

PubMed:

U.S. National Library of Medicine
National Institutes of Health

Articles about H-Wave

J Strength Cond Res. 2009 Dec;23(9):2560-7.

Comparison of swim recovery and muscle stimulation on lactate removal after sprint swimming.

Neric FB, Beam WC, Brown LE, Wiersma LD.

Exercise Physiology Laboratory, Department of Kinesiology, California State University, Fullerton, Fullerton, California, USA.

Competitive swimming requires multiple bouts of high-intensity exercise, leading to elevated blood lactate. Active exercise recovery has been shown to lower lactate faster than passive resting recovery but may not always be practical. An alternative treatment, electrical muscle stimulation, may have benefits similar to active recovery in lowering blood lactate but to date is unstudied. Therefore, this study compared submaximal swimming and electrical muscle stimulation in reducing blood lactate after sprint swimming. Thirty competitive swimmers (19 men and 11 women) participated in the study. Each subject completed 3 testing sessions consisting of a warm-up swim, a 200-yard maximal frontcrawl sprint, and 1 of 3 20-minute recovery treatments administered in random order. The recovery treatments consisted of a passive resting recovery, a submaximal swimming recovery, or electrical muscle stimulation. Blood lactate was tested at baseline, after the 200-yard sprint, and after 10 and 20 minutes of recovery. A significant interaction ($p < 0.05$) between recovery treatment and recovery time was observed. Blood lactate levels for the swimming recovery were significantly lower at 10 minutes (3.50 ± 1.57 mmol.L⁻¹) and 20 minutes (1.60 ± 0.57 mmol.L⁻¹) of recovery than either of the other 2 treatments. Electrical muscle stimulation led to a lower mean blood lactate (3.12 ± 1.41 mmol.L⁻¹) after 20 minutes of recovery compared with passive rest (4.11 ± 1.35 mmol.L⁻¹). Submaximal swimming proved to be most effective at lowering blood lactate, but electrical muscle stimulation also reduced blood lactate 20 minutes postexercise significantly better than resting passive recovery. Electrical muscle stimulation shows promise as an alternate recovery treatment for the purpose of lowering blood lactate.

PMID: 19910818 [PubMed - in process]

Repetitive H-Wave device stimulation and program induces significant increases in the range of motion of post operative rotator cuff reconstruction in a double-blinded randomized placebo controlled human study.

Blum K, Chen AL, Chen TJ, Waite RL, Downs BW, Braverman ER, Kerner MM, Savarimuthu SM, DiNubile N.

Department of Physiology & Pharmacology, Wake Forest University School of Medicine, Winston -Salem, North Carolina, USA.

drd2gene@aol.com

BACKGROUND: Albeit other prospective randomized controlled clinical trials on H-Wave Device Stimulation (HWDS), this is the first randomized double-blind Placebo controlled prospective study that assessed the effects of HWDS on range of motion and strength testing in patients who underwent rotator cuff reconstruction. **METHODS:** Twenty-two patients were randomly assigned into one of two groups: 1) H-Wave device stimulation (HWDS); 2) Sham-Placebo Device (PLACEBO). All groups received the same postoperative dressing and the same device treatment instructions. Group I was given HWDS which they were to utilize for one hour twice a day for 90 days postoperatively. Group II was given the same instructions with a Placebo device (PLACEBO). Range of motion was assessed by using one-way ANOVA with a Duncan Multiple Range Test for differences between the groups preoperatively, 45 days postoperatively, and 90 days postoperatively by using an active/passive scale for five basic ranges of motions: Forward Elevation, External Rotation (arm at side), External Rotation (arm at 90 degrees abduction), Internal Rotation (arm at side), and Internal Rotation (arm at 90 degrees abduction). The study also evaluated postoperative changes in strength by using the Medical Research Council (MRC) grade assessed strength testing. **RESULTS:** Patients who received HWDS compared to PLACEBO demonstrated, on average, significantly improved range of motion. Results confirm a significant difference for external rotation at 45 and 90 days postoperatively; active range at 45 days postoperatively ($p = 0.007$), active at 90 days postoperatively ($p = 0.007$). Internal rotation also demonstrated significant improvement compared to PLACEBO at 45 and 90 days postoperatively; active range at 45 days postoperatively ($p = 0.007$), and active range at 90 days postoperatively ($p = 0.006$). There was no significant difference between the two groups for strength testing. **CONCLUSION:** HWDS compared to PLACEBO induces a significant increase in range of motion in positive management of rotator cuff reconstruction, supporting other previous research on HWDS and improvement in function. Interpretation of this preliminary investigation while suggestive of significant increases in Range of Motion of Post - Operative Rotator Cuff Reconstruction, warrants further confirmation in a larger double-blinded sham controlled randomized study.

