



PREVENTING AMPUTATION: SUCCESSFUL MANAGEMENT AND EXPEDITED HEALING OF DIABETIC WOUNDS WITH NOVEL BOTANICAL SUPERCHARGED WOUND HYDROGEL

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INTRODUCTION

METHODOLOGY

RESULTS

It is estimated that over 1 billion people worldwide have diabetes or prediabetes. Diabetic foot disease is a chronic complication of diabetes mellitus (DM)[1,2]. Diabetic Foot complications are associated with high mortality, infection, reduction in quality of life, increased hospitalization and, if not properly addressed, could lead to amputation and death [3,4]. The risk of ulceration and amputation among diabetic patients increases by up to four-fold with progression of age and duration of diabetes [5]. Foot ulceration is a preventable and treatable condition where proper interventions can reduce amputation by up to 70% [6]. Gangrene is associated with a high incidence of amputation and mortality and early management is essential for preventing wound progression. Current treatments have shown to be moderately effective, leading to the need to identify alternative, minimally invasive treatments.

Here we report on 2 patients:

1. A 46-year-old Haitian-American male with a history of AIDS, sickle cell anemia, blood glucose abnormalities, chronic pain syndrome, deep vein thrombosis (DVT), and deficiency of nutrients who presented with a 4 cm x 3 cm chronic medial malleolus ulcer (venous ulcer) with 100% fibrotic tissue and severe pain (**PHOTO 2**)
2. A 46-year-old Haitian-American female with a history of diabetes and obesity who presented with a dry distal gangrenous 4th digit with necrotic changes, local edema, and erythema (**PHOTO 3**).

After application of a botanical species extract (*Inula Viscosa*- AGS RIED) plant-based supercharged wound hydrogel was initiated, successful closure of the wound was attained in Patient 1 (**PHOTO 4**) and in Patient 2, the gangrenous digit was healed (**PHOTO 5**).

Inula

Inula Viscosa (**PHOTO 1**) is one of 90 species of *Inula*, a large genus of flowering plants native to Europe, Asia, and Africa.



(PHOTO 1) *Inula Viscosa*

- *Inula viscosa* (compositae) is known in traditional medicine for a large range of biological activities including antipyretic, anti-bacterial and antifungal activity.
- A new species of *Inula Viscosa*, AGS-RIED, has been incorporated into an OTC supercharged wound hydrogel (LAVIOR Diabetic Wound Gel®, Lavior Pharma, Miami, FL) yielding a wide array of sesquiterpenoids, especially sesquiterpene lactones (SLs) [7]. SLs and have been shown to exhibit antimicrobial [8], antitumor, anti-inflammatory [9], antifungal [10], and antimalarial activity [11,12].
- After formulation of the *Inula viscosa* (AGS RIED) extract, it has been incorporated into an OTC supercharged wound hydrogel (LAVIOR Wound Care Gel®) and has shown promise in exhibiting anti-inflammatory, antifungal, antibacterial properties, as well as being nontoxic. The wound gel serves as an effective anti-inflammatory treatment by targeting the overstimulation of cytokine secretion.

Patient 1 History and Presentation:

A 46-year-old Haitian-American male with a history of AIDS, sickle cell anemia, blood glucose abnormalities, chronic pain syndrome, deep vein thrombosis (DVT), and deficiency of nutrients. Patient presented with a 4 cm x 3 cm chronic medial malleolus ulcer (venous ulcer) with 100% fibrotic tissue and severe pain.

Prior Treatments: The patient did not receive any prior treatments before seeing the clinician.



PHOTO 2- Initial presentation: Medial Malleolus Ulcer with 100% fibrotic tissue and severe pain on palpation. **Wound size:** 4 cm x 3 cm
After 7 days of Treatment: 100% granulation, no pain on palpation, no drainage and no sign of local infection. **Wound size:** 3 cm x 3 cm
PHOTO 4- Appearance after 51 days of treatment: Wound healed. **Wound size:** 98% closure
PHOTO 5- After 70 days of treatment: The distal eschar detached, and a healed digit was noted. **Appearance - Day 100** Completely healed. Note the nail has grown back.

Patient 2 History and Presentation:

History: A 46-year-old Haitian-American female with a history of diabetes and obesity who presented with a dry distal gangrenous 4th digit with necrotic changes, local edema, and erythema.

Prior Treatments: Previous treatment included Augmentin 500mg p.o Q12h (oral every 12h) x 10 days and Bactroban dressing on daily basis with no improvement.



PHOTO 3- Initial presentation: Distal fourth digit gangrenous necrotic changes, with local edema and erythema.
After 40 days of Treatment: Medial digital maceration, stopped the hydrogel for 1 week. Then applied Betadine. Then returned to Lavior.
PHOTO 5- After 70 days of treatment: The distal eschar detached, and a healed digit was noted.
Appearance - Day 100 Completely healed. Note the nail has grown back.

Methods Used:

For both patients, the wound bed was rinsed with normal saline and the supercharged wound gel* was applied to entire wound surface and covered with a nonadherent dressing, 4x4 gauze and wrapped with Kling. Patients were instructed to apply the wound gel 2x/week with nonadherent dressing as daily changes causes maceration.

Patient 1: After 7 days of treatment, the wound size reduced to 3 cm x 3 cm and there was 100% granulation, no pain on palpation, no drainage, and no sign of local infection. After 51 days of treatment with the hydrogel, the wound was considered healed with 98% closure.
Patient 2: After 70 days of treatment, the distal eschar detached, and a healed digit was noted.

CONCLUSION

Successful wound healing was achieved in patients with significant co-morbidities after use of a novel, OTC, botanical-based, nontoxic, wound care supercharged hydrogel. With its anti-inflammatory, antifungal, and antibacterial properties, and by targeting the overstimulation of cytokine secretion, this hydrogel shows promise in addressing the underlying causes while promoting healing of chronic wounds.

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DISCLOSURES

Oscar Barreto- DPM, AGNP is a practicing wound care clinician. Peter Hurwitz is President of Clarity Science LLC and a scientific consultant and medical writer. There was no funding of this case report. The wound care hydrogel used in this case report was Lavior Diabetic Wound Gel (Lavior Pharma Inc., Miami, FL). No compensation was provided to the clinician. Compensation was provided to Clarity Science LLC, a Clinical Research Organization (CRO), for their assistance in compiling and preparing information for abstract submission.