

Effectiveness of Daily Home Electrical Stimulation As An Adjunctive Therapy to Accelerate Wound Healing In People With Diabetic Foot Ulcer

- A Double-Blinded Randomized control trial -

Alejandro Zulbaran, Naima Rodriguez, Hector Elizondo, Anmol Momin, Jeffrey Ross, Miguel Montero-Baker, Brian Lepow, Joseph L. Mills, Bijan Najafi

Division of Vascular Surgery and Endovascular Therapy,
Michael E. DeBakey Department of Surgery



Baylor
College of
Medicine

MICHAEL E. DeBAKEY
DEPARTMENT OF
SURGERY



Disclosures

- This study was supported in part by a grant from AVAZZIA Inc. (TX, USA). Sponsors did not contribute in participant recruitment, data analysis, interpretation of results, nor in participant training, therapy, intervention or performing the study itself.



BACKGROUND

- **Significance:** Diabetic foot Ulcer (DFU) creates a high expenditure for healthcare systems and could lead to **limb loss**.

-**Premise:** Electrical Stimulation (E-stim) is an alternative treatment option to speed up wound healing.

-**Supporting studies:**

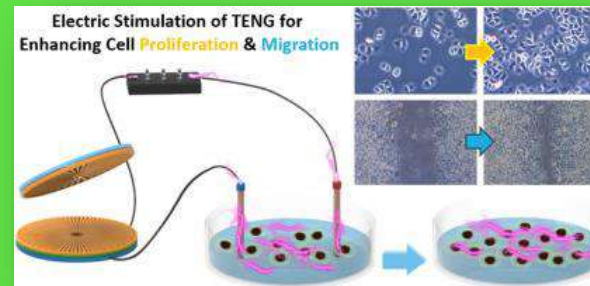
- **In vitro:** association of **angiogenesis** with **E-stim**.
- **Animal studies:** association of increased blood **flow velocity** with **E-stim**.
- **Human studies:** association between **E-stim** and venous **ulcer healing**.



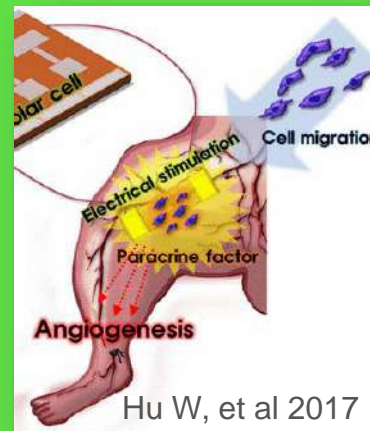
GAPS

-**Pre-clinical and human trials** have **evidenced** the **mechanism** of action of E-stim to speed up wound healing, yet:

There are **no RCT** to **examine effectiveness** of **home-based E-Stim** therapy to speed-up wound healing.



Jeong G et al, 2017



Hu W, et al 2017

Objective

Aim: home-based daily E-Stim therapy to speed up wound healing.



Hypothesis:

1. **Feasibility:** High acceptability to daily home E-Stim therapy
2. **Effectiveness:** Daily E-stim improves speed of wound healing
3. **Mechanism of action:** Daily E-stim improves tissue oxygenation of DFUs.

STUDY DESIGN

Design: 4 weeks double blinded RCT

- **Participants**, 38 patients with DFU and mild vascular deficiency
- **Intervention Group, IG**, n=19
 - Functional device
- **Control Group, CG**, n=19
 - Non-functional device

Intervention:

Treatment location:

Acupuncture points at ankle of the injured foot

Duration of E-stim: 60 min

Frequency: Daily basis

Intensity: Maximum E-Stim magnitude or comfort tolerance

Duration of therapy: 4 weeks

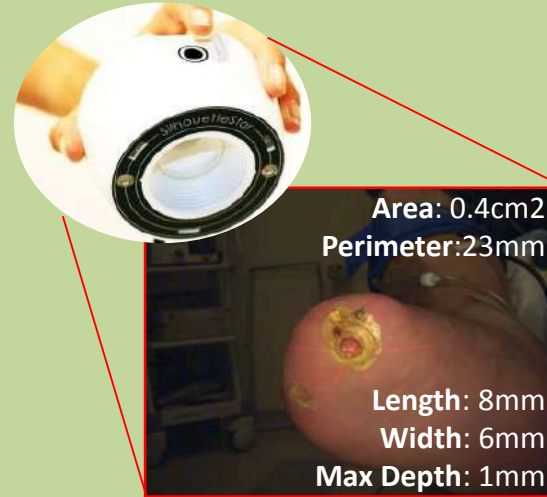


Inclusion criteria	Exclusion criteria
DM type II	ESRD
Mild-mod PAD	Major amputation
1 or more active ulcer/wound(s)	Charcot foot
Ability to provide informed consent	Osteomyelitis
Willing to maintain E-stim	Malignancy/immunocompromised
	Alcohol/drug abuse

