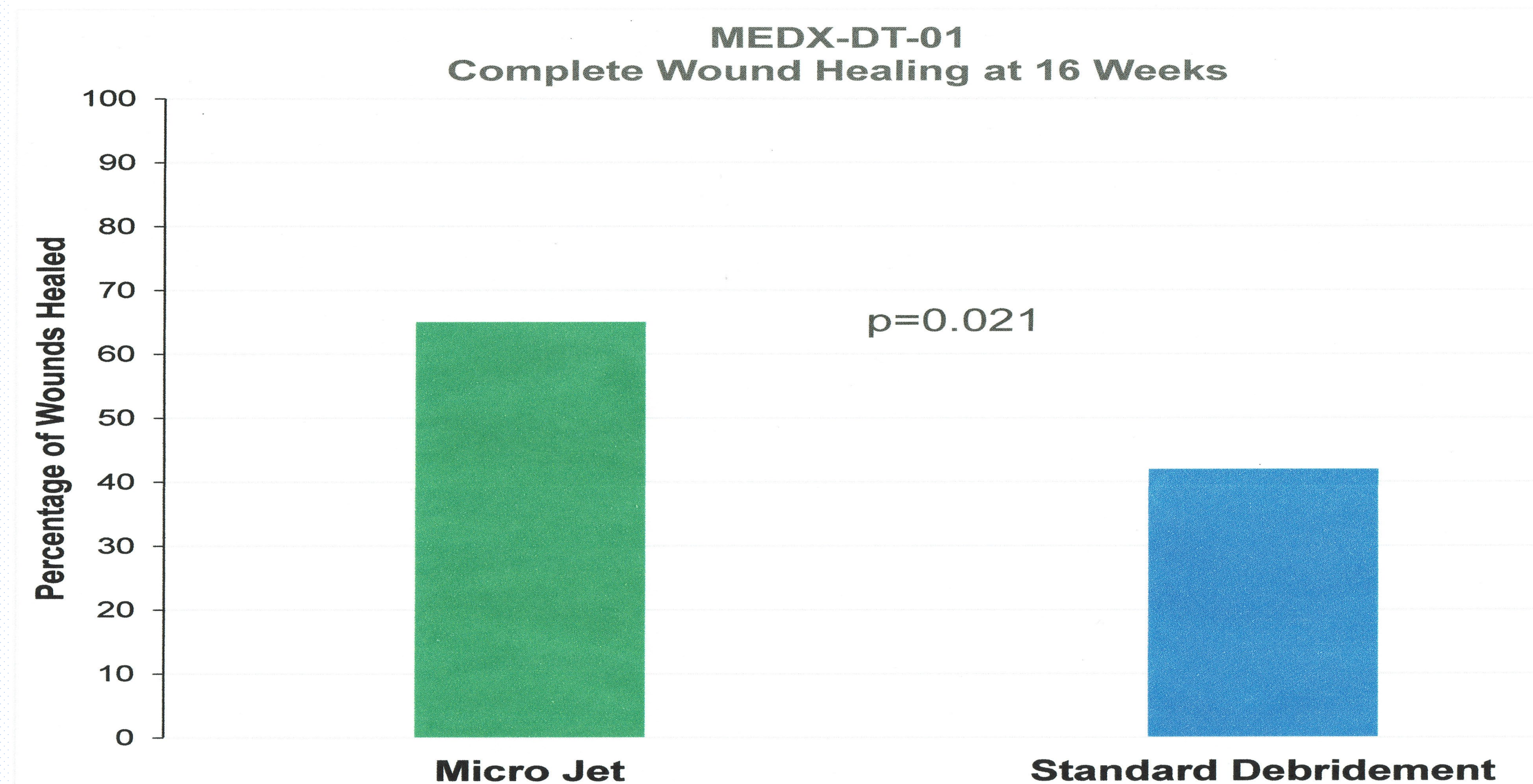
Proportion of Wounds with One Infection



Micro Jet Water Therapy provides precision in debridement

Removes devitalized tissue while leaving healthy tissue intact

Percent of Patients With Complete Healing by Intervention



Results

- At 16 weeks 65%(28/43) of the Micro Water jet treated DFUs healed compared with 42%(22/53) treated with standard sharp debridement p=0.021 (unadjusted).
- The safety analysis with regard to wound related adverse events (AE) and serious adverse events (SAE) showed; 4 AEs and 1 SAE occurring in the Micro Water Jet Therapy group versus 12 AEs and 4 SAEs in the standard of care, sharp debridement group
- Proportion of wound related infections and hospitalizations were 75% less in those patients treated in the Micro Water jet 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

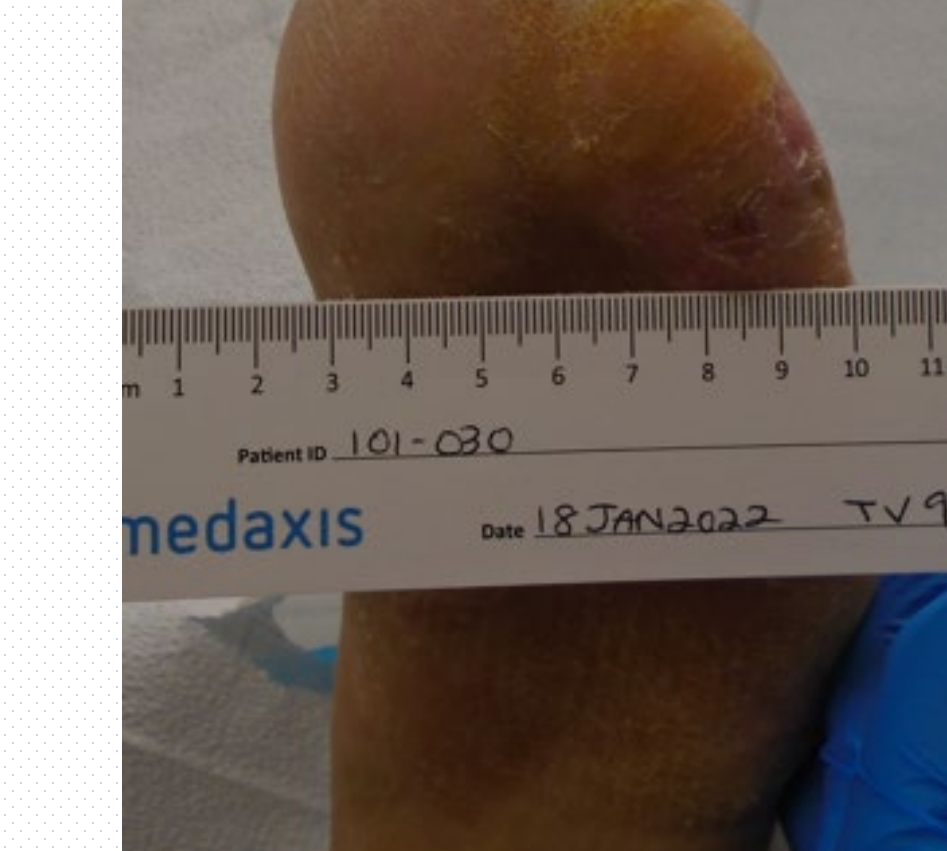
Patient 2



Baseline wound



Treatment visit 4
50% improved



Wound closure at Treatment visit 9

Conclusions: The micro water jet device was able to statistically significantly close more refractory DFUs over 16 weeks, with substantially less adverse and serious adverse events and infections noted in microjet water cohort. Therefore, interim 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 water jet therapy 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.