

EFFECTIVE TREATMENT FOR INFECTED WOUNDS:

HEMASTYL R® TRI-NANOTECH GEL WOUND DRESSING TREATMENT RESULTS OF MULTI-YEAR OLD NON-HEALING INFECTED CHRONIC WOUNDS.



Introduction

Despite decades of advancement in wound healing management, chronic wounds are still a major health issue often requiring surgical management including amputations. Prevalence of chronic wounds are estimated to be 2.21 per 1000 population. In Figures 1 and 2 we document healing of five representative infected chronic vascular and diabetic wounds treated with the Hemastyl R® gel wound dressing (Rapid Nexus Inc, Irvine, CA)

Clinical Study with Hemastyl-R (n=17)

Methods: 17 patients exhibiting co-morbidities with 1 to 40 years old large chronic leg wounds including 11 infected and suggested for amputation, were treated with the Hemastyl R® anti-infective tri-nanotechnology wound healing dressing twice daily without debridement in the patients' own home. Wound areas were measured from wound photographs using NIH ImageJ software. Wound closure rate per week was calculated from wound area measurements.

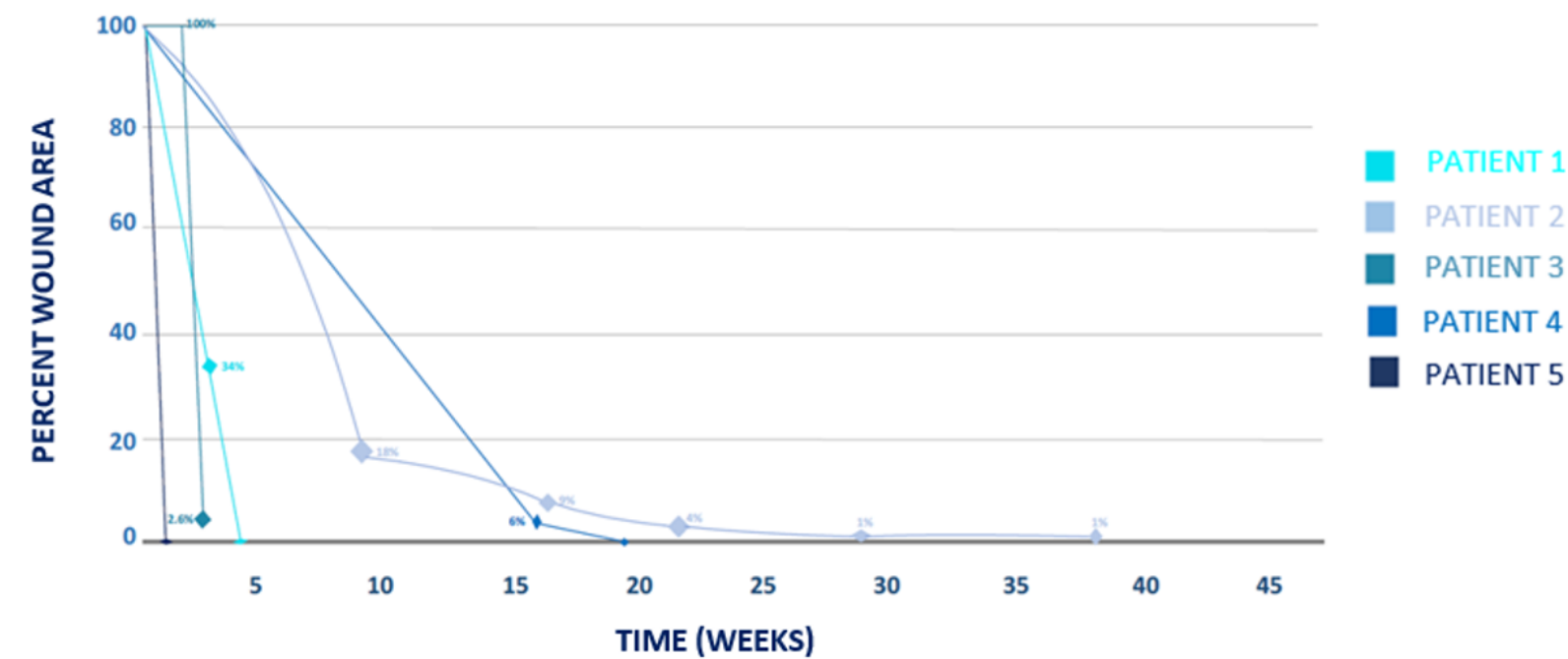


Figure 1: Percent Wound Area over Time (weeks) of 5 Representative Infected Wounds (from a study of 17 High-risk Patients, 9 with diabetes) Treated with Hemastyl-R Twice Daily

Results: 17 wounds of high risk wound patients (11 infected and suggested for amputation prior to study enrollment) were closed on average 94% in 1 to 38 weeks. Wound closure rate ranged from 2.5% to 11.6% per week. Necrosis in and around wounds and severe cyanosis surrounding wounds were cleared in early weeks of the wound management. All 11 amputations were avoided using Hemastyl Rx.

Conclusion: Rapid Nexus Hemastyl R® treatment repaired years old non-healing wounds, eliminating infection on day 1 of treatment. The Rapid Nexus Hemastyl R® is a promising technology to provide an effective wound healing solution for non-healing chronic wounds in patients with co-morbidities. Furthermore, there were no device related adverse events reported throughout the study duration, demonstrating that the benefits afforded by treatment with Hemastyl-R were achieved while presenting few risks to the patient.