OUTCOMES

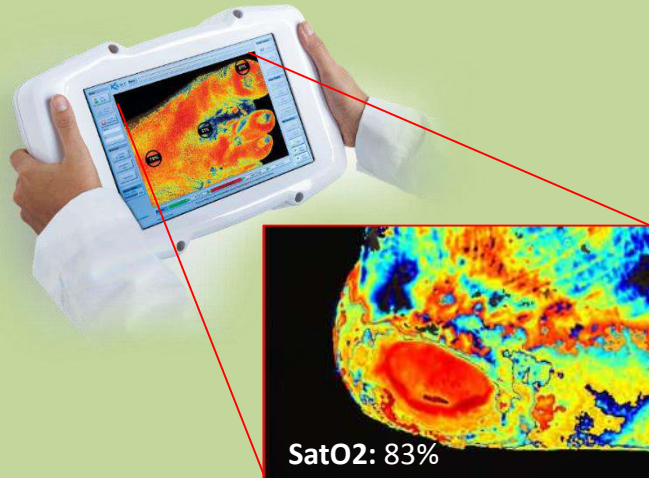
Primary: Wound size

(3D laser technology Silhouette Star camera)



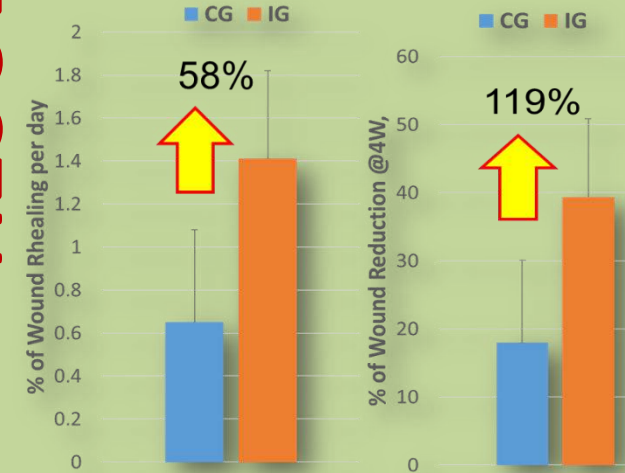
Secondary:

- Tissue SatO2 (Kent Near-Infrared Camera)

