Pain Care Labs M-Stim® Devices: NIH or Investigator-Initiated Studies

Multimodal mechanical stimulation reduces acute and chronic low back pain: Pilot data from a HEAL phase 1 study. Baxter A, Thrasher A, Etnoyer-Slaski JL, Cohen LL. 2023 Front Pain Res (Lausanne). 2023 Apr 26;4:1114633. "Results suggested pain relief independent of thermal modality, patient age, or pain chronicity." Pain reduced 57% on 10-pt VAS scale. DOI:10.3389/fpain.2023.1114633.

Effectiveness of Vibration on Myofascial Trigger Points. Gulick D, Campbell S, Palombaro K. 2023 World Journal of Yoga, Physical Therapy and Rehabilitation. 2023 Oct 25. "VibraCool was as effective as manual compression for pain reduction of myofascial trigger points, suggesting a time saving and physical reduction of hand/thumb strain for therapists using manual therapies." DOI: 10.33552/WJYPR.2023.04.000583

Crossover trial of novel mechanical oscillatory vibration frequency device versus TENS for musculoskeletal pain. Marovino T, Baxter A. Mean pain relief with VC high frequency vibration was 3.60 +/- 1.60 (95%CI 2.85 to 4.35). Pain relief with TENS was 1.40 +/- 1.05 (95%CI 0.91 to 1.89), with a mean difference of -2.2 +/- 1.34 (95%CI-2.85 to -1.55, P<.0001). Pain relief with VC was greatest for spine, injury and post-surgical pain (5-6) and least for OA (2-3). AAPM&R November 2019, Poster 721211A.

Pain Therapy Options for Home: a patient-based outcome review of at-home pain management devices. Marovino T, Majewski M. Practical Pain Management 19(1):56-59. "Valuable for very difficult-to-treat enthesopathic conditions that in many cases are unresponsive or recalcitrant to other forms of energy or manual therapies." OR pain relief for pooled data 2.25 with a 95% CI (1.34 - 3.77) and a z statistic (3.077), (P = 0.0021).

Effects of Focal Vibration on Pain and Opioid Usage following ACL Reconstruction: A Pilot Study. [Authors Redacted] Patients reported using an average of 10.1±10.3 opioid tablets in the first week following surgery, 35% less than in historical cohort (15.6±8.5) (Cohen's d 0.58), and 19.5% less than with opioid reduction coaching. Only 4 patients continued opioids by 4.3±2.3 days post-surgery. (Full abstract on pg. 7)

In progress:
Effect of Vibration and Cold Application on Chest Tube Removal Pain After CABG (CABG) Oyku Kara, Istanbul University - Cerrahpasa (IUC) NCT06217263
Impact of DuoTherm on opioid initiation in low back pain: NCT04491175; Impact of DuoTherm on opioid use in chronic low back pain: NCT04494698
VibraCool for post-op ACL pain and opioid use: Mastroianni, MA, Redler L. Columbia Orthopedics
VibraCool Pro for Opioid Reduction after TKA: Odonkur, C. Yale Medical School.
The Effect of Vibration And Cryotherapy on Lateral Elbow Pain. Gulick DT, Wise CH, Everett TS. Widener University Department of Physical Therapy

Our patented M-Stim® technology blocks pain through spinal gating neuromodulation. The same mechanical forces can be used therapeutically for muscle, bone, and even cellular growth. A gorwing body of M-Stim® research shows that specific frequencies of vibration enhance physical therapy, reduce post-surgical opioid use, increase blood flow and bone growth, and facilitate recovery after stroke. We combine **evidence-based** M-Stim® with thermal therapy (to address spasm or inflammation) and compression, not just to block pain, but to treat the musculoskeletal conditions that cause it.

See Also - Pain Care Labs M-Stim® Devices - Buzzy Literature Review:

PainCareLabs.com/downloadable-resources

VibraCool
« CRYOVIBRATION »

Vibration Pain Relief Physiology

The analgesic effect of localized vibration: a systematic review. Casale R, Hansson P. Part 1: the neurophysiological basis. Eur J Phys Rehabil Med. 2022 Apr;58(2):306-315. "Data indicate that [localized vibration] relieves pain not only by acting on the spinal gate, but also at higher levels of the nervous system." PMID: 35102735

Wearable Focal Muscle Vibration on Pain, Balance, Mobility, and Sensation in Individuals with Diabetic Peripheral Neuropathy: A Pilot Study. Chandrashekhar R, Wang H, Dionne C, James S, Burzycki J. Int J Environ Res Public Health. 2021 Mar 2;18(5):2415. "The participants were highly satisfied with wearable [focal muscle vibration (FMV)] and were 100% compliant. FMV therapy was associated with improved pain, mobility, and sensation." PMID: 33801216

