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Learn on the journey toward best health.

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I am a 2-legged, cisgender, old white man of privilege with chronic pain and occasional acute pain. I'm known as Health Hats because I'm a person with disabilities and chronic pain due to age and Multiple Sclerosis; I've been care partner to several family members' end-of-life; professionally, I'm a nurse, have led EMR implementations, and been Director and VP of Quality Management. As part of my patient caregiver activism, I podcast and vlog (often about pain management[1] , participate in Technical Expert Panels, and am appointed to a Patient Caregiver seat on the Patient-Centered Outcomes Research Institute (PCORI) Board of Governors. I've consulted with chronic pain app developers and hosted virtual conversations and focus groups about chronic and acute pain.

Many people experiencing acute and chronic pain seek a state of function with pain rather than a pain-free state. They avoid opioids unless the pain is more than *seriously annoying* - debilitating. They feel immense frustration that their medical partners, by and large, know little about non-drug, non-surgical pain relief and that their insurance doesn't cover those modalities (chiropractic, massage, acupuncture, vibration, meditation, and more). *Don't they know that these are less expensive, much less?* Several of my family members and cronies in Pain Management use VibraCool® Devices for Fibromyalgia, lower back pain, repetitive strain, and other musculo-fascial injuries, and post-joint replacement to significant effect.

I nominate the topic of External Neuromodulation Mechanical Oscillation Stimulation Therapy for AHRQ's Evidence-based Practice Center (EPC) Program for upcoming systematic reviews. We need this therapy in our toolbox for pain management.

[1] Chronic Pain Management: Science, Art, Experiment | Danny van Leeuwen Health Hats (health-hats.com)

AHRQ

Appropriateness: Pain relief from thermomechanical stimulation (vibration) devices with gate control frequencies for pain have been available in the United States since 2009, and FDA 510K cleared since 2014. Over 90 prospective randomized controlled trials with the Buzzy device demonstrate significant a-delta pain reduction. The VibraCool device reduced opioid use 35% compared to ERAS coaching in a pilot study, and was 3.4x more effective than TENS for physical therapy pain in a crossover trial (Cohen's d=1.12). The frequencies and amplitudes involved in wearable devices, and devices coupled with thermal therapies, have not been formally evaluated. An evidence report could support or refute a new category of drug-free pain relief and musculoskeletal therapy.

Importance: Disease burden: Pain affects 100 million Americans; 80% of opioid use disorder starts with pills prescribed for pain. A modality like thermomechanical stimulation could alleviate pain while reducing potential opioid harm.

Uncertainty for decisionmakers: Both payors and clinicians are unfamiliar with new pain science discoveries, and their access to learning about new modalities are typically through sponsored medical device distribution, or CMS coverage gained by lobbying. The research discoveries of the biology and physics underpinning efficacy are recent. For decisionmakers to feel confident in prescribing vibration therapy, they would have to extrapolate efficacy from procedural needle pain studies on the a-delta pain nerve, or international studies, or unpublished abstracts to support use in the musculoskeletal and post-operative arenas.

While the focal vibration field is increasingly in publications over the past five years, early works often disregarded the critical impact of frequency, orientation, and amplitude impacting efficacy. The field also lacks a coherent terminology between sports medicine, physical therapy, opioid reduction, procedural pain, and rehabilitation. Because US orthopedic investigators command a $500,000 or 2% equity cost per study, and until recently, the NIH required invention of novel devices to test in a new environment, new studies from the US in the proper frequencies for pain relief and rehabilitation have not been conducted (or have not been published without fee payment).

Clinical benefits or harms: **Benefits**: multiple meta-analyses support efficacy of vibration in different frequencies, amplitudes, and positioning: pain relief (180-250Hz), stroke recovery (60 – 300Hz), delayed onset muscle soreness (60 – 120). The vasodilatory effects, the direct mechanisms of hypertrophy and integrin stimulation, and the stimulation of growth hormone and decrease of LDH, and increase of bone growth 8x that from electrical stimulation are among the additional potential clinical benefits. The regenerative properties of mechanical stimulation on overuse injuries, bones, stroke, and hypotrophy could be better studied if the devices were more broadly used for pain. While the FDA granted cold and vibration a novel product code PHW in 2014 for pain relief, the FDA's only other codes are ISA "electric massager" and "electric therapeutic vibrator". The new physics and Nobel Prizes for pain relief via pressure and thermal interactions

aren't part of the delineation of thermomechanical stimulation's benefits. Furthermore, unlike with pharmaceuticals, an endorsement of pain relief by the FDA is insufficient for patients to gain access. CMS considers pain relief through vibration to be a "comfort item" which they categorically won't cover**. Harms:** until the last decade, most research on vibration evaluated the amplitude and frequency as lifetime accumulated risk of nerve damage (hand-arm-vibration syndrome) or low back pain from axial loading. The FDA "electric massager" and "therapeutic vibrator" codes are Class 1 exempt, and ignore potential clinical harms through relying on outdated categories. For example, a percussive massager registered as ISA has been reported to MADGE adverse events reporting, a study on the effects of a percussive massager had to be baffled to reduce the danger of impact, and a case report of rhabdomyolysis was published.

Reducing costs: Thermomechanical stimulation devices are reusable and simple to manufacture. The Buzzy thermomechanical device is $45 and durable: one Humira patient has a photograph of himself now and 12 years ago with the same Buzzy. VibraCool is mechanically the same device with ice and/or heat at $65, and has been used in Canada and the US to reduce opioids and pain instead of Gameready devices. Beyond replacing existing devices, the new understanding of neuroscience and brain pain connectomes support agency, self efficacy, and immediacy as components of an effective pain regimen beyond the peripheral effects. By incorporation into an ERAS program, thermovibration could save the exorbitant costs of addiction, chronic pain, and surgeries. Without funding for potentially biased studies, the savings are difficult to calculate. Without a CMS benefit category, lack of understanding of new gate control and motion pain science, and a low price point prohibiting medical device rep support, the technology will languish.

