A New Approach To Diabetic Foot Ulcers Using Keratin Gel Technology

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Introduction

- In the U.S., 18 million people are diagnosed with diabetes and 7.9 million are diagnosed with pre-diabetes (1).

- Foot ulcers occur in approximately 15% of patients with diabetes mellitus in their lifetime. These ulcers are recalcitrant to healing and place a major impact on patients’ quality of life (2).

- Keratin protein is a novel material with potential as a new treatment approach for a wide range of chronic and acute wounds, including diabetic foot ulcers.

- Previous studies have demonstrated the ability of keratin technology to activate keratinocytes, increase epithelialization of wounds and speed healing in recalcitrant ulcers (3-5).

- A short case series was undertaken to examine the performance of keratin gel in recalcitrant diabetic foot ulcers. The extent of surgical debridement needed to promote healing.
Methods

• Three patients with type 2 diabetes and chronic diabetic foot ulcers who presented for care at the Scholl Foot and Ankle Clinic were recruited for this case series.

• Patients with active infection or osteomyelitis were excluded.

• Wound duration ranged from 6 weeks to 4 months. Wound were treated weekly with Keratin gel technology (Figure 1) and sterile dressings. Treatment continued for up to 10 weeks. Instant Total Contact Cast Used as offloading modality for all patients.
Figure 1. Application of Keratin gel technology.
Case 1

• 42 year old male with type 2 diabetes non healing incision of 3 months duration following exostectomy and bursa excision plantar left foot (Fig. 2a).

• PMH: Type 2 DM with peripheral neuropathy, HTN, hypercholesterolemia, Charcot neuroarthropathy

• Previous therapies: collagen, calcium alginate, foam
Figure 2a

Wound dimensions: 2.0cm x 0.5cm x 0.3cm
Figure 2b

2 weeks following Keratin gel application
Wound dimensions: 1.6cm x 0.4cm x 0.3cm
Figure 2c

4 weeks following Keratin gel application
Wound dimensions: 1.0cm x 0.1cm x 0.1cm
Figure 2d

6 weeks following Keratin gel application
Wound healed
Case 2

- 46 year old male with type 2 diabetes non healing incision of 4 months duration (Fig. 3a).
- PMH: Type 2 DM with peripheral neuropathy, HTN
- Previous therapies: collagen, calcium alginate, foam
Figure 3a

Wound dimensions: 2.8cm x 2.4cm x 0.4cm
Figure 3b

2 Weeks following keratin technology
Wound dimensions: 2.4cm x 2.4cm x0.4cm
Figure 3c

6 weeks following keratin application
Wound dimensions: 1.6cm x 1.2cm x 0.2cm
Figure 3d

8 weeks following keratin application
Wound dimensions: 1.2cm x 1.0cm x0.1cm
Figure 3e

10 weeks following keratin application
Wound dimensions: 1.1cm x 0.5cm x 0.1cm
Case 3

• 56 year old diabetic male with sub met head 1 ulcer left foot x 6 weeks duration (Figure 4a).

• PMH: Type 2 DM with peripheral neuropathy, HTN

• Previous therapies: hydrogel, saline dressing, collagen, foam
Figure 4a

Wound dimensions: 1.9cm x 1.7cm, x 0.2cm
Figure 4b

3 weeks following keratin application
Wound dimensions: 1.2cm x 1.1cm x 0.1cm
Figure 4c

4 weeks following keratin application
Wound dimensions: 1.0cm x 0.8cm x0.1cm
Figure 4d

6 weeks following Keratin gel application
Wound dimensions: 0.5cm x 0.3cm x 0.1cm
Figure 4e

7 weeks following keratin technology application
Wound healed
Results

• All 3 patients showed a substantial reduction in wound area during the treatment period.
• The first patient with a wound duration of 3 months prior to keratin treatment healed after 6 weeks.
• The second patient with a wound of 4 months duration prior to keratin treatment showed substantial reduction in wound volume after 10 weeks.
• The third patient with a wound for 6 weeks duration prior to treatment healed after 7 weeks.

Standard care for this wound type would typically involve collagen and alginate treatment, and show a healing rate much lower than achieved with the keratin gel technology.
Discussion

• The proliferation and migration of keratinocytes can be a rate limiting step in epithelization and wound closure.

• Keratin proteins have been shown to be able to activate keratinocytes present in the wound and to stimulate them to quickly enter a hyperproliferative phase, an essential phase for wound healing.

• Stimulation of keratinocytes achieved by the Functional Keratin proteins can accelerate or increase epithelization to result in good wound healing.
Conclusion

- Keratin gel is a new treatment option for superficial diabetic foot ulcers, in particular those shown to be or with the potential to be slow to heal. Keratin gel appears to improve healing relative to standard of care.
References:


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