H-Wave induces arteriolar vasodilation in rat striated muscle via nitric oxide-mediated mechanisms.

Smith TL, Blum K, Callahan MF, DiNubile NA, Chen TJ, Waite RL.

Department of Orthopedic Surgery, Wake Forest University School of Medicine, Winston-Salem, North Carolina 27157-1070, USA.
tsmith@wfubmc.edu

H-Wave electrical device stimulation (HWDS) is used clinically to expedite recovery from soft tissue injuries. We hypothesized that HWDS induces arteriolar dilation, a mechanism involved in the healing process. Acute effects of HWDS on striated muscle arteriolar diameters were studied. Arteriolar diameters were measured in the cremaster muscle of 57 male anesthetized rats using intravital microscopy before and after HWDS or sham stimulation (SS) at 1 or 2 Hz for periods of 30-60 min. In a separate cohort, the role of nitric oxide (NO) in the response to HWDS was assessed by blocking NO synthase using topical L-NAME at 10(-5) M. Maximal arteriolar responses to stimulation were compared to prestimulation diameters. HWDS both at 1 and 2 Hz resulted in significant arteriolar vasodilation ($p < 0.05$). The arterioles in SS animals demonstrated no changes in diameter. Similarly, microvascular diameters did not change with HWDS following blockade of NO production. Because of Poiseuille's Law, the significant arteriolar dilation induced by HWDS would translate into increases in blood flow of 26-62%. In addition, lack of arteriolar dilation following HWDS with blockade of NO production suggests that NO plays a role in the microvascular response to HWDS. These studies suggest that arteriolar vasodilation accompanying HWDS may result in increased perfusion, contributing to the observed therapeutic effects of HWDS. (c) 2009 Orthopaedic Research Society.

PMID: 19204915 [PubMed - indexed for MEDLINE]

Phys Sportsmed. 2008 Dec;36(1):103-14.

The H-Wave((R)) Device Induces NO-Dependent Augmented Microcirculation and Angiogenesis, Providing Both Analgesia and Tissue Healing in Sports Injuries.

Blum K, Ho CK, Chen AL, Fulton M, Fulton B, Westcott WL, Reinl G, Braverman ER, Dinubile N, Chen TJ.

Department of Physiology and Pharmacology, Wake Forest University School of Medicine, Winston Salem, NC, 27157, USA. drd2gene@aol.com.

The hypothesis that the H-Wave(R) device (Electronic Waveform Lab, Inc., Huntington Beach, CA), a small-diameter fiber stimulator, is a paradigm shift of electrotherapeutic treatment of pain associated with human neuropathies and sports injuries is based on a number of its properties. The primary effect of H-Wave(R) device stimulation (HWDS) is the stimulation of "red-slow-twitch" skeletal muscle fibers. The authors propose, based on the unique waveform, that the H-Wave(R) device specifically and directly stimulates the small smooth muscle fibers within the lymphatic vessels ultimately leading to fluid shifts and reduced edema. In unpublished rat studies, it has been observed that HWDS induces protein clearance. The H-Wave(R) device was designed to stimulate an ultra low frequency (1-2 Hz), low tension, nontetanic, and nonfatiguing contraction, which closely mimics voluntary or natural muscle contractions. The H-Wave(R) device can stimulate small fibers due in part to its exponentially decaying waveform and constant current generator activity. The main advantage of these technologies over currently applied electrical stimulators (eg, transcutaneous electrical nerve stimulator [TENS], interferential [IF], neuromuscular electrical stimulation [NMES], high-volt galvanic, etc.) is that H-Wave(R) small fiber contraction does not trigger an activation of the motor nerves of the large white muscle fibers or the sensory delta and C pain nerve fibers, thus eliminating the negative and painful effects of tetanic fatigue, which reduces transcapillary fluid shifts. Another function of the H-Wave(R) device is an anesthetic