How does vibration reduce pain? Hollins M. et al. Perception. 2014;43(1):70-84 Elegant review of physiologic studies to date, underscores Pacinian influence and lack of cognitive distraction as mechanism. PMID: 24689133

Mechanisms of pain relief by vibration and movement. Kakigi R, Shibasaki H. J Neurol Neurosurg Psychiatry. 1992;55:282–286. PMID: 1583512

Vibration therapy to improve pain and function in patients with chronic low back pain: a systematic review and meta-analysis. Li Q, Liu P, Wang Z, Li X. J Orthop Surg Res. 2023 Sep 26;18(1):727. "The data from this study suggest that [vibration therapy] can reduce pain and improve lumbar function in patients with [chronic low back pain]." PMID: 37752526

Vibratory stimulation for the alleviation of chronic pain. Lundeberg T. Acta Physiol Scand Suppl. 1983;523:1-51 Seventy percent of 596 chronic pain patients reported reduction of pain with vibration; 100-150Hz were most effective, with subsequent cold enhancing duration of pain relief 12 hours or more. PMID: 6609524

Pain alleviation by vibratory stimulation. Lundeberg T, et al. Pain. 1984 Sep;20(1):25-44. In 366 patients with acute or chronic pain, direct application of vibration for 25 – 45 minutes achieved the best pain relief. PMID: 6333660

Reduction of TMD pain by high-frequency vibration: a spatial and temporal analysis. Roy EA, Hollins M, Maixner W. Pain. 2003;101:267–74. 100Hz, but not 20Hz, reduced pain in 17 patients with facial pain. PMID: 12583869

Local Vibratory Stimulation for Temporomandibular Disorder Myofascial Pain Treatment: A Randomized, Double-Blind, Placebo-Controlled Preliminary Study. Serritella E, Scialanca G, Di Giacomo P, Di Paolo C. Pain Res Manag. 2020 Dec 5;2020:6705307. "The study supports the use of local vibration therapy in the control of TMD-related TMJ pain, local muscular pain, and headache." PMID: 33354268

The emerging role of focal muscle vibration in rehabilitation of neurological disorders. Tahir S, Baig MO, Rathore FA, Aslam H. J Pak Med Assoc. 2022 Oct;72(10):2126-2128. PMID: 36661016

Interval Vibration Reduces Orthodontic Pain Via a Mechanism Involving Down-regulation of TRPV1 and CGRP. Thammanichanon P, Kaewpitak A, Binlateh T, Leethanakul C. In Vivo. 2020 Sep-Oct;34(5):2389-2399. "Vibration represents a promising mechanical approach to reduce orthodontic pain." PMID: 32871764

Effects of local pressure and vibration on muscle pain from eccentric exercise and hypertonic saline. Weerakkoby NS, et al Pain. 2003;105:425–435. PMID: 14527703

Vibration reduces thermal pain adjacent dermatomes. Yarnitsky D, Kunin M, Brik R, Specher E. Pain. 1997;69:75–7. "Vibration can reduce pain across dermatomes." PMID: 9060015

Why M-Stim® Instead of E-Stim

Mechanoreceptors respond to mechanical sensations. In contrast to electrical stimulation, high-frequency low amplitude (HFLA) vibration improved physical function and reversed hypotrophy of quadriceps in OA. (Int J Rehabil Res. 2017 Jul 18) While vibration promoted GH gene expression, e-stim did not. In other studies, HFLA vibration vasodilated, likely by releasing endogenous nitric oxide. (J Athl Train. 2012 Sep-Oct;47(5):498-506.) In short, e-stim to twitch a muscle to twitch a motion nerve is less effective than actual motion: M-Stim®.

M-Stim® for Bone Health

Effects of local vibration and pulsed electromagnetic field (PEMF) on bone fracture: a comparative study. Bilgin HM Celik F et al. Bioelectromagnetics 2017 Jul;38(5):339-348. Three and a half hours of PEMF/day was less effective than 15 minutes vibration/day to increase osteogenic (bone) formation. PMID: 28236321

Integration of focal vibration and intra-articular oxygen-ozone therapy in rehabilitation of painful knee osteoarthritis. Paolucci T, Agostini F, Bernetti A, Paoloni M, Mangone M, Santilli V, Pezzi L, Bellomo RG, Saggini R. Dent Res J (Isfahan). J Int Med Res. 2021 Feb;49(2):300060520986705. "An integrated rehabilitation protocol involving O2O3 injections and [mechanical focal vibration] for 3 weeks reduces pain, increases autonomy in daily life activities, and strengthens the quadriceps femoris." PMID: 33641438