Clinical Study with Hemastyl-R + LED (n=22)

Methods: 22 patients exhibiting co-morbidities with 2 to 8 years old large chronic leg wounds including 20 infected and suggested for amputation (6 with pus exudate), were treated with the Hemastyl R® anti-infective tri-nanotechnology wound healing dressing twice daily without debridement in the patients' own home. Patients underwent clinician exams 3 times per week, and the wounds were subject to 15 minutes of LED light treatment every other week to modulate pain. Wound areas were measured from wound photographs using NIH ImageJ software. Wound closure rate per week was calculated from wound area measurements.

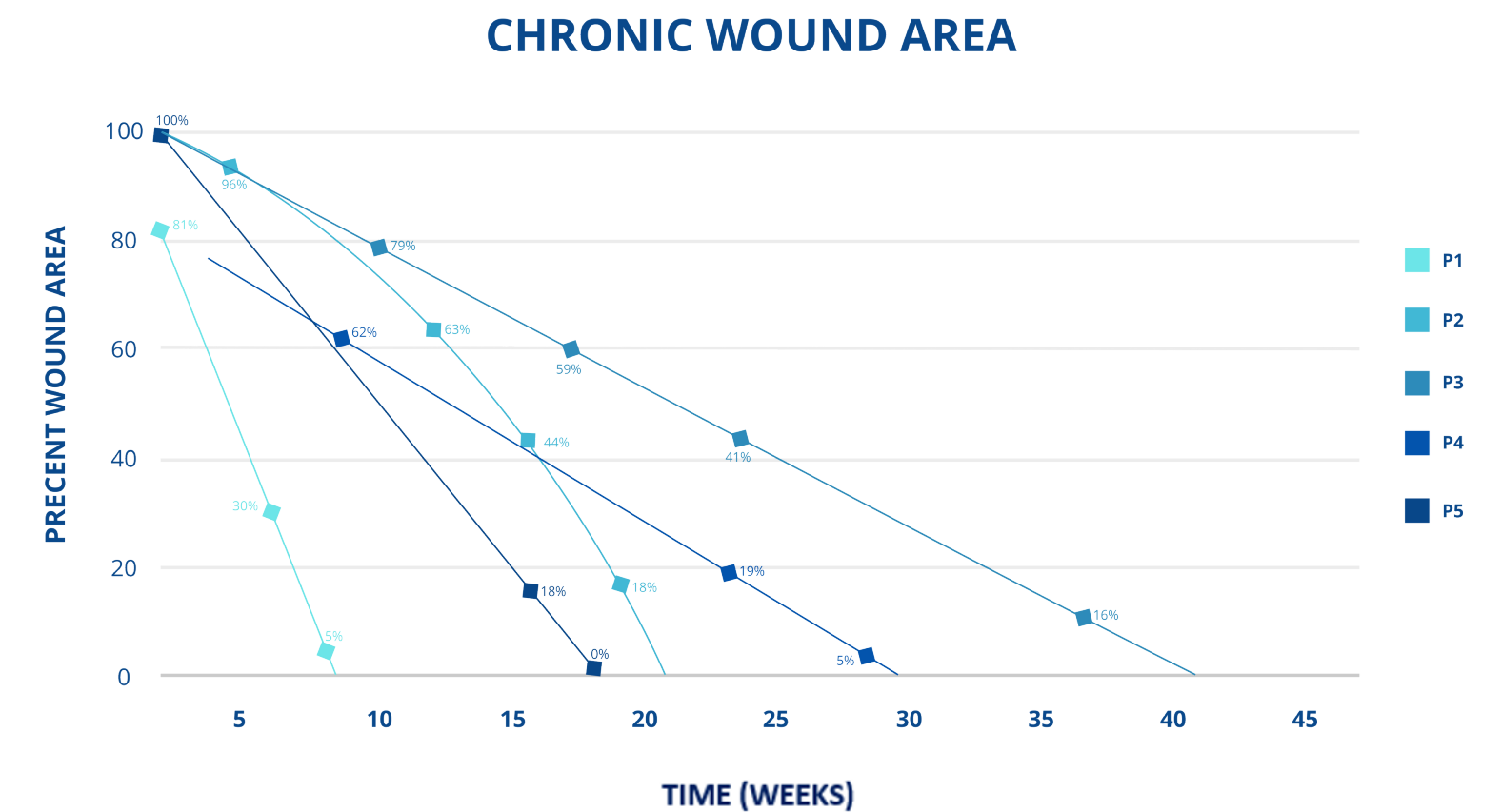


Figure 2: Percent Wound Area over Time (weeks) of 5 Representative Infected Wounds (from a study of 22 High-risk Wound Patients, 8 with diabetes) Treated with Hemastyl-R Twice Daily and treated with Gen-Ray LED every other week

Results: 22 wounds of high risk patients (20 infected and suggested for amputation prior to study enrollment, 6 of those with pus exudate) were closed on average 95.5% in 7 to 40 weeks. Necrosis in and around wounds and severe cyanosis surrounding wounds were cleared in early weeks of the wound management. All 20 amputations were avoided using Hemastyl Rx.

Conclusion: Rapid Nexus Hemastyl R® treatment repaired years old non-healing wounds, eliminating infection on day 1 and day 2 of treatment. The Rapid Nexus Hemastyl R® is a promising technology to provide an effective wound healing solution for non-healing chronic wounds in patients with co-morbidities. Furthermore, there were no device related adverse events reported throughout the study duration, demonstrating that the benefits afforded by treatment with Hemastyl-R were achieved while presenting few risks to the patient.