effect on pain conditions, unlike a TENS unit which in the short term activates a hypersensory overload effect (gate theory) to stop pain signals from reaching the thalamic region of the brain. When the H-Wave(R) device is used at high frequency (60 Hz), it acts intrinsically on the nerve to deactivate the sodium pump within the nerve fiber, leading to a long-lasting anesthetic/analgesic effect due to an accumulative postsynaptic depression. Moreover, HWDS produces a nitric oxide (NO)-dependent enhancement of microcirculation and angiogenesis in rats. Thus, the authors hypothesize that because of these innate properties of the H-Wave(R) device, it may provide a paradigm shift for the treatment of both short- and long-term inflammatory conditions associated with pain due to sports injuries. A recent meta-analysis found a moderate-to-strong effect of the H-Wave(R) device in providing pain relief, reducing the requirement for pain medication, and increasing functionality. The most robust effect was observed for improved functionality, suggesting that the H-Wave(R) device may facilitate a quicker return to the field. Keywords: H-Wave(R) device; sportsmedicine, nitric oxide-dependent blood flow; analgesia; angiogenesis.

PMID: 20048478 [PubMed - in process]

Adv Ther. 2008 Jul;25(7):644-57.

The H-Wave device is an effective and safe non-pharmacological analgesic for chronic pain: a meta-analysis.

Blum K, Chen AL, Chen TJ, Prihoda TJ, Schoolfield J, DiNubile N, Waite RL, Arcuri V, Kerner M, Braverman ER, Rhoades P, Tung H.

Department of Physiology and Pharmacology, Wake Forest University, School of Medicine, Winston-Salem, North Carolina 27157, USA.

drd2gene@aol.com

INTRODUCTION: This meta-analysis was conducted to systematically review the efficacy and safety of the H-Wave (Electronic Waveform Lab, Inc, Huntington Beach, CA, USA) device and programme as a non-pharmacological analgesic treatment in chronic soft tissue inflammation and neuropathic pain. **METHODS:** Five studies related to pain relief, reduction in pain medication and increased functionality obtained with the H-Wave device were included in the analysis. Data were analysed using the random effects model, including adjustment to evaluate variability, size of study and bias in effect size. A total of 6535 participants were included in the meta-analysis; there were 8065 participants' outcomes measured due to multiple measurements per participant. **RESULTS:** The H-Wave device decreased pain ratings across various chronic soft tissue inflammation and neuropathic pain conditions. The mean weighted effect size was 0.59, and the estimated effect size variance was 0.00003 (95% confidence intervals [CI]: 0.580, 0.600). The H-Wave device also decreased the intake of pain medication in patients with various chronic soft tissue inflammation and neuropathic pain conditions. The mean weighted effect size was 0.56, and the estimated effect size variance was 0.000013 (95% CI: 0.553, 0.567). Patient functionality was also improved with use of the H-Wave device. The mean weighted effect size was 0.70, and the estimated effect size variance was 0.00002 (95% CI: 0.691, 0.709). A chi-square test for homogeneous effect sizes found highly significant ($P < 0.00001$) variability, indicating a robust significant effect size for increased functionality relative to both pain relief and reduction in pain medication. There was little to no evidence of any adverse effects

associated with the use of the H-Wave device. **CONCLUSION:** The findings indicate a moderate to strong effect of the H-Wave device in providing pain relief, reducing the requirement for pain medication and increasing functionality. The most robust effect was observed for improved functionality, suggesting that the H-Wave device may facilitate a quicker return to work and other related daily activities.