Duplication: A Whole Body Evidence review done in 2010 is a fundamentally different topic. An orthopedic knee study referencing vibration was long before most of the new studies were available and states "should not be considered to be current".

Feasibility: There are over 300 prospective randomized controlled trials of mechanical stimulation and 100 of thermo-mechanical stimulation from which to analyze. By their nature, blinding is rare. However, the increasing appreciation of the value of placebo effects and agency in reducing pain should mitigate this inherent bias against non-drug studies.

Potential impact of a new evidence report: Coverage of new medical devices for pain is limited by an old CMS policy against "massagers, vibrators, or comfort items." The current labor shortage prohibits miscellaneous code usage by workers' comp and hospitals. New pain and physiologic research demonstrate that specific pain relief frequencies, amplitudes, and thermal constructs impact pain more effectively than transcutaneous electrical stimulation but are lumped together. A new evidence report could validate use in clinical settings, give CMS a rationale for a product category for proven appropriate mechanisms, and influence clinical practice.

Potential for change: Current NIH, FDA, and CMS awareness, direct correspondence (Dr. Shari Ling) and repeated HCPCS applications including July 3 2023 have elevated awareness so that the proposed evidence report timing could influence policy and clinical practice.

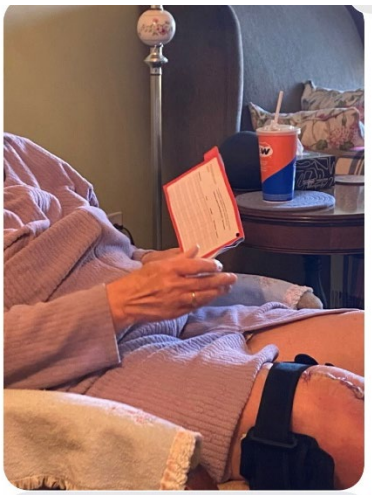
Support for External Neuromodulation

Thermomechanical Stimulation Devices

CONTENTS

1. Clinical Context

Researching thermomechanical stimulation to replace opioid use was initiated when a physician in opioid recovery sought drug-free relief after a total knee replacement. For this purpose, he used an SBIR-funded novel 200Hz vibration + ice needle pain relief device (Buzzy®, MMJ Labs LLC Atlanta GA) created by his colleague. Dr. Amy Baxter had lost her high school best friend to a heroin overdose; when the device worked for her colleague, she decided to research vibration's impact on pain and the history of opioid use full time in 2016. Since then, over 200 studies on high-frequency mechanical stimulation and pain relief and over 100 studies on the 200Hz vibration + thermal technology have been published (Appendix 1,2). Her technology and new discoveries are currently funded by NIDA to reduce opioid use. The devices have been cleared by Health Canada for post-surgical pain relief since 2021, and received expanded 510K clearances for physical therapy, surgery, and tendinitis pain in the US May 2023. This review was solicited after an online comment, used with permission:



Dear Dr. Baxter
I am writing to tell you about my family's recent experience with VibraCool. My 81-year old mother lives independently in Ontario, Canada. One month ago, she had a full knee replacement and I stayed with her…[she] was concerned that post surgery opioids would make drowsy, disoriented, or off balance, provoking falls or mishaps that would affect her recovery and/or future ability to live independently.

After surgery, she immediately began using VibraCool for several sessions a day, alternating with a cold therapy machine, and pain medication at minimal recommended levels. Within a week she had tapered off main medications and cold therapy, relying primarily on VibraCool for pain management.

Some of the advantages of VibraCool that she reports are:

1) The ability to manage pain while still maintaining a clear head and the balance needed to do mobility exercises after surgery.
2) A better understanding of the role of pain in the healing process and how to control pain to tolerable levels. She contrasts this with her previous post-operative experiences which left her with a choice of "intolerable pain" or "out like a light." 3) VibraCool is simple to use and does not have a lot of parts. She kept the device on her bedside table so that if she woke up in the night with pain, she could immediately apply the vibrating elements. Even without the icepacks, the vibration brought relief so she could return to sleep.

In summary, I believe that VibraCool provided my mother with the pain management tools she needed to manage a successful recovery. As an elderly person, she is always concerned about falls and disorientation and she believed that opioids increased her risk of both. VibraCool helped her to heal while maintaining both control and independence. Thank you for a wonderful product. We are delighted that it is now available in Canada.

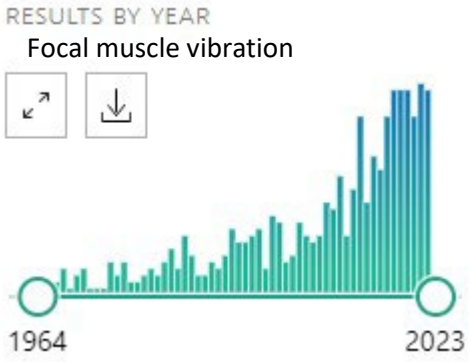
Sincerely,
Laura Dawson, PhD
ldawson@dawsonstrat.com
(202) 297-0543

2. Overview: The underlying rationale for mechanical stimulation in multiple frequencies is based on new discoveries related to gate control. In 1965, Melzack and Wall hypothesized that stimulation of sensation mechanoreceptors "shut the gate" on pain transmission, an inhibitory mechanism known as "Gate Control".[1] A web of acute pain Aδ nerves transmit nociceptive information to the dorsal column, where the substantia gelatinosa's interneurons prioritize competing sensory information. Fast Aδ, faster Aβ mechanoreceptor and slower C-fiber slow pain signals vie for transmission to the brain for sensory perception. Recent research indicates the principal Aβ-transmitted touch mechanoreceptors respond optimally to different stimulation frequencies: fast adapting light touch Meissner corpuscles detect frequencies between 20 and 40Hz,[2] while fast reacting and long acting deep Pacinian corpuscles begin sensing vibration at 65Hz, with maximal sensitivity between 180 and 250Hz.[3] With sufficient Aβ stimulation, pain can be overridden, like rubbing a bumped elbow.