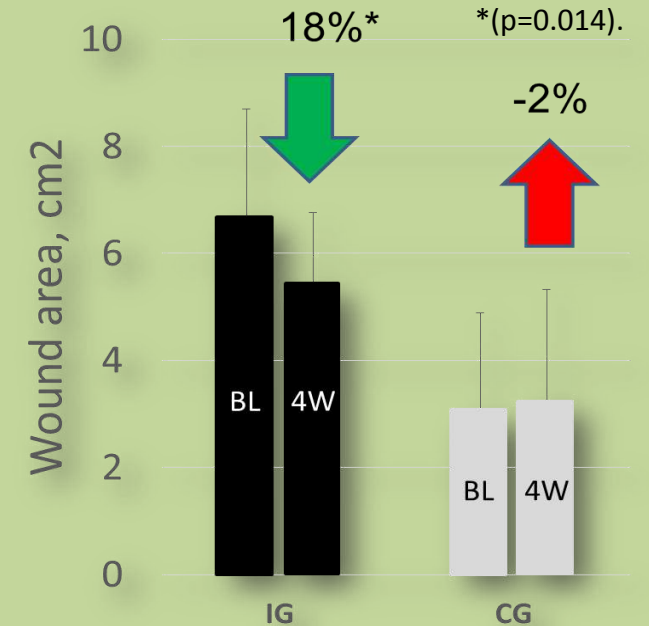


RESULTS

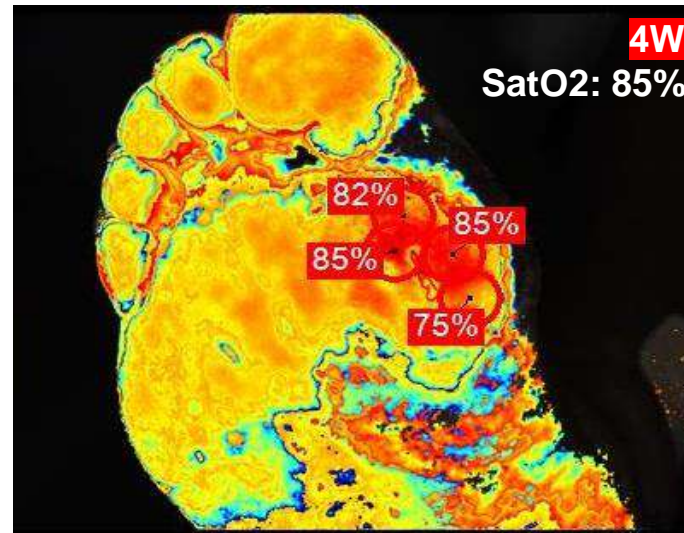
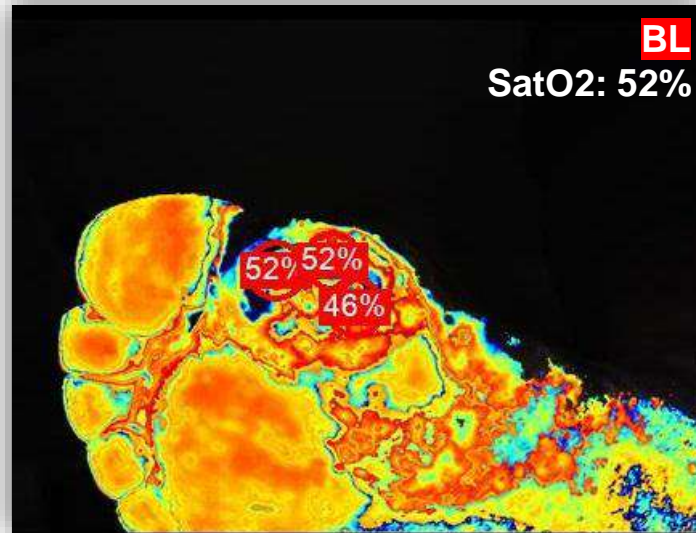
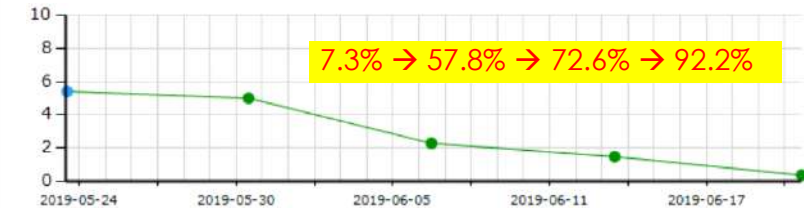
Speed of wound healing



% Size reduction at 4 weeks



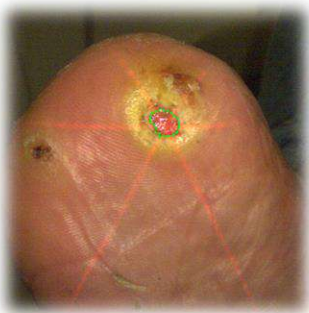
Intervention Group Case – Wound Size, SatO2



**92.2% Area reduction
34% SatO2 Increase**

Conclusions

- ❑ **Innovation:** The first RCT study examined feasibility and effectiveness of home-based E-Stim therapy to improve speed of wound healing.
- ❑ **Feasibility:** Home-based E-stim adjunctive therapy is feasible; daily home-therapy was over 90% of self-adherence.
- ❑ **Acceptability:** Our survey suggests high perceived ease of use and benefit.
- ❑ **Effectiveness:** Significant Time×Group effect observed in this RCT study supports effectiveness of daily home E-Stim therapy to speed up wound healing among people with DFUs.
- ❑ **Mechanism of action:** Our results revealed positive contribution of E-Stim to improve tissue oxygen saturation, a key ingredient for wound healing



Thank you



MICHAEL E. DeBAKEY
DEPARTMENT OF
SURGERY

www.bcm.edu/icamp

Email: zulbaran@bcm.edu