PMID: 18636234 [PubMed - indexed for MEDLINE]

Adv Ther. 2006 Sep-Oct;23(5):739-49.

The H-Wave small muscle fiber stimulator, a nonpharmacologic alternative for the treatment of chronic soft-tissue injury and neuropathic pain: an extended population observational study.

Blum K, Chen TJ, Martinez-Pons M, Dinubile NA, Waite RL, Schoolfield J, Blum SH, Mengucci J, Downs BW, Meshkin B.

Department of Physiology and Pharmacology, Wake Forest University School of Medicine, Winston-Salem, North Carolina 27157, USA.

In a previous study, the H-Wave small-muscle fiber stimulator significantly reduced chronic pain and restored physical function among patients with pain in the lower and upper extremities and spine. In this extended population observational study, a cross-sectional, computer-administered 10-item survey was administered to 6774 patients (3367 men [49.7%], 3406 women [50.3%], and 1 sex not reported [<1%]; mean \pm SD age, 45.28 \pm 10.08 y; range, 18-65 y) with chronic soft-tissue injury or neuropathic pain to assess their therapeutic response. The mean \pm SE duration of self-administered H-Wave treatment before the survey was completed was 87.35 \pm 1.39 d. Sixty-five percent of study participants reported a reduced or eliminated need for pain medication; 79% reported improved functional capacity or activity; and 78% reported 25% or greater reduction of pain. This cross-sectional evaluation represents the largest outcome study on the benefits of the H-Wave device in patients with chronic soft-tissue injury or neuropathic pain. The results suggest that this nonpharmacologic approach may provide an important alternative to standard pharmacologic treatment.

PMID: 17142209 [PubMed - indexed for MEDLINE]

Adv Ther. 2006 May-Jun;23(3):446-55.

H-Wave, a nonpharmacologic alternative for the treatment of patients with chronic soft tissue inflammation and neuropathic pain: a preliminary statistical outcome study.

Blum K, DiNubile NA, Tekten T, Chen TJ, Waite RL, Schoolfield J, Martinez-Pons M, Callahan MF, Smith TL, Mengucci J, Blum SH, Meshkin B.

Department of Physiology and Pharmacology, Wake Forest University School of Medicine, Winston-Salem, NC 27157, USA.

The burden of chronic soft tissue inflammation and neuropathic pain on individuals and society is substantial. This study was conducted to evaluate the H-wave device--an innovative form of treatment for chronic pain and inflammation--in patients with persistent pain associated with injuries or conditions affecting the upper or lower extremities or the back. Patients with at least moderate pain despite conventional therapy were included in a systematic survey after they had been given 2 to 6 wk of treatment with the H-wave device. Measures of improvement involved the proportion of patients with diminished medication requirements, improved function, or pain relief greater than 25%. More than 60% of patients with pain in the lower extremities, upper extremities, or back experienced pain relief exceeding 25%. The proportion of patients whose function improved and who were able to perform a new activity was consistently greater than 50% across the 3 anatomic subgroups. More than 40% of patients in each group were able to reduce or completely eliminate the use of pain medications. These benefits of treatment were independent of the type of pain therapy administered previously. In each anatomic subgroup, the proportion of patients who reported improvement on more than 1 of the 3 endpoints was significantly higher than the expected response to placebo therapy ($P < .001$). Results suggest that the H-wave device provided important benefits to patients with chronic soft tissue inflammation and neuropathic pain.

PMID: 16912027 [PubMed - indexed for MEDLINE]

Diabetes Technol Ther. 1999 Spring;1(1):77-80.

Transcutaneous electrostimulation: emerging treatment for diabetic neuropathic pain.

Alvaro M, Kumar D, Julka IS.

California College of Podiatric Medicine, San Francisco, California, USA.