Vibration therapy: clinical applications in bone. Thompson WR, et al. Curr Opin EndocrDiabetes Obes.2014;21:447–453. "Additional physiological mechanisms [of] vibration include improved blood flow to injury and enhanced hormonal responses, including testosterone and growth hormone, evidence for a more systemic effect [on] tissue healing." PMID: 25354044

Low-level, high-frequency mechanical signals enhance musculoskeletal development of young women with low bone mass density (BMD). Gilsanz V, Wren TA, Sanchez M, Dorey F, Judex S, Rubin C. J Bone Miner Res. 2006;21(9):1464-1474. "Short bouts of extremely low-level mechanical signals, several orders of magnitude below that associated with vigorous exercise, increased bone and muscle mass in the weight-bearing skeleton of young adult females with low BMD." PMID: 16939405

Low-frequency vibratory exercise reduces the risk of bone fracture more than walking: a randomized controlled trial Gusi N, Raimundo A, Leal A. BMC Musculoskelet Disord. 2006;7:92. PMID: 17137514

M-Stim® for Tissue Repair

Clinical effectiveness of focal muscle vibration on gait and postural stability in individuals with neurological disorders: A systematic review. Alashram AR, Padua E, Romagnoli C, Raju M, Annino G. Physiother Res Int. 2022 Jul;27(3):e1945. "The [focal muscle vibration] intervention is safe and well-tolerated in individuals with neurological disorders." PMID: 35279915

Localized muscle vibration reverses quadriceps hypotrophy, improves function. Benedetti MG Boccia G et al. Int J Rehabil Res. 2017 Dec;40(4):339-346. Thirty patients with OA randomized to 150Hz or electrostimulation; only vibration effective. PMID: 28723717

Improvement of stance control and muscle performance induced by focal muscle vibration in young-elderly women: a randomized controlled trial. Filippi GM, Brunetti O, Botti FM. Arch Phys Med Rehabil. 2009 Dec(12):2019-25 . Sixty sedentary women had three 10-minute vibration sessions a day for 3 consecutive days or placebo (non-vibrated group). Sway decreased by 20%, vertical jump increased by 55%, and leg power increased by 35%. Effects maintained for at least 90 days. PMID: 19969163

Mechanical vibration as an adjunct to clear aligner treatment for accelerating tooth movement: A review. Ghadirian H, Yazarloo S, Heidari S, Gholamrezayi E. Dent Res J (Isfahan). 2022 Sep 26;19:753. "It seems that [high frequency vibration] is more effective than low frequency vibration in patients treated with clear aligners." PMID: 36407773

The effect of vibration on the acceleration of wound healing of diabetic neuropathic foot ulcer: A prospective experimental study on human patients. Syabariyah S, Nurachmah E, Widjojo BD, Prasetyo S, Sanada H, Irianto, Nakagami G, Suriadi, Kardiatun T, Hisan UK. Dent Res J (Isfahan). Healthcare (Basel). 2023 Jan 9;11(2):191. "Considering that no clinically adverse effects were found in the patients induced with vibration intervention, [vibration wound therapy] can be regarded as a complementary therapy to the existing ones to accelerate the healing of [diabetic foot ulcers]." PMID: 36673559

Low-intensity vibration(LIV) improves angiogenesis and wound healing in diabetic mice. Weinheimer-Haus EM, Judex S, Ennis WJ, Koh TJ PLoS One. 2014; 9(3):e91355. PMID: 24618702

The anabolic activity of bone tissue, suppressed by disuse, is normalized by brief exposure to extremely low-magnitude mechanical stimuli. Rubin C, Xu G, Judex S. FASEB J. 2001;15(12):2225-2229. PMID: 11641249

VibraCool
« CRYOVIBRATION »

Vibration for Post-Surgical Rehabilitation

Local vibration training improves the recovery of quadriceps strength in early rehabilitation after anterior cruciate ligament reconstruction: A feasibility randomized controlled trial. Coulondre C, Souron R, Rambaud A, Dalmais É, Espeit L, Neri T, Pinaroli A, Estour G, Millet GY, Rupp T, Feasson L, Edouard P, Lapole T. Ann Phys Rehabil Med. 2022 Jun;65(4):101441. "LVT improved strength recovery after ACLR. This feasibility study suggests that LVT applied to relaxed muscles is a promising modality of vibration therapy that could be implemented early in ACLR." PMID: 33059096

Effect of illusory kinesthesia on hand function in patients with distal radius fractures: a quasi-randomized controlled study. Imai R, Osumi M et al. Clin Rehabil. 2017 May;31(5):696-701 "[Tendon vibration] was an effective post-surgery management strategy not only for pain alleviation, but also hand function...with improvements persisting for up to two months." PMID: 28074671

Vibratory tendon stimulation on acute pain after surgery for distal radius fractures. Imai R, Osumi M et al. Clin Rehabil. 2016 Jun;30(6):594-603. After a week of daily vibration, pain reduced at 7 days, 1m, 2m. PMID: 26198893