Vibration was first used focally for pain relief by Lundeberg et al, who found that vibration in a plate on the low back was more effective than electrical stimulation.[4] While he published the frequency used (100Hz), subsequent attempts to replicate the findings used any available frequency from over the counter devices, and were largely unsuccessful. With the advent of more precise motors and controllable amplitude with diaphragmatic force application, new studies were able to identify effective frequencies, amplitude, and outcomes more precisely.

In 2017, Hollins et al reported that Pacinian corpuscles were responsible for 90% of gate control pain relief.[5] This finding explains why fast vibratory pain relief was found to be superior to transcutaneous electrical nerve stimulation (TENS) units for musculoskeletal and chronic pain in the early 80's, but failed to be effective when tried with lower frequency interventions. By transcutaneous electrical stimulation slower frequencies (typically in the 20-40 range), TENS units stimulate the Meissner corpuscles. While higher frequency TENS (60-120Hz) may engage the lower range of Pacinian corpuscle inhibition,[6] the superficial transcutaneous transmission or insulating adipose tissue may inhibit reaching the deep Pacinian nerves. Mechanical stim causes more robust receptor stimulation than electricity and is more comfortable to use (0% of patients chose NMES compared to vibration in one study[7]) Multiple metaanalyses on 200Hz devices since 2009 demonstrate even the sharp pain of needles can be blocked with mechanical stimulation placed proximal to pain.[8 9]

The terminology of mechanical stimulation is in flux, leading Casale in 2015 to call for a consolidation of terminology[10]: searching Pubmed for focal muscle vibration, local mechanical vibration, thermomechanical stimulation, etc., yield different studies in different fields. For pain relief, mechanical stimulation (180-250Hz) stimulate Pacinian corpuscles. Thermomechanical Stimulation is the above focal M-stim with a contemporaneous thermal component.



HCPCS History: HCPCS and PDAC have not granted a benefit category to the narrow band of mechanical stimulation used in

Buzzy or VibraCool applications, stating that massage or therapeutic vibration codes are excluded as "comfort items."

Two HCPCS applications for Buzzy were rejected; the first for being out of mandate due to the design implying exclusive vaccine and injection adherence for children; the second for being a "comfort item". A PDAC application stated that the coverage for electrical stimulation codes didn't apply to mechanical codes, even if they were both stimulating gate control for pain relief in a dermatome, and if the mechanism of mechanical stimulation was superior: and independent investigator compared TENS units with VibraCool mechanical stimulation WITHOUT ICE for physical therapy in a randomized crossover design. The results of this trial demonstrated two to 3.4-fold superior pain relief with VibraCool over TENS units (Appendix).

Due to the opioid crisis, we were asked by Preferred Medical, Cigna, and other providers to acquire a benefit category for them to use VibraCool devices in place of items they're currently covering for pain management. We submitted a HCPCS January 4 2022 and were rejected for being a "therapeutic massager". We went to the FDA, who realigned the product code as containing a "therapeutic vibrator" and we explained to CMS in a hearing why vibration and massage were different. They stated, "The FDA says you're a vibrator. We don't pay for comfort items."

HCPCS Qualifications

- **2.1 CMS Mandate:** There is a national program operating need for pain relief and opioid reduction devices for Medicare, Medicaid, and Private Insurers. CMS explicitly calls for the support of innovation. VibraCool reduces pain and opioid use.
- **2.2 Proven Technology**: The technology on which VibraCool rests has been proven effective for sharp procedural pain in over 90 Randomized controlled trials, with and without ice.
- **2.3 New FDA 510K indications:** indicated for the temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. It is also indicated for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion and muscle tension. (K202993, May 15 2023)

3 Function of Devices:

- **3.1** VibraCool is attached to or proximal to the affected area in the same dermatome with a neoprene strap, with hot or cold solid thermal packs to transmit vibration without loss of frequency or amplitude.
  - **3.1.1** Stereotactic vibratory stimuli for low back may have improved efficacy over a single unit.[11]
  - **3.1.2** The efficacy of vibration units alone is best on overuse injuries, spine and joints where Pacinians are most common.(See Marovino et al, Appendix 3.)
- **3.2 Mechanism of Action:**
  - **3.2.1** TENS units use 20-40Hz or 60-120Hz electrical current to activate "Gate Control" pain inhibition. One surface light touch motion receptor (the Meissner mechanoreceptor) transmits the low frequency current's sensation on large fiber afferents known as A-Beta nerves.[6] At sufficient amplitude of current, muscles are twitched, which trigger the

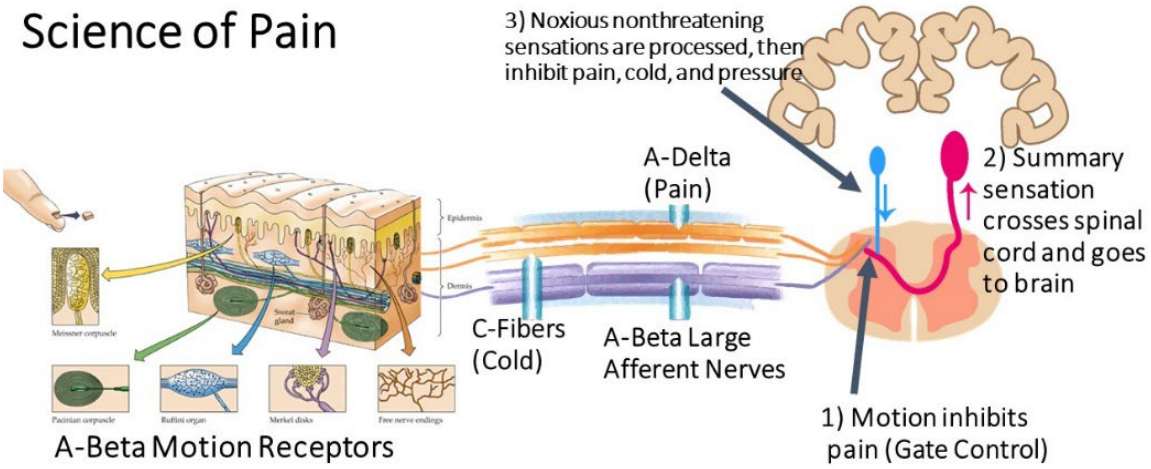
deeper pressure and vibration Pacinian receptors to transmit inhibition on large fiber A-Beta nerves. TENS units may have variable efficacy because users do not increase the electricity to sufficient amplitude to activate the Pacinian corpuscles [12] and because the maximal sensitivity of the deep A-Beta transmitted Pacinian corpuscles is 180 – 250 Hz.[2]