Diabetes Technol Ther. 1999 Spring;1(1):81-3.

Three independent studies utilizing transcutaneous electrical nerve stimulation to relieve diabetic peripheral neuropathic pain were reviewed. The proprietary equipment, an H-wave machine, administered all electrotherapy. The first two studies assessed the efficacy of electrotherapy alone and electrotherapy with amitriptyline. The treated electrotherapy group reported an overall greater reduction of symptoms, 52% with 2-3 weeks of active treatment. Amitriptyline alone produced a 26% reduction of pain after 4 weeks. The addition of active electrotherapy to amitriptyline produced a 66%

reduction of pain. The final study looked at patients who have utilized electrotherapy for over one year. A reported 44% improvement of symptoms was attained with continuous electrotherapy treatment. The data also suggested that a maintenance treatment protocol for long-term pain relief would have to be developed.

PMID: 11475308 [PubMed - indexed for MEDLINE]

Diabetes Care, 1998 Aug;21(8):1322-5.

Diabetic peripheral neuropathy. Effectiveness of electrotherapy and amitriptyline for symptomatic relief.

Kumar D, Alvaro MS, Julka IS, Marshall HJ.

Department of Medicine, Los Angeles County University of Southern California Medical Center 90033, USA.

OBJECTIVE: To evaluate the efficacy of combining electrotherapy with amitriptyline for the management of chronic painful peripheral neuropathy in patients with type 2 diabetes. **RESEARCH DESIGN AND METHODS:** Patients (n = 26) with peripheral neuropathy were treated with amitriptyline. After 4 weeks, those patients (n = 23) who failed to respond to amitriptyline or who only had partial relief were randomized between a sham treatment group (control) or an electrotherapy group. Transcutaneous electrotherapy was given for 12 weeks by a portable unit (H-wave machine) that generated a biphasic exponentially decaying waveform (pulse width 4 ms, 25-35 V, > or = 2 Hz). The degree of pain and discomfort was graded on a scale of 0-5. An analog scale was used to record the overall change in symptoms. **RESULTS:** Amitriptyline produced some degree of symptomatic relief in 15 (60%) of the 26 patients by the 4th week; pain scores decreased from 3.8 +/- 0.1 to 2.9 +/- 0.2 (P < 0.1) and the overall reduction in pain was 26 +/- 5% on an analog scale. In the amitriptyline plus sham treatment group (n = 9), pain scores declined from 2.8 +/- 0.3 to 1.9 +/- 0.5 (P < 0.03) and the overall reduction in pain was 55 +/- 12%, suggesting a procedure-related placebo effect. In the group receiving combined electrotherapy and amitriptyline (n = 14), symptomatic improvement occurred in 12 (85%) patients. Five (36%) of the patients in this group became asymptomatic. Pain scores declined from 3.2 +/- 0.2 to 1.4 +/- 0.4 (P < 0.01) and the overall reduction in pain was 66 +/- 10%. The degree of reduction in pain scores and the incremental relief (above the amitriptyline effect) were significantly greater (P < 0.03) with electrotherapy as compared with sham treatment. The outcomes indicate a substantial beneficial effect of electrotherapy over and above any placebo influence.

CONCLUSIONS: Our clinical observations suggest that transcutaneous electrotherapy is effective in reducing the pain associated with peripheral neuropathy. This form of therapy may be a useful adjunctive modality when it is combined with a pharmacological agent, such as amitriptyline, to augment symptomatic relief.

PMID: 9702441 [PubMed - indexed for MEDLINE]

J Foot Ankle Surg. 1998 May-Jun;37(3):191-4.

Beneficial effects of electrical stimulation on neuropathic symptoms in diabetes patients.

Julka IS, Alvaro M, Kumar D.

Department of Medicine, Los Angeles County University of Southern California Medical Center, University of Southern California School of Medicine 90033, USA.

