

# CLINICAL FACT SHEET

## BEST\*\* (BioElectric Stimulation Therapy) and Wound Healing in Diabetic Patients



### Improved wound healing with BEST in diabetic foot ulcers

Design	12 week, double-blind, randomized, placebo-controlled clinical study.
Patients	40 patients consecutively sampled, 20 per group. 5 patients (2 treated, 3 placebo) withdrew due to severe infection.
Interventions	BEST for 20 min per hour, every night for 8 hours. Additional wound care : weekly debridements, topical hydrogel, and off-loading with removable cast walkers.
Endpoints	1 <sup>0</sup> Proportion of healed wounds 2 <sup>0</sup> Compliance with use of device, healing rate, and time until healing.
Results	65% of patients healed in the BEST group, whereas 35% healed with placebo (p = .058). After stratification by compliance, a significant difference was identified in the compliant treatment group (71% healed) vs compliant patients in the placebo group (39% healed, linear-by-linear association = 4.32, p = .038). There was no significant difference in compliance or time to healing between the 2 groups.
<b>Conclusion</b>	<b>BEST enhances wound healing when used in conjunction with appropriate off-loading and local wound care.</b>

Peters EJ et al. Electric stimulation as an adjunct to heal diabetic foot ulcers: a randomized clinical trial. *Arch Phys Med Rehabil.* 82(6):721-5. 2001

### BEST improves healing of venous leg ulcers in diabetic patients

Design	12 week, double-blind, randomized, placebo-controlled clinical study.
Patients	64 patients consecutively sampled, 20 per group. 5 patients (2 treated, 3 placebo) withdrew due to severe infection.
Interventions	BEST for 40 min per day, 20 min x 2 times. Electrode placement outside wound area. Standard treatment regimens continued in both groups.
Endpoints	1 <sup>0</sup> Proportion of healed wounds 2 <sup>0</sup> Reduction ulcer size
Results	BEST healed significantly more ulcers (p<0.05) after both 8 weeks (25% vs 11%) and after 12 weeks (42% vs 15%). In addition, ulcer size was significantly smaller in the BEST group (61% reduction vs 41%, p , 0.05).
<b>Conclusion</b>	<b>These results support the use of BEST in diabetic patients with venous leg ulcers. In addition, it was easy to apply and could be used by patients at home.</b>

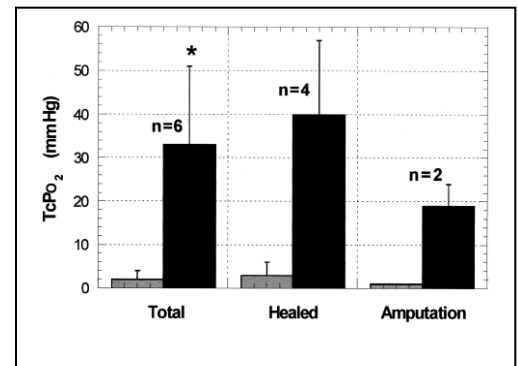
Lundeberg TC, et al. Electrical nerve stimulation improves healing of diabetic ulcers. *Ann Plast Surg.* 1992;29(4):328-31.

\*\* BEST is used throughout this document to indicate external electrical stimulation. Different authors use different terms e.g. electrical stimulation, electrotherapy, transcutaneous nerve stimulation, etc, and it can lead to confusion. All publications summarized here use comparable bioelectric signals to KFH Novo.

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**BEST\*\* (BioElectric Stimulation Therapy)**  
**and Wound Healing in Diabetic Patients**

**BEST reoxygenates critically ischemic foot ulcers in diabetic patients**

Design	clinical case series of 6 consecutive patients
Patients	6 diabetic patients with <ul style="list-style-type: none"> <li>- below ankle wounds or ulcers</li> <li>- periwound ischemia (TcPO<sub>2</sub> &lt; 10 mm Hg)</li> </ul>
Interventions	Daily BEST treatment at home Electrode placement over wounds Standard local wound care continued in all patients
Endpoints	1 <sup>o</sup> Cutaneous microcirculation (measured by periwound TcPO <sub>2</sub> ) 2 <sup>o</sup> Reduction in ulcer size
Results	BEST caused a marked and significant (p<.05) improvement in periwound microcirculation. (Grey = pre-BEST, and black = after BEST). 4 wounds healed and 2 patients underwent amputations.
<b>Conclusion</b>	<b>These results suggest that BEST can improve microcirculation around ischemic wounds in diabetic patients.</b>



Goldman RJ et al. Electrotherapy reoxygenates inframalleolar ischemic wounds on diabetic patients: a case series. *Adv Skin Wound Care*. 1992;29(4):328-31.

**Enhanced healing rates with BEST in diabetic ulcers**

Note	only an abstract is available for this study, hence information not complete.
Patients	80 patients with diabetic ulcers, divided into 2 treatment groups plus controls. Patients treated until wound healed or wound management changed.
Interventions	BEST used daily as <ul style="list-style-type: none"> <li>A. Asymmetrical biphasic wave form or</li> <li>B. Symmetrical biphasic square wave pulse.</li> </ul>
Endpoints	1 <sup>o</sup> healing rate
Results	60% enhancement in healing rates with protocol A versus controls. Protocol B did not increase healing rates compared to controls.
<b>Conclusion</b>	<b>BEST (as a short, pulsed biphasic waveform) increases diabetic ulcer healing rates.</b>

LL Baker e al. Effects of electrical stimulation on wound healing in patients with diabetic ulcers. *Diabetes Care*, 1997;20(3): 405-412.

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