Whole body(WBV) and local muscle vibration(LMV) reduce quadriceps muscle inhibition. Blackburn JT Arch Phys Med Rehabil. 2014 Nov;95(11):2021-8 (WBV p=.021, LMV P<.001) "WBV and LMV improve quadriceps function equivocally after simulated knee pathology." PMID: 25083559

A randomized, double-blinded, placebo-controlled clinical trial evaluating the effectiveness of daily vibration after arthroscopic rotator cuff repair. Lam PH, Hansen K, et al. Am J Sports Med 2015 43: 2774. Five minutes of vibration was applied daily after arthroscopic rotator cuff repair for 6 months. Vibration did provide acute pain relief at 6 weeks after surgery (visual analog scale [VAS] score, 2.24 (0.29 cm)) compared with placebo (VAS score, 3.67 (0.48 cm)) (P=.003). PMID: 26337247

Local muscle vibration after ACL repair. Pamukoff DN et al Arch Phys Med Rehabil 2016 Jul;97(7):1121-9 Increase in Central Activation Ratio (+2.7%, P=.001) and a reduction in quadriceps active motor threshold (-2.9%, P<.001) after LMV. PMID: 26869286

Rehabilitation Program Combined with Local Vibroacoustics Improves Psychophysiological Conditions in Patients with ACL Reconstruction. Park JM, Park S, Jee YS. Medicina (Kaunas). 2019 Sep 30;55(10):659. "The results indicate that the [local body vibration] intervention mitigated the participants' pain and symptoms and improved their leg strength and ROM, thus highlighting its effectiveness." PMID: 31574964

Improvement of posture stability by vibratory stimulation following anterior cruciate ligament reconstruction. Brunetti O, Filippi GM, Lorenzini M, et al. Knee Surg Sports Traumatol Arthrosc. 2006; 43(11):1180-1187. PMID: 16763853

Pain Care Labs makes revolutionary science-backed therapies that tap into the body's physiological pain response system to stop pain cold, naturally and drug-free. Our clinically-proven products are trusted by hospitals, doctors and patients across the globe. We give people power over their pain, eliminating the unnecessary suffering and anxiety that comes with it. FDA 510k Cleared for Post-Op pain relief.

Vibration for Muscle Damage

Does vibration benefit delayed-onset muscle soreness?: a meta-analysis and systematic review. Lu X, Wang Y, et al. J Int Med Res. 2019 Jan;47(1):3-18. "Vibration significantly improved the VAS at 24, 48, and 72 hours after exercise, and significantly improved CK levels at 24 and 48 hours." PMID: 30526170

Local high-frequency vibration therapy following eccentric exercises reduces muscle soreness perception and posture alterations in elite athletes. Iodice P et al. Eur J Appl Physiol 2018 Oct 30. 120Hz vibration applied for 15 minutes decreased eccentric effect of exercise on pain and posture in 30 professional athletes. PMID: 16763853

Effectiveness of using wearable vibration therapy to alleviate muscle soreness. Cochrane DJ. Eur J Appl Physiol 2017 Mar;117(3):510-509. Thirteen males used VT or nothing prior to eccentric arm exercises in a crossover trial separated by arms over 14 days. Acute and short-term VT significantly attenuated muscle soreness, creatine kinase and improved range of motion. PMID: 28168554

To compare the effect of vibration therapy (VT) and massage in prevention of delayed onset muscle soreness (DOMS). Imtiyaz S, Vegar Z, Shareef MY. J Clin Diagn Res. 2014 Jan;8(1):133-6. Forty-five nonathletic women were randomized to 15 minutes of massage, 5 minutes of focal vibration, or no intervention prior to exercise. Vibration therapy and massage prevented DOMS equally versus control; only VT decreased 48h lactate dehydrogenase level. PMID: 24596744

Effect of vibration treatment on symptoms associated with eccentric exercise-induced muscle damage. Lau WY et al. Am J Phys Med Rehabil 2011 Aug;90(8):648-57. Thirty minutes of vibration after exercise reduced DOMS and improved recovery of range of motion. PMID: 21273897

Effects of Vibration and Non-Vibration Foam Rolling on Recovery after Exercise with Induced Muscle Damage. Romero-Moraleda B, González-García J, Cuéllar-Rayo Á, Balsalobre-Fernández C, Muñoz-García D, Morencos E. J Sports Sci Med. 2019 Feb 11;18(1):172-180. "The results suggest that the [vibrating foam roller] group achieved greater short-term benefits in pain perception and passive extension hip joint ROM." PMID: 30787665