3.2.2 VibraCool units use 180-250Hz vibrating mechanical oscillatory strain to activate "Gate Control" pain inhibition. Light touch, stretching, pressure and vibration motion receptors transmit the vibration motor's sensation of motion on large fiber afferents known as A-Beta nerves.[3 4] VibraCool performs the same function as TENS units (pain relief) with the same physiologic mechanism of action (Gate Control). The high-frequency motor is a more effective method of operation for stimulating multiple motion receptors and selectively stimulating the most effective one.

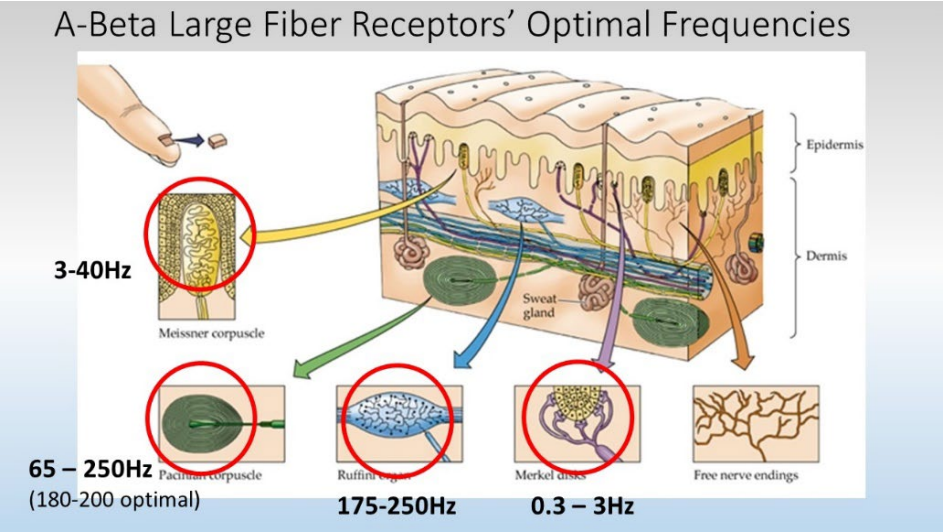
4 Method of Operation

4.1 The parameters of M-stim include frequency, orientation to the body, amplitude, location of application, and duration.

4.2 Physiology of Gate Control: Muscle, skin, and injury pain travel from the body to the substantia gelatinosa in the posterior half of the spine on Aδ ("A-Delta") fibers. In addition to Aδ pain fibers, Aβ ("A-Beta") nerves transmitting motion sensations and C-fibers transmitting cold information join in the substantia gelatinosa of the spinal cord. Sensory input is inhibited, enhanced, or modified; then summary sensations are transmitted to the brain. When Aβ large fiber afferents or C-fibers inhibit Aδ pain fibers, this is known as "Gate Control" pain inhibition. Only 5% of neurons in the substantia gelatinosa transmit signals to the brain – 95% are responsible for sensation modification and inhibition, so that stronger signals arrive at the dorsal horn inhibit weaker ones.[1]



The large A-Beta afferents transmit information from four receptors: Meissner (light touch), Pacinian (pressure, vibration), Ruffini (stretching and vibration passing in waves), and Merkel discs (deep touch). Each receptor has a maximally receptive frequency, and distribution in the body. Messiner are on the surface, Pacinian corpuscles are deeper and concentrated most prominently in cartilage and joints. Fast adapting light touch Meissner corpuscles detect frequencies between 20 and 40 Hz, while fast-reacting and long-acting deep Pacinian corpuscles begin sensing vibration at 65 – 250 Hz, with maximal sensitivity between 180-200Hz.[13-16]



To trigger the deeper Pacinian motion receptors, the amplitude of the electricity must be high enough to cause the muscle fibers to twitch. Recent research indicates considerable variability in what therapists using TENS consider "high amplitude"; many patients don't tolerate the sensation of high amplitude electrical stimulation.[12] Because of this variability and the physiology that the twitch and surface electrical sensations only trigger two of the four motion receptors, research on TENS units demonstrates variable efficacy for pain conditions.[6]

By transmission to limbs through weight bearing, motion, and mechanical force pass through bones, tendons, muscles, and the cells that make them up. Integrins on cells recognize and respond to mechanical stressors; mechanical force can deform cells to open sodium channels, allowing ions to enter and leading to action potentials. The excitation of mechanical receptors can be accomplished with auditory or ultrasonic waves, pulsed electromagnetic fields, electrical stimulation, shockwaves, mechanical devices with motor-driven shaking platforms, or eccentric flywheels. Because the transmission of mechanical force decays at different rates through skin, fat, muscle, and bone, an initial frequency decays slightly to slower frequencies as the waves of mechanical energy spread.[2] This allows focal vibration to stimulate four Aβ receptors for more robust pain inhibition.