Transcutaneous electrical nerve stimulation is utilized for relieving pain in the diabetes peripheral neuropathy. Previous studies were short-term and did not document sustained beneficial effects. In this study, the authors evaluated long-term effectiveness of electrotherapy administered by proprietary equipment, an H-wave machine. A detailed questionnaire concerning patients' symptoms prior to and following electrotherapy was mailed to the users of H-wave machine. The responses of 34 individuals who had diabetes mellitus were analyzed (age 74.1 +/- 1.6 SEM years, body mass index 28.5 +/- 0.8 kg/m², duration of diabetes 15.8 +/- 2.0 years and duration of neuropathic symptoms 8.0 +/- 1.8 years). Telephone interviews were conducted with 20 additional diabetes patients selected randomly from the persons who did not return the questionnaire. Forty-one (76%) patients reported a 44.0 +/- 4.0% subjective improvement in their neuropathic pain. The overall improvement in pain was also significant on an analog scale of 10 ($p < .01$), and correlated well with the percent amelioration data ($r^2 = .65$). These data suggest an effectiveness of electrotherapy in managing neuropathic pain as an adjunct to the analgesics. It appears to provide continued benefit as the responders have used this nonpharmacological treatment modality for an average period of 1.7 +/- 0.3 years.

PMID: 9638542 [PubMed - indexed for MEDLINE]

Diabetes Care. 1997 Nov;20(11):1702-5.

Diabetic peripheral neuropathy: amelioration of pain with transcutaneous electrostimulation.

Kumar D, Marshall HJ.

Department of Medicine, Los Angeles County University of Southern California Medical Center 90033, USA.

OBJECTIVE: To evaluate the efficacy of transcutaneous electrotherapy for chronic painful peripheral neuropathy in patients with type 2 diabetes. **RESEARCH DESIGN AND METHODS:** Thirty-one patients with symptoms and signs of peripheral neuropathy were randomized to the electrotherapy or sham treatment (control) group. The electrostimulation was given by a portable unit (H-Wave machine) than generated a biphasic, exponentially decaying waveform (pulse width

4 ms, 25-35 V, > or = 2 Hz). Patients treated each of their lower extremities for 30 min daily for 4 weeks at home. Nine patients from the sham-treatment group participated for a second period, during which all of them received the active electrotherapy. Patient's degree of pain and discomfort was graded on a scale of 0 to 5. **RESULTS:** In the sham-treated group (n = 13), the neuropathic symptoms improved in five (38%) patients, and the pain score declined from 2.92 +/- 0.13 to 2.38 +/- 0.26 (P < 0.04), suggesting a procedure-related placebo effect. In the electrotherapy group (n = 18), symptomatic improvement was seen in 15 (83%) cases, 3 of which were completely asymptomatic; the pain score declined from 3.17 +/- 0.12 to 1.44 +/- 0.25 (P < 0.01) and the posttreatment pain scores were considerably lower (P < 0.03), indicating a substantial treatment effect over and above any placebo influence. Patients in the electrotherapy group reported greater reduction in symptoms (52 +/- 7% vs. 27 +/- 10% in control subjects, P < 0.05) on an analog scale. Moreover, the electrotherapy decreased pain scores (from 3.0 +/- 0.62 to 1.56 +/- 0.32, P < 0.02) in nine patients who had received sham treatment earlier. **CONCLUSIONS:** A form of transcutaneous electrotherapy ameliorated the pain and discomfort associated with peripheral neuropathy. This novel modality offers a potential non-pharmacological treatment option.

PMID: 9353612 [PubMed - indexed for MEDLINE]

Submitted for Publication

Cases Journal (accepted ... publication date pending)

Healing enhancement of chronic venous stasis ulcers utilizing h-wave® device therapy: a case series

Kenneth Blum^{1,4,6,7,9*}, Amanda LH Chen², Thomas JH Chen³, B William Downs⁴, Eric R Braverman^{5,6}, Mallory Kerner⁶, Stella Savarimuthu,⁶Anish Bajaj,⁶ Margaret Madigan⁷, Seth H Blum⁷, Gary Reinl⁸, John Giordano,⁹Nicholas DiNubile¹⁰

