

Clinical Effects and Underlying Molecular Mechanisms of Low Frequency Noncontact Ultrasound on Diabetic Foot Ulcers

Vickie R Driver^{1,2}, Silvia Garcia-Lavin, Matteo Fabbi, Hisae Hayashi, Nanjin Park, Min Yao, Khaled Attala, and Michael A French

Limb Preservation and Wound Care Research
Department of Surgery
Boston University Medical Center and
Boston University School of Medicine

¹ Presenter

² Corresponding author

Background/Purpose: Low frequency non-contact ultrasound (LFNC-US) devices have been increasingly used for the treatment of chronic non-healing wounds. The appropriate dose for LFNC-US is still debated. The aims of this study are to evaluate the relationship between dose and duration of treatment for subjects with non-healing diabetic foot ulcers (DFU's) and to explore the correlation between wound healing and cytokines/growth factors expression

Design and Methods: This study is a prospective randomized clinical trial designed to evaluate subjects for five weeks with non-healing DFU's followed at Boston University Medical Center. Subjects were randomly assigned to one of three groups: application of LFNC-US 3 times per week (Group 1), once per week (Group 2) and the control (Group 3) which received no LFNC-US. Group1 and 2 subjects received the same therapeutic LFNC-US 4 minute dose. All subjects received standard wound care 3 times per week for a total of 4 weeks, including a one week run in period. Wound fluids, biopsied wound tissues were collected from each patient once a week during clinic visit and then profiles of cytokines/growth factors are quantified using Luminex-based multiplex protein assays. A comparison analysis was performed of wound percent area reduction (PAR) over the 5-week duration for each group.

Results: Twelve patients, 2 (16.7%) type 1 and 10 (83.3%) type 2 diabetes, average age of 58 ± 10 years with 12 foot ulcers were enrolled. Average ulcer duration 36.44 ± 24.78 weeks and 0.91 ± 0.06 average ABI. Group1 had the greatest wound reduction with an 86% PAR; Group 2 had a 25% PAR and a 39% PAR for Group 3(control) from baseline. Group 1 had a significant wound reduction at weeks 5 and 6 compared to Groups 2 and 3 ($P < 0.05$). However, there are no statistical differences between group 2 and group 3 over time. Profiles of cytokines/growth factors and their correlation with wound healing will be identified.

Conclusion: Our results demonstrate that LFNC-US is effective in treating diabetic foot ulcers. Three times per week therapy application renders the best wound reduction. Investigation of the molecular mechanisms of LFNC-US on tissue and wound fluid and their correlation with wound healing will be reported.