Data presented has not been reviewed or evaluated by the US FDA. Devices are not intended for the diagnosis or treatment of disease condition. Avazzia devices are US FDA cleared as TENS For symptomatic relief and management of chronic, intractable pain, and adjunctive treatment in the management of post-surgical and post-traumatic pain. This study is for Microcurrent as an adjunct therapy in accelerating wound healing and reducing pain in patients with chronic wounds. Avazzia microcurrent devices are US FDA cleared for pain relief.

MICROCURRENT AS AN ADJUNCT THERAPY IN ACCELERATING WOUND HEALING AND REDUCING PAIN IN PATIENTS WITH CHRONIC WOUNDS

Harikrishna K.R. Nair, MD FMSWCP, Wound Care Unit, Dept. of Internal Medicine, SCACC Hospital Kuala Lumpur, Malaysia

ABSTRACT

Patients with chronic wounds were randomly selected to assess the efficacy of Microcurrent as an adjunct therapy in reducing wound size, pain score and other parameters for a period of four weeks. Patients enrolled had the following conditions- 64 Diabetic Foot Ulcer, 24 Venous Leg Ulcer, 5 Pressure Injury and 7 other types of wounds.

The efficacy of microcurrent therapy was assessed according to the reduction in wound area as well as in pain and other inflammatory symptoms which was attributed to its effect on vasodilatation of the vessels and increase in perfusion. Inspection and physical assessment was done with the Visual Analog Scale for pain. There was significant reduction in pain and wound area during the treatment period as well as improvements in other parameters such as gait, sensation, sleeping quality among others. There were no adverse events reported.

INTRODUCTION

Chronic wounds are regarded as a major problem in terms of social and psychological impact to patients. The mode of action for microcurrent therapy is **reducing Inflammation** and **increasing perfusion**. Most chronic wound patients are stuck in the inflammatory phase of healing with associated pain which will affect their health-related quality of life (HRQoL) such as sleep, mobility etc.[1] Pain is a known stressor which impedes wound healing[2] and physiological stress is one of the factors that lead to poor bowel movement.[3]

Studies have shown that microcurrent stimulates cellular activity and regeneration by increasing ATP production and repairs tissue by increasing protein synthesis.[4] Microcurrent has been proven to reduce Cortisol and TNF-α levels in terms of pain management,[5] and increase Nitric Oxide, a potent vasodilator which increases perfusion to the wound.[6] Exogenous electrical stimulus has been found to increase growth of blood vessel networks by as much as 50 percent,[7] activating the pathway for angiogenesis and enhancing vascular network growth. As a result, wound closure would be enhanced, leading to faster healing.[8]

METHODOLOGY

100 patients with chronic wounds were enrolled via simple randomized sampling in this case series conducted at the Wound Care Unit, Hospital Kuala Lumpur for a period of four weeks. Patients who walked into the Wound Care Unit, Hospital Kuala Lumpur, Malaysia from Mondays to Fridays between 8 a.m. to 12.30 p.m. and who satisfied the Inclusion Criteria stated below were enrolled in this study and consent was taken from them to be treated with microcurrent as an adjunct therapy.

Inclusion criteria:
- All types of wounds including diabetic foot ulcer, venous ulcer, pressure ulcer, others
- Wound surface area must be ≥ 0.5 cm^2 and ≤ 22 cm^2
- Able to comply with weekly visits to clinic
- Able to perform microcurrent treatment at home on daily basis

Exclusion criteria:
- User of any microcurrent device in the past six (6) months prior to study
- Electrical implant such as pacemaker or neural stimulator
- Low blood pressure
- Malignancies (cancers) undergoing treatment or any malignancies (in remission or not) with involvement of the musculoskeletal system

Each patient had microcurrent therapy delivered while having their wounds cleansed. The settings used with the microcurrent therapy were an *anti-inflammatory* frequency (139-147 Hz) followed by a *vasodilation* frequency (4-99 Hz). Patients were loaned a home-microcurrent device to treat themselves 2 to 3 times a day for a period of four weeks. This therapy was applied around the bandaged area (thus not having to open the wound dressing to deliver treatment).

Primary objectives of the treatments:
- reduction in wound area
- reduction in pain

Secondary objectives of the treatments:
- reduction in inflammatory symptoms-swelling, stiffness
- improvement in sleep quality
- increased vasodilation (skin discolouration, leg heaviness, early morning erection, sensation)
- improvement in gait
- frequency of bowel movement

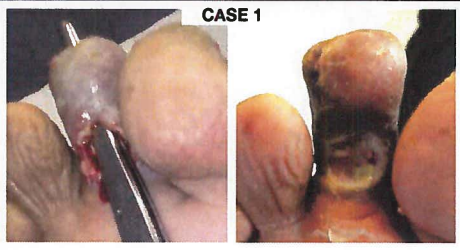
Wound care was performed with Microcurrent Treatment as an adjunctive therapy.

