The Use of Ovine Collagen Extracellular Matrix and Gentian Violet and Methylene Blue Antibacterial Foam Dressings in the Effective Treatment of Wounds with Exposed Tendon and Bone in the High Risk Diabetic Foot

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Objective:

Demonstrate the use of ovine collagen extracellular matrix (CECM)* and gentian violet/methylene blue (GV/MB) antibacterial foam dressings as an adjunct therapy in the treatment of wounds with exposed tendon and bone in diabetic limbs.

Introduction:

Diabetes has become more prevalent in our society, affecting 29.3 million Americans and more than 415 million people worldwide. If Diabetes was a country, it would be the 3rd largest in the world.² An estimated 15% of patients with diabetes will develop a lower extremity ulcer during the course of their disease.^{3,4} Foot ulcerations are the precursor to many lower leg amputations in persons with diabetes. This is a large concern in the care of the diabetic. The field of wound care is ever expanding with many advances in technology. Advanced modalities such as skin substitutes, biologic wound products and growth factors help facilitate healing.⁵ There are other wound care dressings, such as CECM with an extracellular matrix (ECM), that help promote tissue granulation⁶ and provide a temporary scaffold to help cells migrate, leading to tissue epithelialization for final wound closure. 7,8 GV/MB antibacterial foam dressings may support autolytic debridement. 9,10 The broad-spectrum antibacterial activity helps provide bioburden management and the dressing helps maintain moisture balance. 9,10 Tendon and/or bone exposure in a wound increases the complexity and provides challenges in healing the wound. These severe wounds may increase the likelihood of amputation, therefore requiring the need for aggressive and advanced wound care.

Methods:

These cases involve high risk diabetic patients with diabetic foot ulcers (DFUs) that were Wagner 3 or greater, with tendons and/or bone exposed. The wounds were surgically debrided, patients placed on IV antibiotics, and advanced wound care modalities such as hyperbaric oxygen therapy (HBOT) were used, in conjunction with CECM to prepare the wound bed for more advanced modalities, GV/MB polyvinyl alcohol (PVA)** antibacterial foam dressing was used to support autolytic debridement and reduction of biofilm. GV/MB polyurethane (PU)*** antibacterial foam dressing was also used depending on exudate level of wound. CECM was used prior to skin graft placement and again two weeks after skin graft to complete healing. Dressings were removed prior to HBOT weekly therapy.

In the cases provided, the combination of CECM and GV/MB antibacterial foam dressings were implemented throughout the entire course of treatment. This form of treatment showed favorable results in preparation of these wounds with exposed tendon and/or bone. This wound care management approach in conjunction with other modalities, skin grafts and skin substitute application was also shown to be favorable.

Patient: 63 year-old male presented with skin graft with exposed bone after a great toe amputation Past medical history:

Week 2 Wound measurement

Week 9 Wound measurement:

CECM applied to wound bed in area of

exposed tissue covered by GV/MB PU

antibacterial foam dressing and HBO1

Wound Description:

Small granular area

Wound Management:

Wound has granulation tissue with little auto

CECM applied to wound bed covered by GV/MB PVA antibacterial foam dressing and HBOT

Wound Description:

skin graft incorporated

Wound Management:

· Diabetes, hypertension, gangrene



4 0 cm x 4 0 cm x 1 5 cm Wound Description: Non-healing chronic full thickness surgical wound with muscle and bone exposed, large



6.6 cm X 4.0 cm X 0.2 cm (before sutures were placed) Wound Description: Wound sutured together after debridement Wound Management: CECM applied to wound bed covered by GV/ MR PLL antibacterial foam dressing and HROT

Week 5 Wound measurement:



Week 10

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 ***Hydrofera Blue™ classic form dressing Distributed by Hollister Incorporated.

 ***Hydrofera Blue READY™ foam dressing Distributed by Hollister Incorporated.

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Case Study 2

Patient: 57 year-old male status post-amputation to the right 4th and 5th toes/rays

• Type II diabetes, heart disease, hypertension, congestive heart failure



Initial Visit Wound measurement: 8.5 cm x 2.4 cm x 0.6 cm Wound Description: Wound dehisced with sutures intact Wound Management: No previous wound care



Week 6 Wound measurement: 3.4 cm X 1.2 cm X 0.3 cm Wound Description: Wound remains fibrotic and can still probe Wound Management:

Debridement CECM applied to wound bed covered by GV/MB PVA antibacterial foam dressing and HBOT



Week 15 Wound measurement: 2.0 cm X 0.5 cm X 0.1 cm Wound Description: No exposed bone and no longer able to probe to bone, no fibrotic tissue, and granular base Wound Management:

Continued with previous protocol



Week 1 Wound measurement: 8.5 cm X 2.4 cm X 0.8 cm Wound Description: Fibrotic tissue at the distal aspect of the wound with depth and probing to bone; little granulation: moderate drainage Wound Management: Collagenase covered by GV/MB PVA antibacterial foam dressing for one month

Changed to CECM applied to wound bed covered by GV/MB PVA antibacterial foam dressing and HBOT. Applied 1-2 times per week



3.0 cm X 1.0 cm X 0.3 cm Wound Description: Fibrotic and granulation tissue Wound Management: Application of cellular tissue product (CTP) every other week. Application of CECM in between CTP applications covered by non-adherent dressing and a dry sterile



Week 21

Patient: 46 year-old male right foot non-healing wound

• Type II diabetes, hypertension, end stage renal disease, hemodialysis



Initial Visit Pre-debridement: 12 0 cm X 5 5 cm X 0 3 cm Wound Description:



Initial Visit Post-debridement 12.0 cm X 6.0 cm X 0.3 cm

Fibrotic tissue at the center with bone and tendon exposed. X-rays are consistent with

Wound Management:

Debridement, collagenase and HBO



Week 4 Wound measurement: 9.4 cm X 4.2 cm x 0.3 cm Wound Description: Granulation tissue with exposed tendons and bone at the center

Wound Management:
Debridement, CECM covered by a non-adherent with NPWT changed twice weekly and with daily HBOT



Week 12 Wound measurement: 7.0 cm X 3.5 cm X 0.2 cm Wound Description: 100% granulation tissue, no exposed tendons or bone

Wound Managem Debridement, CECM applied to wound bed covered by GV/MB PVA antibacterial foam dressing and HBOT



Week 17 Wound measurement: 4.0 cm X 2.0 cm X 0.1 cm Wound Description: 100% granulation tissue Wound Management: Continued application of CTP every 2-3 weeks using CECM applied to wound bed covered

by GV/MB PU antibacterial foam dressing in

between applications of the CTP with HBOT



9.0 cm X 4.0 cm X 0.2 cm Wound Description: Wound bed is 100% granular Wound Management: Discontinued NPWT Debridement CECM applied to wound bed covered by GV/MB PVA antibacterial foam dressing and HBOT



Week 14 Wound measurement 6.5 cm X 3.3 cm X 0.2 cm Wound Description: 100% granulation tissue Wound Management: Application of CTP every 2-3 weeks using CECM applied to wound bed covered by GV/MB PU antibacterial foam dressing in between application of the CTP with HBOT



Week 18 Wound measurement: 3.0 cm X 1.5 cm X 0.1 cm **Wound Description:** 100% granulation tissue. Wound size reduction of 03 75%

Wound Management

Continued application of CTP every 2-3 weeks using CECM applied to wound bed covered by GV/MB PU antibacterial foam dressing in between application of the CTP with HBOT