VibraCool delivers low amplitude (0.1G) oscillatory mechanical strain using an eccentric flywheel on a high-frequency motor rotating at 10000 - 12000 RPM (180-200Hz). To stimulate descending inhibitory control and reduce inflammation, VibraCool also incorporates an icepack that stimulates C-fiber inhibition.

In summary: While both TENS units and VibraCool use gate control pain inhibition, VibraCool uses a frequency better attuned to reach the primary Pacinian target for inhibition in joints, and its mechanical nature propagates as a wave to stimulate **all four** Aβ mechanoreceptors directly rather than TENS stimulating Messiner directly and Pacinian only at high amplitudes, and even then at

sub-optimal frequencies. Because the mechanical vibration is a uniform speed and amplitude, there isn't the potential for insufficient intensity of application. The simultaneous application of a thin solid ice pack transmits vibration while stimulating a **fifth** pain inhibitory pathway.

4.3 Descending (or diffuse) noxious inhibitory control

Ice or deep pressure are transmitted by C-fibers, unmyelinated fibers running alongside A-beta nerves. When stimulated over time, they are processed in the anterior cingulate gyrus and send descending inhibition of pain. This mild stimulus of pain inhibiting a stronger stimulus is also called "conditioned pain modulation" or CPM response.[17 18]

4.4 Vibration **does not** reduce pain through distraction-

> **"**Vibro-tactile stimulation effectively recruited analgesic mechanisms not only in NC[normal controls] but also in patients with chronic musculoskeletal pain, including FM[fibromyalgia]. Distraction did not seem to contribute to this analgesic effect. "[19]
>
> **"…**the results suggest that touch gating is a robust, stimulus-locked form of sensory interaction, rather than a transitory result of distraction or other cognitive processes."[20]
>
> **"**… little evidence to support the view (widely held by subjects) that distraction is the mechanism of vibratory analgesia."[21]

5 Therapeutic Comparisons - The research on mechanical stimulation therapy for joint pain, recovery, and post-operative pain has primarily arisen in the past 8 years, often by therapists comparing new physics modalities of light or stimulation. VibraCool was compared to a TENS unit (Quell) and infrared device (Willow Curve) [22] with the following commentary in the journal Practical Pain Management:
"The vibratory frequency utilized targeted pain-specific receptors (mechanoreceptors) and nerve pathways that might further activate the spinal gating mechanism(s). Vibration (whole and/or focal) is being used therapeutically to reduce muscle atrophy, improve joint active range of motion (AROM), and reduce joint pain. The authors found the VibraCool device to be a valuable adjunct to our clinical treatments, especially for very difficult-to-treat enthesopathic **[NB: tendinopathy, joint overuse]** conditions that, in many cases, are unresponsive or recalcitrant to other forms of energy or manual therapies. These observations were consistent with the inherent predilection that vibration energy might have on ligamentous, capsular, and musculotendinous structures based on the high concentration of mechanoreceptors found in collagen-based tissue.[5 23] Patients showed both high compliance and tolerance for using the VibraCool device; chronic pain patients who had some hypersensitivity to general tactile stimulation did fine with the unit."[22]

5.1 Clinical Efficacy –

5.1.1.1 Vibration and ice for acute pain (180-200Hz + ice). Vibration and ice device has been tested for acute a-Delta pain in over 90 independent clinical trials.[8 24-62]Appendix 2

5.1.1.2 A meta-analysis in 2019[25] found "the device was significant in reducing self-report procedural pain (SMD: -1.11; 95% CI: -1.52, -0.70; P<0.0001), parent-reported procedural pain (SMD: -0.94; 95% CI: -1.62 to -0.27; P=0.006), observer-report procedural pain (SMD: -1.19; 95% CI: -1.90 to -0.47; P=0.001), observer-reported procedural anxiety (SMD -1.37; 95% CI: -1.77 to -0.96; P<0.00001), and parent-reported procedural anxiety (SMD -1.36; 95% CI: -2.11 to -0.61; P=0.0004)."

5.1.1.3 A systematic review for intramuscular a-delta pain in 2018 found "Interventions using coolant and vibration together, as well as a combination of site-specific and patient-led interventions, showed the most consistent effects in reducing self-reported pain, fear or distress."[63] Many trials are in pediatric populations; because descending inhibitory control develops over time, pain reduction is typically stronger in adults. In addition, fear increases pain, and pediatric populations have increased anxiety about procedural pain.

5.1.1.4 A meta-analysis found that compared to other vibration devices the 200Hz plus ice technology "In the stratified analysis of device type, the effect size for the BUZZY tended to be higher than that for the other devices," and "Cooling stimulation might have contributed to the reduction in pain."[9]

5.1.1.5 Our device reduced sharp and burning pain and increased satisfaction. *Pain Management Nurs 2018 Dec:19(6):645. N=65, average age 52, Pain 74% reduced, satisfaction 95 v. 84. P<.001 both).[24]*

5.1.2 Efficacy of our technology: Vibration and ice for overuse injury (180-200Hz + ice)

5.1.2.1 Prospective comparison of pain relief devices using odds ratio of likelihood of reduced pain after 30 minutes of use compared to no intervention: "modified OR for the combined devices (Quell, Willow Curve, and VibraCool) for the pooled data is 2.25 with a 95% CI (1.34 - 3.77) and a z statistic (3.077), all at a significance level (P = 0.0021)."[22] Private communication with the author revealed VibraCool significantly outperformed the TENS Quell unit. Tmarovino@msn.com

5.1.2.2 8 patients used VibraCool for plantar fasciitis. Pain was reduced from 4/10 to 2/10, with 30% increase in pain free days. Efficacy greatest with 2 20-minute sessions daily.[64]

5.1.3 Efficacy of our technology: Vibration and ice for postoperative opioid reduction (180-200Hz + ice) 14 individuals (27±11 years, 9 males; 5 females) used VibraCool after ACL repair. Compared to an historic cohort of 77 patients undergoing an opioid reduction coaching intervention, 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. By Day 6 post-surgery, average pain levels dropped to 2.3±2.2, which was slightly less than pain levels (2.7±1.4) in historical cohort. Only 4 patients continued to use opioids by their first post-operative visit (4.3±2.3 days post-surgery). Effect size 0.58. (pre-submission)

5.2 Clinical Effectiveness of High Frequency Low Amplitude Local Vibration without Ice (see also Appendix 1)

5.2.1 Post Operative: 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 PMID: 28074671 "[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."

