

Summary Of A Randomized, Double-Blinded, Comparative Crossover Trial Of The Safety And Efficacy Of A Non-Invasive Targeted Electronic Pain Control Device (“Homewave® System”) Versus Transcutaneous Electrical Nerve Stimulation (TENS) For The Symptomatic Treatment Of Chronic Low Back Pain

Location: Weill Medical College of Cornell University
New York Presbyterian Hospital
New York, NY

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The IRB approved study was a double blinded, randomized, controlled study for the treatment of chronic low back pain. The study was conducted at Weill Medical College of Cornell University/New York Presbyterian Hospital in New York City. The purpose of the study was to show that (1) the Homewave® System has superior efficacy over an active control, specifically a TENS (Transcutaneous Electrical Nerve Stimulation) device for the treatment of chronic low back pain, and (2) that the Homewave® System provides a much longer residual period of pain relief than TENS following a 20-minute treatment.

In order to be eligible for the study, patients had to record a baseline pain measurement of 40 mm or higher on a visual analog scale (VAS) that was 100 mm in length. Once a patient was enrolled they were exposed to both devices through the use of a crossover design. The order of the devices to which each patient was exposed, was randomly determined before the study began.

36 treatments were performed on 18 patients. Each patient received one treatment on each device. The treatments were separated one week to ensure a proper washout period between the two devices. The patients were blinded from the devices by having the devices concealed within a large carton. There were two investigators: the investigator interviewing the patient and collecting initial patient data was also blinded from which device was being used; the second investigator was responsible for controlling the intensity of the device. For each treatment, the leadwires and electrodes were identical in appearance: 3 leadwires emanated from the carton and 3 electrodes were placed on the patient. One large electrode was placed on the abdomen, and two smaller electrodes were placed bilaterally on the lower back. For the Homewave treatment, only one of the electrodes on the lower back and the electrode on the abdomen were active. For the TENS device, only the two electrodes on the lower back were active.

Before being exposed to each device, the patient recorded the level of both their surface back pain and their deep back pain on the visual analog scale (VAS). The patient’s range of motion (ROM) was also assessed at baseline according to the protocol description. Each patient was then exposed to the first device for 20 minutes. Subsequently, the patient recorded their level of surface pain and deep pain at 0, 30, and 60 minutes following treatment, and in addition, at 4, 6, 12, 24, and 48 hours following treatment. The patient’s ROM was also re-assessed at 0, 30, and 60 minutes following treatment. A period of at least one week was allowed to pass before each patient was exposed to the second device.

Nine patients were exposed to TENS first and Homewave® second, while nine patients were exposed to Homewave® first and TENS second.

Attached are table and charts with data from the study summarizing the results for the 18 patients. Patients completed two sets of Pain Visual Analog Scale (Pain VAS) scores for baseline and post treatment pain scores. One set is for evaluating "Surface Pain" and one set is for "Deep Pain". The tables and charts show data for average percent reduction in VAS pain scores at different points in time from baseline (pre-treatment) to 24 hours post treatment for both surface and deep pain.

The data shows not only that the Homewave® System is more efficacious, but also that it has a substantially longer residual carryover effect when compared against TENS. This is true for the analyses shown in each chart.

The specific results in Table 1 and Figure 1 showed that the average percent reduction in surface pain for the Homewave® System across all 18 patients was 82% at 1 hour, 82% at 6 hours and 73% at 24 hours post treatment, versus 63% at 1 hour, 63% at 6 hours and 36% at 24 hours for TENS. In Table 2 and Figure 2, for deep pain, the average percent reduction in pain for the Homewave® System across all 18 patients was 75% at 1 hour and 53% at 24 hours post treatment versus 63% at 1 hour and 37% at 24 hours for TENS.

The controlled, randomized, double blinded results to date show that for the treatment of chronic low back pain, the Homewave® System has as much as a 24% improvement over TENS at one hour post treatment, and as much as a 51% improvement over TENS at 24 hours post treatment.

It should be noted that from the evaluation of both surface pain and deep pain, that for the Homewave® System, patients' pain relief improved over the first 1 to 4 hours post treatment, as compared to TENS, where the level of patients' pain relief exhibited an immediate decline post-treatment. It was also noted that for future studies, because patients had difficulty differentiating between "deep pain" and "surface pain," that only "pain" would be assessed using VAS measurements.

Biowave Corporation
 Confidential Test Results - Phase 3
 Cornell Blinded Controlled Randomized Crossover Chronic Low Back Pain Study
 Comparing Biowave vs. TENS
 n=18 Patients

