

MIST assisted healing in wound bed preparation for bioengineered tissue

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INTRODUCTION:

Chronic wounds can be stimulated to heal by the use of bio-engineered tissues like Apligraf, as proven in pivotal clinical trials for diabetic foot ulcers and venous leg ulcers. In order to maximize success with this therapy however, bioburden management and superior wound bed preparation are paramount. MIST ultrasound therapy (Celleration Inc. Eden Prairie, MN) has developed a new non-contact ultrasound therapy device which addresses both of these issues. This study is a sub-group analysis of wounds that were sequentially treated with MIST, followed by closure with Apligraf. This 30 wound prospective trial is displayed on a separate poster at this meeting.

METHODS:

Recently, a non-randomized, prospective, intent to treat trial was conducted using MIST ultrasound, a new, FDA cleared, non-contact ultrasound therapy. The wounds were on average 9 months in duration on enrollment and various wounds of all etiologies were included. Of 30 wounds enrolled, 33.3% were healed using only MIST therapy. The trial was designed to allow the investigator to use an additional modality if the healing trajectory stalled. MIST therapy is used for cleansing and debridement and therefore the positive effects on wound bed preparation were considered an adjunct for the use of cell therapy (Apligraf, Organogenesis) After wound healing was considered stalled, and the Apligraf was applied, MIST therapy was terminated. The author's standard Apligraf protocol includes excisional preparation of the wound bed on the day

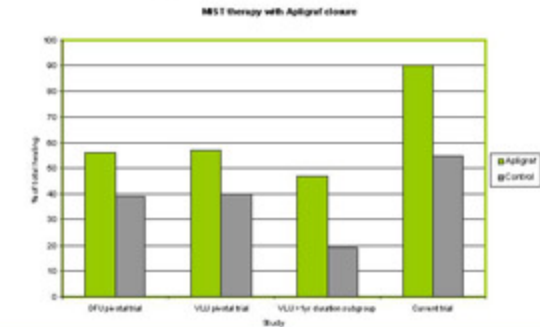
of application. The graft is perforated with an 11 blade on a 1:1.5 meshing card and applied dermal side down on the wound bed. The graft is applied to allow for the overlap onto the peri-wound skin of at least 1 cm. Iodoflex gauze (Healthpoint LLC) is applied directly onto the graft followed by fluff 4x4, kerlex roll and a Coban wrap (3M Inc.). The dressing is changed in 72 hours and a new Iodoflex is applied with a Profore wrap (Smith and Nephew). The dressings are then changed weekly. A dry stable eschar builds up at the wound bed. This eschar is removed at the end of 4 weeks and a decision is made as to the need for any additional graft placement. (No wound required more than 1 graft in this study)

RESULTS:

In this trial a total of 10 wounds were treated with Apligraf after MIST therapy was used for wound bed preparation. In all, 9 of the 10 (90%) healed on average 5.7 weeks after Apligraf application. Studied in this way, the remaining 20 wounds demonstrated a 55% healing rate at a maximum of 24 weeks of therapy. All patients received MIST therapy initially as part of the protocol. After application of Apligraf, we noted that within 10 days, a firm eschar formed over the wound bed. At the end of 4 weeks, this eschar was sharply removed with a #10 blade and new epithelium was noted covering the majority of the wound bed. Additional compression therapy with Iodoflex as a primary dressing was carried out for an additional 1-2 weeks until closure.

DISCUSSION:

It is likely that MIST therapy has an effect on the wound bio-burden. In a recently completed randomized trial on diabetic foot ulcers, baseline quantitative culture biopsies done on enrollment revealed 90% of both wounds in MIST or Sham demonstrated greater than 105 bacteria per gram of tissue. This may explain why MIST therapy was statistically more effective in healing these patients than Sham control. Bioburden management is an important part of wound bed preparation when considering the use of Apligraf. The combination of these 2 therapies appear to have better outcomes than previously published results using Apligraf against control (see table) Further studies are being planned.



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2. Veves A, Falanga V et al "Graftskin, a human skin equivalent is effective in the management of noninfected neuropathic diabetic foot ulcers" Diabetes Care 2001; 24:290-295.
3. Falanga V, Sabolinski M. "A bilayered living skin construct (Apligraf) accelerates complete closure of hard to heal venous ulcers" Wound Rep Reg 1999;7(4):201-207.

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Product notation: * Apligraf® is a registered trademark of Novartis, Inc., East Hanover, NJ © 2004 Organogenesis, Inc., Canton, MA

† MIST™ ultrasound is a registered trademark of Celleration Inc. Eden Prairie, MN