Addresses:

¹Department of Psychiatry, University of Florida College of Medicine, Gainesville, FL, USA, ²Engineering & Management of Advanced Technology, Chang Jung University, Taiwan, Republic of China, ³Department of Occupation Health and Safety, Chang Jung University, Taiwan, Republic of China, ⁴ Department of Nutrigenomics, LifeGen, Inc. La Jolla, CA, USA, ⁵ Department of Neurosurgery, Weill Cornell School of Medicine, New York, NY, USA, ⁶Department of Clinical Research, Path Research Foundation, New York, NY USA, ⁷Department of Personalized Medicine, Synaptamine, Inc. San Antonio, Texas, USA, ⁸Nautilus, Inc. Vancouver, WA, USA, ⁹Department of Holistic Medicine, G&G Holistic Addiction Treatment Center (Pain Track) North Miami Beach, Florida, USA, ¹⁰Department of Orthopedic Surgery, Hospital of the University of Pennsylvania, Philadelphia, PA, USA

KB*: Drd2gene@aol.com

Abstract

Approximately 15% (more than 2 million individuals, based on these estimates) of all people with diabetes will develop a lower-extremity ulcer during the course of the disease. Ultimately, between 14% and 20% of patients with lower-extremity diabetic ulcers will require amputation of the affected limb. Analysis of the 1995 Medicare claims revealed that lower-extremity ulcer care accounted for \$1.45 billion in Medicare costs. Therapies that promote rapid and complete healing and reduce the need for expensive surgical procedures would impact these costs substantially. One such example is the electrotherapeutic modality utilizing the H-Wave® device therapy and program.

It has been recently shown in acute animal experiments that the H-Wave device stimulation induces a nitric oxide-dependent increase in microcirculation of the rat Cremaster skeletal muscle. Moreover, chronic H-Wave device stimulation of rat hind limbs not only increases blood flow but induces measured angiogenesis. Coupling these findings strongly suggests that H-Wave device stimulation promotes rapid and complete healing without need of expensive surgical procedures.

Hospital Practice (in final review)

H-Wave Device® Augments Healing by Inducing Cellular Mechanisms Responsible For Increased Blood Flow and Loading of Injured Tissue: A hypothesis Having implications for Clinical Practice.

Kenneth Blum^{a,b,f,g,i,l,n}, Thomas JH Chen^b, Gary Reinl^c, Amanda LH Chen^d, Nicholas DiNubile^e, Margaret Madigan^f, B. William Downs^g, Abdalla Bowirrat^h, Anish Bajaj^l, Siohban Morseⁱ, John Giordano^k, Wayne Westcott^l, Leonard Smith^m, Mallory Kerner,ⁿ Uma Damleⁿ and Eric R. Braverman^{n,m}.

^aDepartment of Psychiatry, University of Florida, College of Medicine & McKnight Brain Institute, Gainesville, Florida, USA. ^bDepartment of Health and Occupational Safety, Chang Jung Christian University, Taiwan, Republic of China ^cNautilus Inc., Vancouver, WA ^dDepartment of Advanced Engineering, Chang Jung Christian University, Taiwan, Republic of China ^eDepartment of Orthopedic Surgery, Hospital of the University

of Pennsylvania, Philadelphia, Pennsylvania . ^f Department of Molecular Nutrition, Synaptamine, Inc. San Diego, California. ^g Department of Nutrigenomics and Personalized Medicine, LifeGen, Inc, San Diego, California ^h Clinical Neuroscience and Population Genetics, Ziv Government Medical Center, Safed, Israel, ⁱ Department of Executive Health, Path Research Foundation NY, New York, New York. ^j Department of Holistic Rehabilitation, National Institute of holistic Studies, North Miami Beach, Florida ^{jk} Department of Holistic Medicine and Pain Track, , G & G Holistic Addiction Treatment Center, North Miami Beach, Florida ^{ll} Department of Exercise Science, Quincy College, Quincy, Massachusetts ^{mm} Department of Surgery, University of Miami School of Medicine, Miami, Florida., ⁿⁿ Department of Neurological Surgery, Weil Cornell College of Medicine, New York, New York., ^{oo} Path Research Foundation NY, New York, New York

