A Pilot Model of A New Paradigm of Combination Treatment of Wound Bed Preparation with Negative Pressure for Chronic Lower Extremity Wounds

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Prospective, Open-Label, Single-Arm Pilot Clinical Trial | SAWC Spring 2026

BACKGROUND & RATIONALE

Chronic lower extremity wounds affect approximately **2.5% of the U.S. population** — prevalence among Medicare beneficiaries rose from **8.2M (2014) to 10.5M (2019)**. Annual management costs range from $22.5B to over **$96.8B**, driven by prolonged treatment, hospitalizations, and complex comorbidities.

Hydroprep Wound Therapy (Medaxis) uses a high-energy fluid jet to remove non-viable tissue and biofilm. **Motion® NPWT** then promotes granulation, reduces edema, and removes exudate. This sequential dual-modality paradigm may offer a cost-effective path to healing.

STUDY OBJECTIVES

Primary Endpoints

- **Percent Area Reduction (PAR)** — wound area reduction, baseline to Week 4
- **Weeks to Cessation of NPWT** — median time to closure sufficient to cease NPWT
- **Graft-Ready Determination** — time to investigator decision for closure/graft/CAMP

Secondary Endpoints

Wound infection incidence · VAS pain · Time to complete closure · Quality of life · # Hydroprep treatments · Adverse events · Cosmetic outcome at 3 months

STUDY DESIGN

Design: Prospective, open-label, single-arm pilot trial
Sample Size: N = 20 (min) to 50 (max) patients
Duration: 4 weeks active treatment + follow-up to closure or 12 weeks
Control: Each patient serves as their own control

Eligible Wounds: Venous leg ulcers, arterial ulcers, diabetic foot ulcers, pressure injuries, and traumatic wounds present ≥ 4 weeks with size ≤ 36 cm²

STUDY POPULATION & ELIGIBILITY

INCLUSION CRITERIA

- All ages (minors with parental consent & assent)
- Chronic lower extremity wound ≥ 4 weeks
- Wound size ≤ 36 cm²
- Non-progressive: <20% area reduction despite SOC
- ABI 0.7–1.3, TBI >0.6, TCOM ≥30 mmHg, or StO_2 >60%
- Willing and able to comply with study procedures

KEY EXCLUSION CRITERIA

- Active wound infection requiring systemic antibiotics
- Untreated osteomyelitis
- Malignancy in or near the wound bed
- Exposed vasculature, nerves, or organs
- Systemic immunosuppression or cytotoxic chemo
- Pregnancy, breastfeeding, or life expectancy < 1 yr

TREATMENT PROTOCOL

Screening	Hydroprep	Motion® NPWT	Wound Depth	Closure Phase	Follow-up
Wk −1/Day 0	2×/wk × 4 wks	Continuous	≤0.1 cm?	STSG/CAMP	Wk 12/closure

Screening	Medical history, physical exam, digital photography, wound tracing & depth, ABI/TBI/TCOM, HbA1c, CBC/CMP as clinically indicated
Hydroprep Rx	Debridement of non-viable tissue & biofilm with normal saline via high-energy fluid jet; applied twice weekly for 4 weeks per manufacturer guidelines
NPWT Settings	Pressure −80 to −125 mmHg; dressing changes every 48–72 hrs or more frequently if clinically indicated
Sub-Protocol	When wound depth ≤0.1 cm and bed granulated & infection-free: transition to STSG or CAMP/CTP at investigator discretion
Assessments	Weekly: digital photography, wound tracing (cm²), depth, exudate & periwound assessment, VAS pain, NPWT compliance, adverse events

WOUND ASSESSMENT SCHEDULE

Timepoint	Key Assessments
Screening (Day 0)	Exam, photography, wound tracing, ABI/TBI/TCOM, HbA1c
Weeks 1–4 (Weekly)	Photography, tracing, depth, VAS pain, NPWT compliance
Week 4	Final Hydroprep; comprehensive wound assessment
Wks 5–12 (Biweekly)	Photography, tracing, depth, VAS, adverse events
Post-Closure (3 mo)	Cosmetic outcome — investigator + patient assessment

U.S. CHRONIC WOUND BURDEN

2.5%
U.S. population affected annually

10.5M
Medicare recipients with chronic wounds

$96.8B
Annual estimated management cost

CONCLUSIONS & SIGNIFICANCE

This prospective pilot study presents a new paradigm in the sequential management of chronic lower extremity wounds — combining active wound bed preparation via Hydroprep Wound Therapy with the sustained healing environment of Motion® NPWT.

By systematically removing non-viable tissue and biofilm, then immediately applying continuous negative pressure, this protocol addresses the two most critical barriers to wound healing: inadequate debridement and insufficient granulation tissue formation.

Results from this pilot will generate rigorous preliminary efficacy and safety data to support a larger, definitive clinical trial. Findings may help establish a more cost-effective, evidence-based treatment algorithm that reduces hospitalizations, decreases time to wound closure, and meaningfully improves patient quality of life.