Promotion of Wound Healing in Diabetic Foot Ulceration with the Tennant Biomodulator and Tennant BioTransducer

Background

Diabetic foot ulceration is major source of morbidity with an estimated prevalence of 9-25% among the estimated 30.3 million people with diabetes in the United States (1-4). Approximately 5.0 per 1,000 people with diabetes will undergo limb amputation annually (5). As ulceration significantly amplifies risk of amputation, improvements to limb salvage efforts are needed.

Current best practices in the management diabetic foot wounds involve three major elements: regular monitoring, wound cleaning and dressing, and mechanical off-loading (6-7). These strategies focus on mitigation of factors that may inhibit wound healing. Estimated rates of wound healing are 1-2% per day with standard methods (8). While glucose control is standard in management of diabetes, significant evidence has not been found to correlate glucose control and wound healing (9). A large number of treatments undergoing evaluation focus on reducing risk of infection while waiting for wound closure but do not yield enhanced rates of closure. Hyperbaric oxygen therapy has shown some evidence of improving healing rates, but quality of data does not yet support generalized recommendations for this treatment (10). Other approaches to biochemically enhance biological processes at work in the wound have not provided evidence of improved rates of healing. Physical therapies such as microcurrent and pEMF have shown positive but limited evidence in small studies of improving rates of healing (11-12).

The community clinic is the primary interface within the medical system for many socioeconomically disadvantaged individuals. These clinics fulfill a critical role in providing primary care, particularly with patients requiring medications and supplies for treatment. Because lower socioeconomic status is correlated with higher rates of diabetes, the community clinic bears a substantial burden in treating patients with diabetes-related comorbidities. As these facilities are classically resource limited, tools for treatment of conditions such as diabetic foot ulcers do not include forthcoming options available at major academic centers, such as hyperbaric oxygen. As such, prevailing research developing methods to enhance rates of healing diabetic foot ulceration is unlikely to influence treatment regimens at the community clinic.

As recent refinements to standard of care for diabetic foot ulceration have not yielded significant improvements in wound healing rates, alternative methods become worthy of investigation. Microcurrent and pEMF devices have shown some limited evidence of healing in academic centers and warrant further investigation. The Tennant Biomodulator includes a unique microcurrent implementation, which is currently under investigation as a tool to promote wound healing at two major academic centers. The Tennant Biomodulator also pairs with a unique pEMF attachement, the Tennant BioTransducer, which has not yet been studied in wound healing. As no current studies treating diabetic foot wounds with microcurrent or pEMF devices have been performed at the community clinic, opportunity exists for supporting a segment of the population with known health disparities who do not typically benefit from advances through research.

Research Question
Will the Tennant Biomodulator and Tennant BioTransducer enhance rates of closure with diabetic foot ulceration in the setting of a community clinic?

Study Architecture
To answer this question, a study is proposed to investigate use of the Tennant Biomodulator and Tennant BioTransducer through a community clinic affiliated with the Southwest College of Naturopathic Medicine and Health Sciences. The clinic in question will be the Roosevelt Health Center in Phoenix, AZ. The proposed study will be a small prospective case series in structure with 3-5 patients anticipated to complete the study. Patients will be recruited through the Roosevelt Community Clinic and treated there exclusively. It is anticipated the study will require up to six months to complete.

Methods and Materials
The care provided for patients enrolled in this study will be consistent with the standard already provided at the facility for management of diabetes and comorbidities. This may include but is not limited to screening labs, dietary counseling, herbal medicines, pharmaceuticals, and supplements, depending on patient needs. Wound care will be given according to standard practices, and patient education will be provided. Relevant patient data and wound characteristics, including images, will be collected at every visit.

In addition to standard of care treatments, patients will be treated with the Biomodulator and the BioTransducer at every visit. The devices will be provided by Senergy Medical Group, Inc., for patient care and will be donated to the clinic at the end of the study for future use at the clinic. It is anticipated three patients will complete the study, with the overall study period lasting up to six months. Treatment with the Tennant Biomodulator and Tennant BioTransducer will be performed, at minimum, once a week, and up to three times per week. Treatments will be provided by research team members trained by Senergy Medical Group to use the Tennant Biomodulator and the Tennant BioTransducer.

Key Players
Principal Investigators:
- Lilia Feria, ND, Site Director, Roosevelt Health Center, Staff Physician, SCNM
- Anthony Pinazza, ND, First-Year Resident, SCNM

Additional Research Team Members
- Joseph Tilchen, 4th-year student, SCNM
- One currently unidentified student or Resident also providing treatments

Device/Manufacturer Contacts
- Scott Tennant, CEO Senergy Medical Group, Inc.
- Karla Bass, VP Business Development, Senergy Medical Group, Inc.

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