5.2.2 Localized muscle vibration (LMV) reverses quadriceps hypotrophy, improves function. Benedetti MG Boccia G et al. Int J Rehabil Res. 2017 Dec;40(4):339-346. PMID: 28723717 Thirty patients with OA randomized to 150Hz or electrostimulation; The high frequency LMV group showed a significant change in Western Ontario and McMaster Universities

Osteoarthritis Index score, Visual Analogue Scale score, Timed Up and Go test, Stair Climbing Test, and knee flexion. These improvements were not significant in patients treated with neuromuscular electrical stimulation. sEMG analysis suggested an increased involvement of type II muscle fibers in the group treated with LMV. In conclusion, the present study supports the effectiveness of local vibration in muscle function and clinical improvement of patients with knee OA.

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

5.2.4 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

5.2.5 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

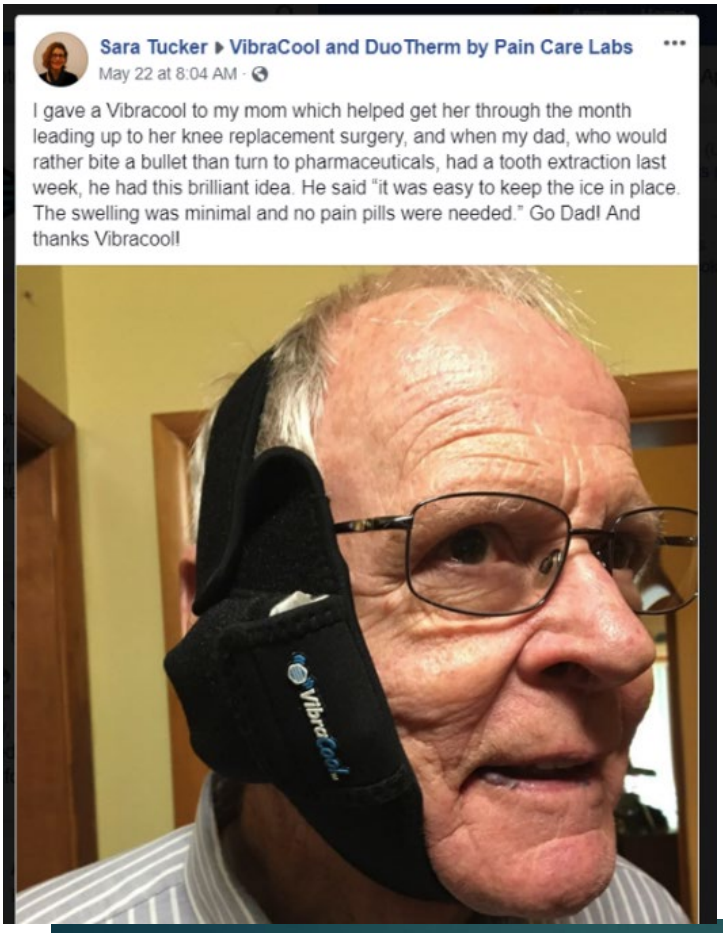
5.3 High Frequency Low Amplitude Mechanical Stimulation alone – Delayed onset muscle soreness

5.3.1 "The meta-analysis indicated that vibration significantly improved the VAS at 24, 48, and 72 hours after exercise, and significantly improved CK levels at 24 and 48 hours, but not at 72 hours." Does vibration benefit delayed-onset muscle soreness? A meta-analysis and systematic review. Lu X, Wang Y, Lu J et al. J Int Med Res. 2019 Jan;47(1):3-18 PMID: 30526170

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

5.3.3 Effectiveness of using wearable vibration therapy to alleviate muscle soreness. Cochrane DJ. Eur J Appl Physiol 2017 Mar;117(3):510-509. PMID: 28168554 Thirteen males used vibration therapy 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.

5.3.4 Further Clinical Commentary (testimonials)



"I'm on disability but I'm desperate, I broke my hip and femur and I'm only 29 two months ago and I have a rod in my femur and in my hip and it's bolted to my knee so I have severe knee pain. I've been on fentanyl for a couple years from knee pain but even though I have more pain now I won't let my dr give me more.

Anyway, I wanted to thank you as I forgot to change my patch today and I was on my feet volunteering at an animal rescue all day and I got home and tried to workout but couldn't I hurt so bad I wanted to cry. Then I remembered **VibraCool** had just arrived in the mail. I didn't think it would work but after one use without the **ice it relieved the pain so much** I think I may actually be able to sleep tonight pain free! Thank you so much!! **This is a wonderful device!** I just wanted to thank you SO MUCH!!! I could never have afforded this if you hadn't done the sale nor would I have taken the risk. It is worth EVERY PENNY!!! If you tell me how to leave you reviews I sure will!!

I LOVE this thing!! Thanks again, J.H."

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

AUTHORS: [*REDACTED*]

INSTITUTIONS: [*REDACTED*]
PRESENTATION TYPE: Abstract
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: Historically controlled trial

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 (150Hz) 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).

Level of Evidence: Level III pilot study

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. By Day 6 post-surgery, average pain levels dropped to 2.3±2.2, which was slightly less than pain levels (2.7±1.4) in historical cohort. 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 standard of care. 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.