Vibration therapy in Management of delayed onset muscle soreness (DOMS). Vegar Z, Imtiyaz S. J Clin Diagn Res. 2014 Jun;8(6)LE01-4. "Vibration therapy improves muscular strength, power development, kinesthetic awareness, decreased muscle sore, increased range of motion, and increased blood flow under the skin. VT was effective for reduction of DOMS and regaining full ROM... and lower creatine kinase levels in the blood." PMID: 25121012

Effects of vibratory stimulations on maximal voluntary isometric contraction from delayed onset muscle soreness. Koh HW, Cho SH et al. J Phys Ther Sci. 2013 Sep;25(9):1093-5. DOMS was induced in the musculus extensor carpi radialis longus of 60 adults. Ultrasound or vibratory stimulation for 10 minutes or control was used. Vibration had a positive effect on recovery of muscle function from DOMS compared to the control group, while ultrasound did not. PMID: 24259922

Vibration therapy(VT) reduces plasma IL6 and muscle soreness after downhill running. Broadbent S, Rousseau J, J. Throp RM, Choate SL, Jackson FS, Rowlands DS. Br J Sports Med. 2010;44:888–894. PMID: 18812416

Effect of vibration treatment on symptoms associated with eccentric exercise-induced muscle damage. Lau W.Y., Nosaka K. (2011) American Journal of Physiology Medicine & Rehabilitation 90(Pt 8), 648-657. PMID: 21273897

Why Use Vibration and Cryotherapy Together?

Cryotherapy reduces inflammation but also constricts blood flow. HFLA vibration vasodilates, canceling the vasoconstriction effect while adding pain relief and separating muscle fibers to reduce stiffness. An increased number of residual cross-bridges between myosin heads and actin is thought to largely contribute to this exercise-induced increased stiffness (Proske and Morgan, 2001); M-Stim® improves this stiffness.

Vibration for Athletic Training and Physical Therapy

Focal vibration of quadriceps muscle enhances leg power and decreases knee joint laxity in female volleyball players. Brunetti O, Botti FM et al. J Sports Med Phys Fitness. 2012 Dec;52(6):596-605. Eighteen volleyball athletes, (age=22.7 ± 3 years) were assigned to vibration on contracted or relaxed quads or sham vibration (NV). Combined contraction and vibration can significantly and persistently improve muscle performance and knee laxity in women volleyball players. PMID: 23187322

Comparison of a vibration roller and nonvibration on knee pain and ROM. Cheatham SW J Sport Rehabil. 2018 Oct1:1-7 Vibrating roller superior for knee pain relief and ROM to regular roller or sham P<.001. PMID: 28787233

Effectiveness of Focal Muscle Vibration in the Recovery of Neuromotor Hypofunction: A Systematic Review. Fattorini L, Rodio A, Filippi GM, Pettorossi VE. J Funct Morphol Kinesiol. 2023 Jul 25;8(3):103. "The motor improvements were immediate and obtained without loading the joints." PMID: 37606398

Wearable Technologies Using Peripheral Neuromodulation to Enhance Mobility and Gait Function in Older Adults-A Narrative Review. Kahya M, Hackman D, Jacobs L, Nilsson D, Rumsey Y, Oddsson LIE. J Gerontol A Biol Sci Med Sci. 2023 May 11;78(5):831-841. "Existing literature suggests that these technologies may lead to physiological changes in the brain through sensory reweighting or other neuroplastic mechanisms to enhance the performance of mobility and gait function in older adults over the age of 65." PMID: 35179580

Effect of low-magnitude, variable-frequency vibration therapy on pain threshold levels and mobility in adults with moderate knee osteoarthritis-randomized controlled trial. Pasterczyk-Szczurek A, Golec J, Golec E. BMC Musculoskelet Disord. 2023 Apr 13;24(1):287. "Our data demonstrated that the use of vibrations of variable frequency and low amplitude in patients with the knee OA is a safe and effective therapy." PMID: 37055733

The acute effects of local vibration therapy on ankle sprain and hamstring strain injuries. Peer KS, Barkley JE, Knapp DM Phys Sports Med. 2009;37(4):31-38. "Local vibration for 10 minutes increased ankle dorsiflexion and eversion and hamstring flexibility (P < 0.03 for all), and significantly (P <or= 0.05) decreased perceived ankle and hamstring stiffness." PMID: 20048538

Improvement of Gait after 4 Weeks of Wearable Focal Muscle Vibration Therapy for Individuals with Diabetic Peripheral Neuropathy. Rippetoe J, Wang H, James SA, Dionne C, Block B, Beckner M. J Clin Med. 2020 Nov 22;9(11):3767. "Results indicate that [focal muscle vibration] therapy was associated with improvements in gait parameters." PMID: 33266464

