CLINICAL REVIEW OF A NEW BIO-ENGINEERED COLLAGEN DRESSING ON DIABETIC ULCER WOUNDS

Subramanian Gunasekaran [Ψ], M. Kwolek[⊗], A. Dhanikachalam[τ], P.G. Kilaru[√],
[Ψ]President, Encoll Corp., Fremont, CA, USA; [⊗]Cosmetic Dermatologist, Danville, CA; USA; [τ]Head of Plastic Surgery, KMC Hospital, Chennai, India; [√]Plastic & Reconstructive Surgeon, Deccan Pacific Medical Group, Fremont, CA-94538, USA.

INTRODUCTION: Most chronic wounds can be classified into three major types: pressure ulcers, venous ulcers, and diabetic ulcers (1). Mustoe et al proposes a unifying hypothesis of chronic wound pathogenesis based on four main causative factors for chronic wound pathogenesis: hypoxia, bacterial infection, repetitive ischemia-reperfusion injury, and an altered cellular response. Traditional strategies for the treatment of chronic wounds have shown limited success. The authors of this report explore potential treatment success with reference to cellular response measured as rate of healing or closure of chronic wounds. Furthermore, they explore the outcome of a new bio-engineered Collagen Dressing applied on Chronic Wounds that failed to heal by other dressings. These results could be of substantial interest for clinicians and researchers, while offering significant benefit to patients with chronic wounds.

MATERIALS & METHODS: Type-I collagen wound dressing product (Helicoll™) approved by FDA has been scientifically documented by the manufacturer to effectively promote ulcer wound healing. It is claimed to be devoid of immunogenic contaminants and function properly to treat chronic ulcer patients. This high purity and charge modified collagen dressing has been used on chronic ulcer wounds to determine the effectiveness of healing through some Case Studies. The objective of the present study is to clinically assess this high purity, non-immunogenic and charge modified bioactive collagen wound dressing (8"x8" sheet of Helicoll. - U.S. Patent Nos. 5,814,328; 6,127,143, and 6,548,077) through potential cell signal phenomenon.

In this case report, patients were treated for their chronic non-healing large size ulcer wounds. The patient began the treatment with the Helicoll collagen wound dressing following other unsuccessful treatments. The size and condition of the wound was monitored periodically and the area of healing was measured to assess the effectiveness of the Helicoll collagen wound dressing.

Results/Discussion:

Case Report-I: 78 year-old male with diabetes mellitus and venous stasis disease had a re-opened wound over the right lateral leg that was treated for almost three years with debridement, multiple skin grafts, OASIS and Unna boot dressings. Following Silvasorb gel dressings, as on 11/29/05, Helicoll collagen wound matrix was applied after the wound was débrided. The wound was monitored periodically with continued repeat dressings with Helicoll. By 8 weeks the wound size was significantly reduced and the patient was totally healed and discharged from the wound clinic within 25 weeks.

CASE-1

Before HELICOLL After HELICOLL

Case Report-II: 85 year-old male with a history of scleroderma had open wound over the posterior aspect of his left leg for over seven years. In the past, the patient had a skin graft, multiple applications of Apligraf without much improvement in his condition. He had VAC dressing changes, Unna boots, and was being treated with Bactroban ointment, Silvasorb gel dressings to the ankle. The wound was further treated with calcium alginate dressing with the Unna boot on 09/06/05; later with Panafil ointment, Kaltostat and Unna boot dressings which was followed by the Oasis wound matrix. Finally the patient was treated with Helicoll collagen wound matrix on 11/14/05 when the wound measured 5.2 x 3.5 x 0.2 cm with an area of 18.2 sq. cm. Gradually the wound size has been reduced to 3.5 x 2.5 x 0.1 cm on 6/29/06 (8.75 sq. cm).

CASE-2

Before HELICOLL After HELICOLL

These anecdotal clinical case results indicate a closure of the wound in the case of the patient-I from 37.5 sq. cm to complete healing within 25 weeks treatment with the Helicoll collagen wound dressing.

In the more complex case of Patient –II, it is calculated as >52% healing of the wound by this modified collagen dressing on a non-healing chronic ulcer wound within the time period given above. These results and the other reports indicate that the dressing made of non-immunogenic collagen can expedite healing of ulcer-wounds. Further clinical studies are required to confirm this healing rate of wound and the effectiveness of Helicoll collagen wound dressing. The details of cell-signal phenomenon induced by the bio-engineered high purity native type-I collagen will be discussed.

Reference:

1. Mustoe, Thomas A.; O'Shaughnessy, Kristina; Kloeters, Oliver, 2006, Chronic Wound Pathogenesis and Current Treatment Strategies: A Unifying Hypothesis, Plastic & Reconstructive Surgery. Current Concepts in Wound Healing. 117(7S): 35S-41S, 2006.