Pre-publication pending $200,000 to orthopedist who did the trial

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Needle pain and fear are barriers to health. In 1995, James Hamilton published one of the first needle fear papers.[1] At the time, he concluded that 10% of adults and 25% of children feared needles - and that it was a serious health risk. By 2012, research showed 24% of adults and 63% of those born in 2000 feared injections.[2] We now know fear correlates the number of injections given on a single day in the 4-6 year window.[3] At this preschool age, children remember pain and fear, but can't abstract enough to understand why people they trust are hurting them. Before 1985, the number of scheduled preschool injections was zero; by 2000, it was often as high as five. Buzzy is the most proven needle pain reliever and the only intervention proven to reduce fear. Addressing needle pain is a public health priority - Buzzy Helps!

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The following references are all unfunded independent investigations of Pain Care Labs' products Buzzy and/or DistrACTION Cards as of 02/03/2022.
Studies by the inventor (Baxter) were funded by grants from Hope Street Kids and NICHD Grant Number 4R44HD056647-02.
Adult and All-Age Studies Italicized; Pediatric Studies plain font.

Reviews and Meta-Analyses

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Buzzy® is the **Most Proven** & **Most Effective Solution** for Needle Pain & Fear

"Conclusion: Interventions using **coolant and vibration together, as well as a combination of site-specific and patient-led interventions, showed the most consistent effects** in reducing self-reported pain, fear or distress."
Lee VY, Caillaud C et al.

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Venipuncture

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*In Progress/Completed: Stein K. **Buzzy Use for IV access in Dentistry.** University of Iowa College of Dentistry. NCT03619135

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*In Progress: Marcio Boniatti, Hospital Nossa Senhora da Conceicao Rio Grande Do Sul, Brazil, **Minimizing pain during childhood vaccination. Infants, outcome crying in seconds** NCT03540589

*In Progress: Mesterman R. **Pain Perception of Children and Youth Receiving Non-sedated Botulinum Toxin-A Injections Using the Buzzy®.** NCT02273284

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In progress: Ricardo JW, Lipner SR. Weill Medical College of Cornell University. **The Evaluation of External Thermomechanical Stimulation for Pain Reduction in Patients Undergoing Nail Injection NCT04422795 est. completion 2/2024*

In Progress: Ryan Cobb MD: **Thermomechanical distraction and social anesthesia in interventional radiology Temple University, Philadelphia. NTC04236674*

Recruitment Complete: Seda CEVHEROĞLU: **The Effect of Three Different Local Cold Applications on Pain and Ecchymosis in Subcutaneous Heparin Injections: NCT04235244*

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Misc.

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Hwang LK, Nash DW, Yedlin A, Greige N, Larios-Valencia J, Choice C, Pothula A. **The Effect of Vibration on Pain During Intravenous Injection of Propofol: A Randomized Controlled Trial** Ann Plast Surg. 2021 Jul 1;87(1s Suppl 1):S36-S39. PMID: 33833179

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PhD Thesis & Dissertations

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Buzzy® Reduces Impact of Prolonged Tourniquet Application for Hematology:

In a study by Dr. Lima-Olivieri et al., it was found that leaving a tourniquet in place 120 seconds caused the largest derangement of hematology lab values compared to free flowing blood collection. (1) Dr. Lima-Olivieri et al. then tested Buzzy®, leaving it in place between 90 and 180 seconds and comparing results to free-flowing blood.(2)

The changes from leaving a tourniquet in place for 2 minutes were greater than the changes from leaving Buzzy® in place 2 minutes. Dr. Lima-Olivieri did not reference his earlier work, or discuss his labs funding by the maker of the free-flow unit. The Journal solicited an opinion.

Table 1 - Both Buzzy and a tourniquet were left on 90 – 180 seconds and compared to a transilluminating free flowing collection device where blood was collected without a tourniquet. Comparison numbers between free-flow versus Buzzy® and free-flow versus Tourniquet with percentage Mean Difference between paired results. **Buzzy® caused less difference after two minutes than a standard tourniquet** for all outcomes except lymphocytes: prolonged tourniquet +2.6%, prolonged Buzzy -3.9%. **The greatest clinical concern is overestimating WBC and neutrophils, failing to recognize immunocompromise.**

	Units	Free-Flow	Buzzy®	%Diff Buzzy	Free-Flow	Tourniquet	%Diff Tourniquet
RBC	(10^{12}/L)	4.80±0.55	4.90±0.55	**2.0**	4.68(0.45	4.81(0.46)	**2.8**
Hb	(g/L)	137.9±12.7	141.4±13.2	**2.5**	14.1(1.4)	14.6(1.4)	**2.6**
Hct	(%)	40.6±4.0	41.5±4.0	**2.2**	41.7(4)	42.9(4)	**2.9**
MCV	(fL)	84.4 (81.8-88.3)	84.6 (81.9-88.1)	0.2	88(5)	89(5)	1.1
RDW	(%)	12.7±0.5	12.7±0.6	0			
WBC	(10^9/L)	7.35±1.94	7.10±1.89	-3.5	6.59(1.87)	6.9(2.02)	4.8
Neu	(10^6/L)	4.27±1.57	4.15±1.49	-2.9	3.72(1.31)	3.87 (1.4)	4.2
Lymp	(10^6/L)	2.41±0.80	2.32±0.80	-3.9	2.23(0.73)	2.29(0.75)	2.6
Mono	(10^6/L)	0.29±0.08	0.28±0.05	-3.6	0.33(0.11)	0.34(0.13)	3.9
Eos	(10^6/L)	0.16±008	0.16±0.07	0	0.30(.34)	0.37(0.36)	**24.1**
Baso	(10^6/L)	0.046±0.02	0.041±0.02	-12.2	0.026(0.02)	0.021(0.02)	**23.8**
Plt	(10^9/L)	274±66	272±66	-0.7	200(46)	208(46)	3.6
MPV	(fL)	9.12±0.81	9.09±0.71	-0.3			