Intermediate muscle length and tendon vibration... Souron R. et al. Front Physiol. 2018 Sep 5;9:1226 Motor- evoked potentials more than doubled with vibration, with the best results applying vibration to the tendon at an intermediate muscle length. Vibration significantly increased knee extensor neuromuscular function. PMID: 30233417

Localized application of vibration improves passive knee extension in women with apparent reduced hamstring extensibility: a randomized trial. J of Physiotherapy. Bakhtiary AH, Fatemi E, Khalili MA, Ghorbani R. 2011;57:165–171. PMID: 23888287

Muscle performance changes induced by muscle vibration. Fattorini L, et al. Physiol 2006;98:79-87. PMID: 16896736

A portable vibrator for muscle performance enhancement by means of direct muscle tendon stimulation. Luo J, McNamara BP, Moran K. Med Eng Phys. 2005;27(6):513-522. PMID: 15990068

Focal Cryotherapy for Pain

Compressive cryotherapy versus cryotherapy alone in patients undergoing knee surgery: a meta-analysis. Song M et al. 2016 Jul 13;5(1):1074. "Compressive cryotherapy is beneficial to patients undergoing knee surgery at the early rehabilitation stage." PMID: 27462522

Cryotherapy for Recovery

Quadriceps muscle function after rehabilitation with cryotherapy in patients with anterior cruciate ligament reconstruction. Hart J et al. J Athl Train. 2014 Nov-Dec; 49(6): 733–739. After ACL reconstruction, patients who performed rehabilitation exercises immediately after cryotherapy experienced greater strength gains than those who performed cryotherapy or exercises alone. PMID: 25299442

Comparison of the effects of pressurized salt ice packs with water ice packs on patients following total knee arthroplasty. Liying Pan et al Int J Clin Exp Med 2015;8(10):18179-18184 A compressing pack with -18 degree C cold worked better than standard ice and water for pain and swelling. PMID: 26770417

Time-course of changes in inflammatory response after whole-body cryotherapy multi exposures following severe exercise. Pournot H. et al. PLoS One. 2011;6(7):e22748. IL-1b (Post 1 h) and CRP (Post 24 h) levels decreased and IL-1ra (Post 1 h) increased following cryotherapy, supporting the decrease in pro-inflammatory cytokines activity, and increase in anti-inflammatory cytokines. PMID: 21829501

Cold and Focal Vibration for Acute Pain in Adults

Efficacy of the Buzzy device for pain management during needle-related procedures: a systematic review and meta-analysis. Ballard A, Khadra C, Adler S, Doyon-Trottier E, Le May S. Clin J Pain. 2019 Jun;35(6):532-543. (N= 1138, pain reduction -1.11; 95% confidence interval [CI]: -1.52 to -0.70; P<0.0001) , anxiety reduction (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001). PMID: 30829735.

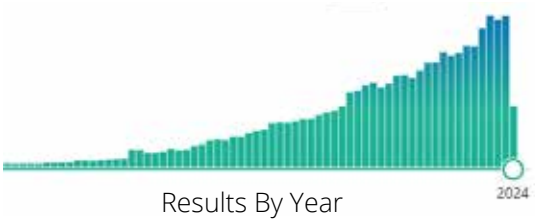
Influencing vaccinations: a Buzzy approach to ease discomfort randomized controlled trial. Redfern RE et al. Pain Manag Nurs. 2018 Nov 10. In 497 adults, ice wings and 180Hz vibration reduced pain (0.87 v. 1.12, p=.035) and gave a better than previous vaccination experience (62% vs. 23.9%, p<.0001). PMID: 30425014

Effect of Buzzy on pain and injection satisfaction in adult patients receiving IM [diclofenac] injections. Sahin M. Pain Manag Nurs. 2018 Dec;19(6):645-651. In 65 adults, ice wings and 180Hz vibration reduced pain (4.67 +/- 4.94 v. 17.69 +/- 9.85 p=.000) and increased satisfaction (94.82 v. 85.06, P<.0001). PMID: 30318424

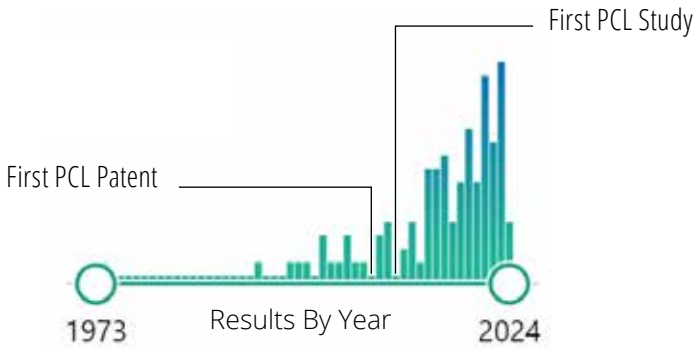
Individual satisfaction of blood donors. Yilmaz D et al. Pain Manag Nurs. 2017 Aug;18(4):260-267 In 90 male participants, ice "wings" and 180Hz vibration decreased pain and increased satisfaction (p<.05). PMID: 28601479

Pain Care Labs has led the field in research and advocacy for non-drug pain relief.