STATISTICAL ANALYSIS

Primary objectives were analyzed using SPSS version 20 using paired t-test method.

RESULTS

CASE 1



Before After

A 66 year old Indian gentleman presented with Right Diabetic Foot Ulcer at the 2nd toe for more than 4 months. After 1 month of Microcurrent treatment, wound area reduced by 95%. Neuropathy pain reduced by 75% resulting in improved sleep quality. Foot stiffness and swelling reduced as well as requirement of Tramadol which reduced from 50mg OD to nil. Foot discolouration improved due to improved sensation. This led to improved gait. Patient also noticed improvement in bowel movement in terms of frequency as he previously experienced poor bowel output predominantly.

CASE 2

Before After

A 66 year old Chinese gentleman presented with Venous Ulcer on Left Lower Limb for more than 5 years. After 1 month of Microcurrent treatment, the wound healed with full epithelialization. Leg pain reduced by 80%. Leg stiffness and swelling reduced causing improvement in gait. Requirement of Tramadol 50mg BD was reduced to nil. Improvement in leg colour as well as improvement in early morning erection and frequency of bowel movement were noted.

CASE 3

Before After

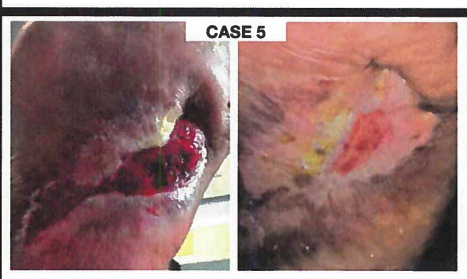
A 58 year old Indian gentleman presented with 3rd stage sacral sore for more than 5 months. After 1 month of Microcurrent treatment, the wound healed with 88% epithelialization. There was 67% reduction in leg pain. There was reduction in leg stiffness causing improvement in gait. In addition there was improvement in the quality of sleep.

CASE 4

Before After

A 66 year old Malay gentleman presented with a Right Diabetic Foot Ulcer with Ray's Amputation done in 2015. After 1 month of Microcurrent treatment, there was 100% epithelialization. Neuropathy pain reduced by 83% resulting in requirement of Tramadol 50mg BD reduced to nil and improved sleep. Patient's gait improved due to reduction in foot stiffness, numbness and ankle swelling. Foot colour and sensation improved. Patient experienced improvement in early morning erection and frequency of bowel movement.