S U M M A R Y

The hypothesis is that the H-Wave ® device (Electronic Waveform Lab, Inc., Huntington Beach, CA) a small diameter fiber stimulator, is a paradigm shift in electrotherapeutic treatment used to augment tissue healing associated with human neuropathies and injuries. Its effect is based on known cellular mechanisms, which increase blood flow and loading of injured loci. The primary effect of H-Wave ® device stimulation (HWDS) is the stimulation of “red –slow-twitch” skeletal muscle fibers. We are proposing that HWDS directly stimulates the smooth muscle fibers within the lymphatic vessels. This leads to reduced edema, the induction of nitrous oxide (NO)-dependent augmented microcirculation and angiogenesis. It is further hypothesized that these cellular mechanisms coupled with the unique ability of HWDS to load healing injured muscle tissue by inducing small muscle contraction will lead to accelerated healing. Since unlike others (TENS, IF, NMES etc) the device does not trigger an activation of the motor nerves of large white muscle fibers or the sensory delta and C pain nerve fibers. Thus, the negative and painful effects of tetanizing fatigue, which reduces trans-capillary fluid shifts are eliminated and healing is accelerated. Accordingly clinical scientists correctly suggest that patients with musculoskeletal injuries and those who have recently undergone surgery should be treated with controlled physical activity that loads their healing tissues. Once a decision to introduce activity that loads the healing tissue is made, techniques that help calm irritated muscles and nerves and/or around the healing tissue like: lymphatic massage, accupressure, trigger point release, muscle activation (i.e. ankle pumps, non-tetanizing powered muscle stimulation) will assist in this process. The H-Wave ® device was designed using a unique waveform, to stimulate an ultra low frequency (1-2Hz), low tension, non-tetanizing and non-fatiguing contraction, which closely mimics voluntary muscle contractions. In support of the beneficial outcome of HWDS a recent meta-analysis found a moderate-to-strong-positive effect of the H-Wave ® device in providing pain relief, reducing requirement for pain medication, and increasing functionality. The most robust effect observed was for improved functionality, suggesting that HWDS may facilitate a quicker return to work and thus warrants further intense investigation. In agreement with Buckwalter and Grodzinsky [1] and others, the promotion of healing of bone, fibrous tissue and muscle should include consideration of the effects of loading on tissue repair and remodeling. Utilizing controlled intensity the HWDS approach provides the basis for early induction of loading potentially even before the repair process occurs. In this hypothesis we intend to show the relevance of loading derived from HWDS (repetitive muscle contractions) coupled with increased blood flow (increased perfusion due to NO and angiogenesis) as an important electrotherapeutic approach to treat musculoskeletal disorders, tissue and sports injuries, neuropathies and for enhancement of overall performance.

Hypothesis

H-wave® electrical device stimulation (HWDS) is used clinically to expedite recovery from soft tissue injuries. The process of healing tissues involves many factors predominantly: (a) Loading of bone, fibrous tissue and muscle; (b) Nitric –oxide dependent increase in blood flow (c) increased formation of new blood vessels or angiogenesis and (d) increase in protein clearance at injured loci. While loading in by itself may promote healing through these known elements and the loading of injured tissue seems parsimonious (when the injury reaches stability), we hypothesize that since HWDS accomplishes all of these required healing elements, it may become a frontline approach to promote soft tissue healing. Support of this hypothesis, albeit the need for more intensive research, is derived from both animal and human studies delineated in this hypothesis article. It is further hypothesized that genotyping for certain genetic antecedents for pain and tissue healing may significantly increase positive outcomes (e. g. mu-opioid receptor, dopamine D2 receptor, TNF-alpha, interleukens and eNOs) of the utilization of the HWDS [see schematic figure 1].