New publications by year, PUBMED
"Mechanical Stimulation"



New publications by year, PUBMED
"Focal Vibration Pain"



TITLE: Effects of Focal Vibration on Pain and Opioid Usage following ACL Reconstruction: A Pilot Study

AUTHOR/Institution [Redacted] 2019

CURRENT CATEGORY: Musculoskeletal & Sports Medicine

Objective: To determine the effects of a cold and focal vibration unit (VibraCool) on post-operative pain levels and opioid usage following anterior cruciate ligament reconstruction (ACLR). We hypothesized that VibraCool would reduce pain levels and decrease number of opioid tablets taken, compared to a historical control group that was part of an opioid reduction intervention trial].

Design: Prospective case series compared to a historically controlled trial of opioid reduction coaching

Setting: Orthopedic clinic and patient home

Participants: 14 individuals (27±11 years, 9 males; 5 females) with primary ACLR participated.

Interventions: VibraCool is an FDA-cleared medical device that provides combination of ice and focal vibration to treat pain. Its high-frequency (200Hz) vibration targets mechanoreceptors that inhibit pain via spinal gating mechanisms. Patients received VibraCool on day of surgery and were instructed to use 20mins 3x/day on knee proximal to pain locations. All patients, including historical control group, received standard of care: adductor canal nerve block and 30 tablets of Percocet 7.5/325mg.

Main Outcome Measures: Pain via 11-point visual analog scale and number opioid tablets used over 7 days were tracked on Smartphone application developed in-house (Fuse: Postop Journal).

Results: Patients reported using an average of 10.1±10.3 opioid tablets in the first week following surgery, which is 35% less than the average number of tablets (15.6±8.5) used in the historical cohort (Cohen's d 0.58), and 19.5% less than with opioid reduction education. Only 4 patients continued to use opioids by their first post-operative visit (4.3±2.3 days post-surgery).

Conclusions: Patients who used VibraCool demonstrated reduced opioid usage and similar pain levels to a historical control group receiving opioid reduction coaching. Neuromodulatory devices, such as VibraCool, show potential as alterative and/or adjunctive therapies to opioids. Future work will include a randomized controlled trial to validate findings of this pilot study.

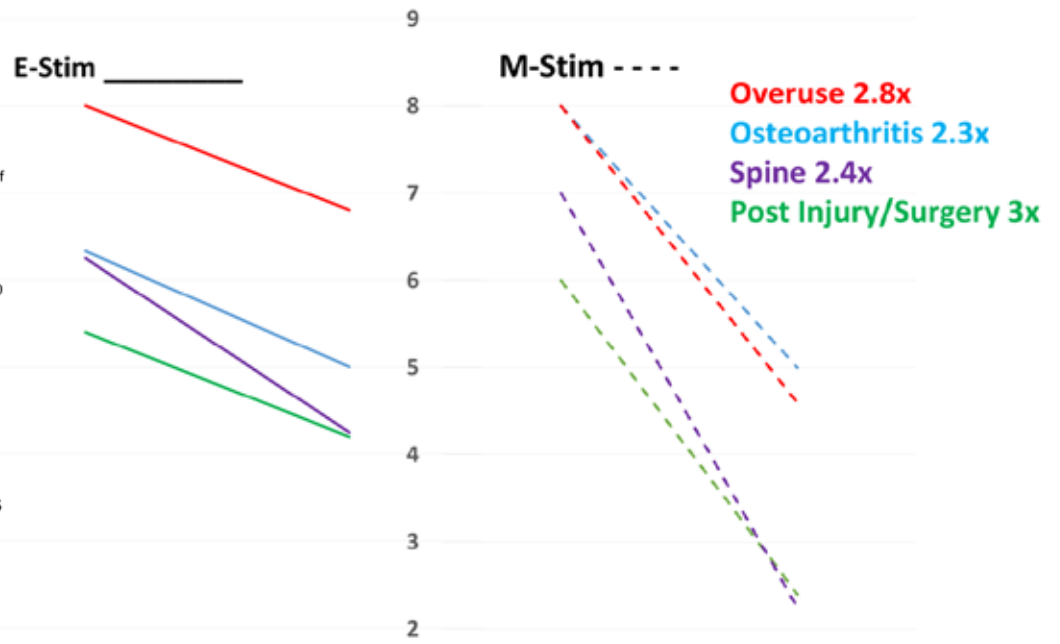
[Author requested equity to publish paper. PCL does not pay for independent research. Paper remains unpublished.]