CASE 5



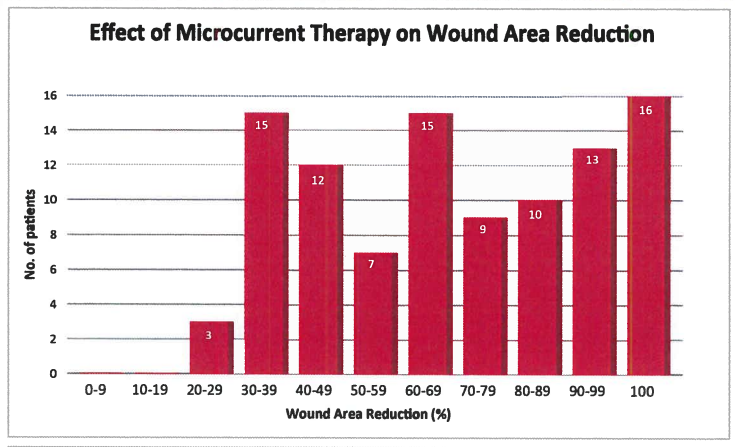
Before After

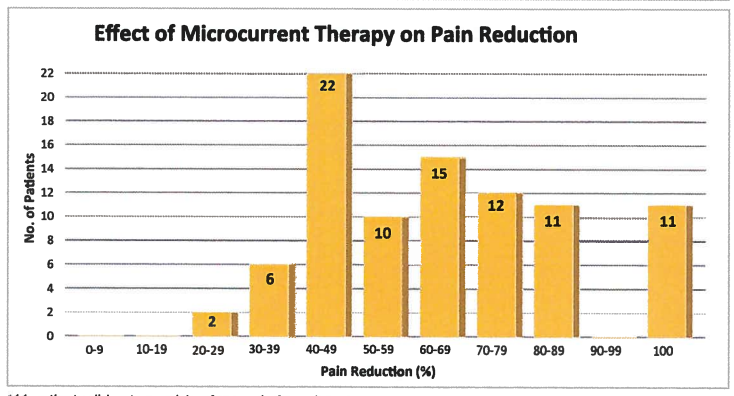
A 54 year old Malay gentleman presented with a Left Diabetic Foot Ulcer at the lateral plantar aspect for the past 1 year. Within 1 month of treatment, the wound area reduced 98%. Neuropathy pain reduced by 75% resulting in patient having improved sleep. Foot stiffness and ankle swelling also reduced. He used to require wheelchair assistance but after treatment he could walk without aid. There was noticeable improvement in leg discolouration due to reduction in scar tissues and hyperpigmentation. Patient experienced early morning erection and more frequent bowel movement.

CASE 6

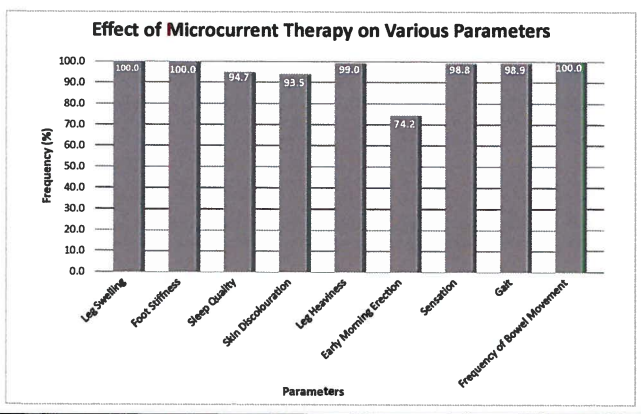
Before After

A 62 year old Malay gentleman presented with Venous Ulcer on Right Lower Limb for more than 5 months. After 1 month of Microcurrent treatment, the wound healed with 100% epithelialization. Although pain reduced by 88% and sleep quality improved, patient maintained his pain medication intake OD. Leg stiffness and swelling reduced causing improvement in gait. Improvement in leg discolouration as well as improvement in early morning erection and frequency of bowel movement were noted.





*11 patients did not complain of any pain from the start



All 100 subjects had reduction in wound size. Reduction in pain resulted in improved sleep quality. Patients had a likely increase in perfusion as well as improved skin discolouration, early morning erection and sensation due to the effect of vasodilatation of the vessels. There were also reduction in inflammatory symptoms such as leg swelling, foot stiffness and the leg felt lighter resulting in improvement of the gait. Improvement in frequency of bowel movement was noted. There were no adverse events reported.

CONCLUSION

The combination of good wound care coupled with microcurrent as an adjunctive therapy in this 100-patient study were proven to be effective in terms of wound area reduction ($p<0.001$) and pain management ($p<0.001$) which are statistically significant. These parameters showed the following improvements: leg swelling (100.0%), foot stiffness (100.0%), sleep quality (94.7%), skin discolouration (93.5%), leg heaviness (99.0%), early morning erection (74.2%), sensation (98.8%), gait (98.9%) and frequency of bowel movement (100.0%).

It can be postulated that microcurrent's role in reducing inflammation and improving perfusion accelerates wound healing and improves HRQoL in terms of pain management, sleep quality and mobility.

Increased perfusion due to vasodilation not only improves sensation and early morning erection but also improves skin discolouration. Poor bowel movement can be either due to physiological stress or damage to the digestive tract nerves in Diabetic Mellitus patients.[9, 10] Activating the pathway for angiogenesis and enhancing vascular network growth improves frequency of bowel movement.

In this study, Avazzia BEST™ (Biofeedback Electro Stimulation Technology)[11] devices were used.

The ease of use of microcurrent devices advocate its use in accelerating wound healing. It could be applied as a first priority on the list of adjunctive wound care therapy.

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The Principal Investigator and author of this 100 patient wound care case series is Dr. Harikrishna K.R. Nair, Head of Wound Care Unit, Department of Internal Medicine, Kuala Lumpur Hospital, and president of the Southeast Asia International Wound Care Conference. Dr. Harikrishna K.R. Nair was not compensated by Avazzia for performing the case series. Nor, does Dr. Harikrishna K.R. Nair hold any financial position in Avazzia, nor any disclosable financial interest or arrangements. Avazzia provided funding for the conduct of the study relating to Microcurrent as an adjunct therapy in accelerating wound healing and reducing pain in patients with chronic wounds. A bibliography of references of other articles is included.