MatriStem®

MatriStem Wound Care Evaluation

Primary Investigator:

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PROTOCOL

Study Objective:
A controlled trial to measure the rate of healing with one FDA cleared device (single layer lyophilized MatriStem Wound Sheet) against the standard of care (wet to dry dressing changes) in connection with the treatment and reconstruction of soft tissue for lower limb ulcers.

Device Description:
The MatriStem Wound Sheet is an extracellular matrix scaffold derived from the porcine urinary bladder. The device is designed and developed for the treatment of lower limb wounds such as diabetic, venous and pressure ulcers. The devices possess the following properties:

1) Composition that consists of various types of collagens, elastin, adhesion proteins, glycosaminoglycans, and glycoproteins.
2) Ability to biodegrade in the presence of wound fluid.
3) Ability to promote natural wound healing through a synergistic process, which is a topic of active research in many academic and clinical institutions.

Natural healing may be described as the replacement of injured or missing tissues with host tissues that resembles closely, the original native tissue.

MatriStem devices are composed of complex biomolecules, some cited above, and are derived from a porcine urinary bladder that is processed in a proprietary manner. Each device is supplied in a sterile individual package for single use. MatriStem technology has been the subject of several peer reviewed publications which are pertinent to this study and probe the molecular level interactions that may be key to the natural wound healing properties associated with the product. Based on these studies, MatriStem devices seem to possess the right mixture of biomolecular components that elicit the natural healing response.

Study Design:
The study was conducted from April-July 2005 in one accredited wound care center within the United States. Thirteen patients (20 wounds) with established and historically documented leg ulcers treated for a minimum of 2 weeks with standard of care were enrolled into the study when it was determined that their wounds were not healing. Patients served as their own control (Control group) during standard of care treatment. Once enrolled, standard of care treatment continued for an additional 21 days. Wound sites were evaluated and monitored through the end of treatment.

After 21 days, patients were transferred from the Control group to the Treatment group and were treated for a minimum of 21 days with MatriStem. Wound sites were evaluated and monitored through the end of treatment.

Wound evaluation was assessed by the Wound Matrix® software system. This system requires a digital photograph to be taken of all wounds at the time of wound dressing to provide an empirical basis for measuring the size of the wound as it heals.

The study chart recorded diet, weight, medications, physical activity, vital signs, complications and other medically important information of the patient throughout the study. All wound care and ancillary care such as physical therapy was recorded. Wound observations and treatments along with MatriStem device resorption and frequency of application were recorded.

Control group:
Standard of Care – Xeroform dressing, foam secondary dressing, gauze dressing and bandage applied to wound. Dressing changes applied at 3, 7, 11, 15, and 21 days.

Treatment group:
MatriStem applied to wound and covered with non-adherent dressing followed by gauze dressing, then bandaged. MatriStem reapplied at 3, 7, 11, 15, and 21 days after initial application. Additional MatriStem applications beyond the 21 days of treatment were left up to the discretion of the treating physician depending on the patient's wound healing rate.

Inclusion criteria:

- Chronic diabetic foot or leg ulcer treated for more than 3 months
- Known cause of leg ulcer with a minimum size of 9 cm^2

Exclusion Criteria:

- Allergy to porcine products
- Critical illnesses such as those requiring ventilator support, systemic infection, or hemodynamic instability
- Major acute or chronic medical illnesses that could affect wound healing
- Subjects receiving treatment with medications that inhibit/compromise wound healing
- Cellulitis

End Points:

- MatriStem resorption rate (Days)
- MatriStem frequency of application (Days)
- Achieve 100% wound healing
- Wound healing with MatriStem must be equal to or better than standard of care as assessed by Wound Matrix software system

RESULTS

- The area of lesions treated was comparable in both groups:
  - MatriStem - 41.08 cm^2
  - Control - 40.43 cm^2
- The area of wound healing per day:
  - MatriStem - 0.08 cm^2
  - Control - 0.04 cm^2
- The average wound healing rate per day:
  - MatriStem - 1.82% per day
  - Control - 0.09% per day
- Average days of treatment for complete wound healing
  - MatriStem – 39 Days; range (7-59 Days)

Conclusion:
All wounds were healed after treatment with MatriStem.

- MatriStem was resorbed by Day 3 after initial application.
- Weekly applications of MatriStem are sufficient to achieve 100% wound healing.
- MatriStem wound healing rate was twice as fast as standard of care.

Note:
Study data analyzed by primary investigator – Joe Gonzalez, DPM.