VibraCool
« CRYOVIBRATION »

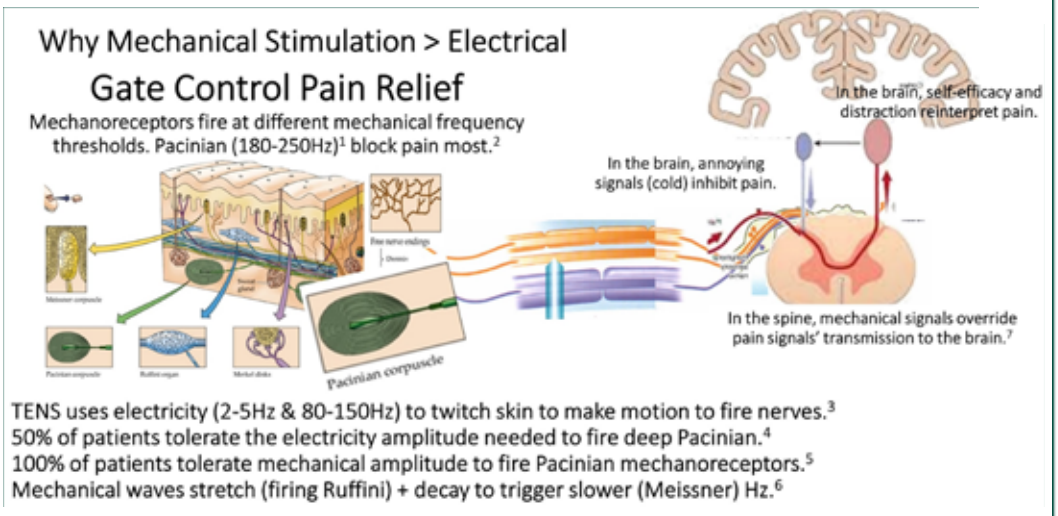
Crossover Trial of Novel Mechanical Oscillatory Vibration Frequency Device versus TENS for Musculoskeletal pain. AAPMR 2019 San Antonio

Objective
To evaluate whether high frequency mechanical vibration in the Pacinian stimulation range (180-250Hz) relieves pain more than electrical stimulation
Design
Randomized non-blinded crossover trial
Setting
Outpatient physical therapy
Participants
13 females and 7 males aged 25 – 81 receiving physical therapy for OA (6), sacroiliac dysfunction (2), shoulder injury (5), post-surgery (3), epicondylitis (1), plantar fasciitis (1), fibromyalgia (1), and bone cancer of the spine (1).
Interventions
Consented patients got a randomized 20-minute session of 180-200Hz mechanical oscillatory vibration, 0.1m/s2 amplitude (VibraCool (VC), Pain Care Labs, Atlanta, GA) or a generic model-TENS 3000 applied to pain. TENS units used 150Hz frequency with a pulse width of 200ms, asymmetrical biphasic square pulse waveform, and amplitude as high as comfortable on a 0-80mA using a 500 ohm load per channel. Most patients tried the devices on different days. On 2 occasions when TENS was applied with no relief VC was used the same day.
Main Outcome Measures
Visual analog scale (VAS) pre- and post-therapy pain scores (from 0 "no pain" to 10.
Results
Mean pain relief with VC high frequency vibration was 3.60 +/- 1.60 (95%CI 2.85 to 4.35). Pain relief with TENS was 1.40 +/- 1.05 (95%CI 0.91 to 1.89), with a mean difference of -2.2 +/- 1.34 (95%CI-2.85 to -1.55, P<.0001). Pain relief with VC was greatest for spine, injury and post-surgical pain (5-6) and least for OA (2-3). One patient had no relief with VC (plantar fasciitis); five patients had no relief with TENS (plantar fasciitis, OAx2, shoulder arthralgia, and s/p ORIF).
Conclusions
Mechanical high frequency vibration in the Pacinian corpuscle frequency was superior to electrical stimulation for pain relief, with highest efficacy for injury, post-surgical and spinal conditions.

VibraCool Stimulation relieved pain better than TENS in a randomized crossover 20m physical therapy trial.



VibraCool -2.2 +/- 1.34 more than TENS (95%CI-2.85 to -1.55, P<.0001)
(Ice was **not** used with VibraCool; mechanical only.)



TENS uses electricity (2-5Hz & 80-150Hz) to twitch skin to make motion to fire nerves.[3]
50% of patients tolerate the electricity amplitude needed to fire deep Pacinian.[4]
100% of patients tolerate mechanical amplitude to fire Pacinian mechanoreceptors.[5]
Mechanical waves stretch (firing Ruffini) + decay to trigger slower (Meissner) Hz.[6]

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