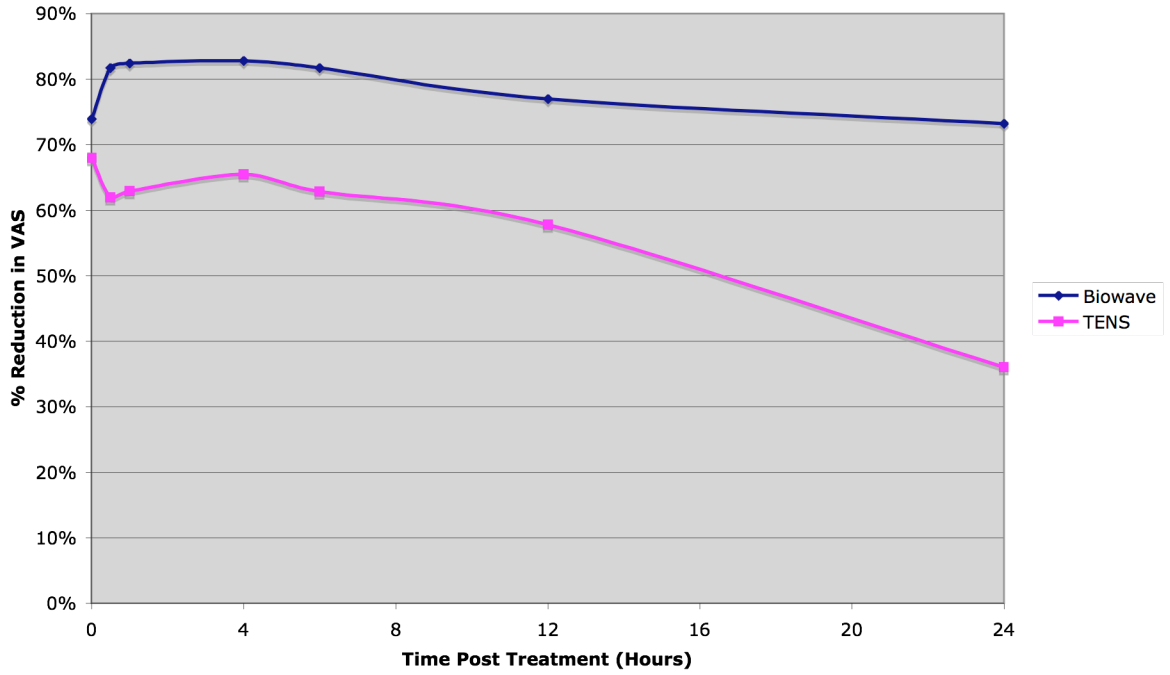
SURFACE PAIN AVG % REDUCTION in VAS			
Time (Hrs)	Biowave	TENS	Biowave
			Improvement Over TENS
0	74%	68%	8%
0.5	82%	62%	24%
1	82%	63%	24%
4	83%	65%	21%
6	82%	63%	23%
12	77%	58%	25%
24	73%	36%	51%

Table 1

DEEP PAIN AVG % REDUCTION in VAS			
Time (Hrs)	Biowave	TENS	Biowave
			Improvement Over TENS
0	62%	66%	-6%
0.5	69%	57%	18%
1	75%	63%	17%
4	69%	61%	12%
6	67%	58%	13%
12	56%	51%	11%
24	53%	37%	31%

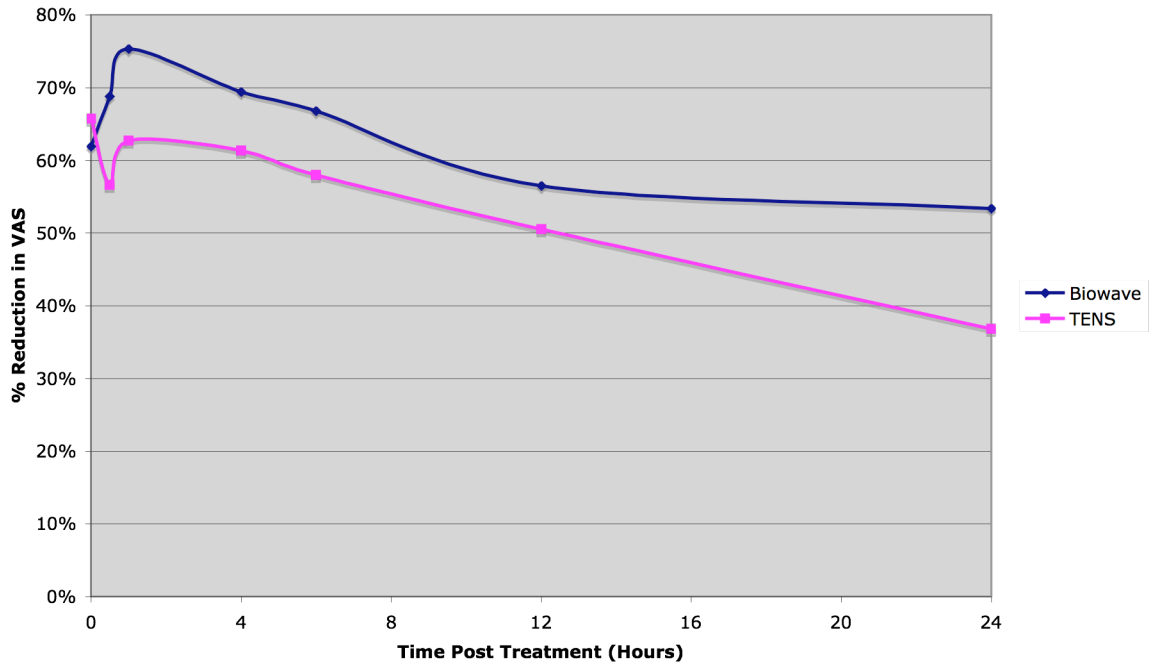
Table 2

**AVG % Reduction in VAS
for Surface Pain**



**Figure 1. Average Percent Reduction in VAS for Surface Pain-
Cornell Double Blinded Controlled Randomized Crossover Chronic Low Back Pain Study**

**AVG % Reduction in VAS
for Deep Pain**



**Figure 2. Average Percent Reduction in VAS for Deep Pain
Cornell Double Blinded Controlled Randomized Crossover Chronic Low Back Pain Study**