1. Lima-Oliveira G, Lippi G, Salvagno GL, et al. T**ransillumination: a new tool to eliminate the impact of venous stasis during the procedure for the collection of diagnostic blood specimens for routine haematological testing.** International Journal of Laboratory Hematology. 2011 Oct;33(5):457-62. PMID: 21412480

2. Lima-Oliveira G, Lippi G, Salvagno GL et al. **A new device to relieve venipuncture pain can affect haematology test results.** Blood Transfus. 2014 Jan; 12(Suppl 1): s6–s10 PMID: 24120583

3. Baxter AL, Lawson ML. **Concerns with the methodology, analysis and discussion of the Buzzy® and transillumination comparison article.** Blood Transfus. 2014 Jan;12(Suppl 1): s3–s5 PMID: 24599904

Buzzy® Reduces Impact of Prolonged Tourniquet Application for Chemistry:

In one study by Dr. Lima-Olivieri et al., it was found that leaving a tourniquet in place 2 minutes caused the largest derangement of chemistry lab values from free flowing blood using a device made by a manufacturer in his town.(4)

Dr. Lima-Olivieri et al. then tested Buzzy®, leaving it in place also for 2 minutes and comparing to free-flowing blood.(5) The changes from leaving a tourniquet in place for 2 minutes were greater than the changes from leaving Buzzy® in place, and in neither case was there a derangement in potassium from lysed cells that was clinically significant.

Dr. Lima-Olivieri did not reference his earlier study or note funding from the free flowing unit, and the journal solicited an editorial.(6)

	Units	Free-flowing	Buzzy	%Diff	Free-flowing	Tourniquet	%Diff
Glucose	mmol/L	4.66 (4.33–5.11)	4.66 (4.27–5.11)	**0**	4.77±1.0	4.83±1.0	**1.2**
Total Protein	g/L	78.9 ± 3.6	80.1 ± 4.4	**1.5**	76.0±6.0	79.0±6.0	**3.8**
Albumin	g/L	47.9 ± 3.4	48.9 ± 3.7	**2**	46.0±4.0	48.0±5.0	**4.2**
AlkPhos	µkat/L	1.14 ± 0.3	1.19 ± 0.3	**4.2**	1.53±0.37	1.56±0.39	**1.9**
Triglyceride	mmol/L	78.9 ± 3.6	80.1 ± 4.4	**1.5**	1.63±0.95	1.68±0.96	**3.0**
Potassium	mmol/L	4.0 ± 0.3	4.0 ± 0.4	**0**	4.2±0.2	4.3±0.4	**2.3**
Sodium	mmol/L	144.3 ± 1.8	144.3 ± 1.9	**0**	142.2±3.2	142.7±3.2	**0.4**
Phosphate	mmol/L	1.32 ± 0.2	1.30 ± 0.2	**-1.5**	1.17±0.16	1.18±0.19	**0.8**
Calcium	mmol/L	2.36 ± 0.1	2.37 ± 0.1	**0.4**	2.35±0.12	2.40±0.12	**2.1**
Magnesium	mmol/L	0.81 ± 0.06	0.81 ± 0.07	**0**	0.810±0.08	0.827±0.08	**2.0**

4. Lima-Oliveira G, Lippi G, Salvagno GL, et al. **New ways to deal with known preanalytical issues: use of transilluminator instead of tourniquet for easing vein access and eliminating stasis on clinical biochemistry.** Biochemia Medica. 2011;21(2):152-9. PMID: 2213855

5. Lima-Oliveira G, Lippi G, Salvagno GL et al. **Quality impact on diagnostic blood specimen collection using a new device to relieve venipuncture pain.** Indian J Clin Biochem. 2013 Jul;28(3):235-4. PMID: 24426217

6. Baxter AL, Lawson ML. **Methodological concerns comparing Buzzy® to transilluminator device.** Indian J Clin Biochem. 2014 Jan;29(1):114-5. PMID: 24478562

Buzzy®
« DRUG FREE PAIN RELIEF »

Pain Reliever	Prep time	Ease of use	Duration	Pain Relief	RCTs IVs*	RCTs for injections*	Head to head
Buzzy® high frequency mechanical stim, Ice	1 min	****	1 min	****	******** ******** ******** ****++X	****** ****** *+***** **** ***** ***	Potts: LMX = Buzzy® for IV; Canbulat: Buzzy® > Shotblocker IM
DistrACTION® Cards	10 sec	*****	n/a	***	*******	n/a	97% say better phlebotomy experience(11)
EMLA®- Eutectic mixture local anesthetics	60 min	*	2 hours	***	****** ****** ****** **+	X***** *	Vasoconstricts until 90 min; Emla> Buzzy® for IV <6 year olds
LMX-4® - liposomal 4% lidocaine formulation	20 min	**	20 min	***	****** ***++		Try Glad Press-n-Seal instead of Tegaderm for comfort(13)
Ice Pack	1 min	***	30 seconds	**		**	
Shotblocker® - plastic with prongs	1 min	***	0 seconds	**		*+XXX	SB = Buzzy® for insulin; SB < Buzzy® vaccines

3 Buzzy meta-analyses,
2 systematic reviews

* Reduced Peds' Pain
* Reduced Dental Pain
* Reduced Adults' Pain
* Reduced Fear/Anxiety
X Negative Study Peds
X Negative Study Adults
+ Equivalent Study

Ballard A et al. Clin J Pain. 2019 June;35(6):532-543
(N= 1138, **pain -1.11**; 95% [CI]: -1.52 to -0.70; P<0.0001)
anxiety -1.37; 95% CI: -1.77 to -0.96; P<0.00001)
Lee VY, et al Hum Vaccin Immunother. 2018;14(11):2737-2747 **"coolant and vibration together… most consistent effects in reducing self-reported pain, fear or distress."**

Included Analyses

- Descriptive Statistics
- Two-Tailed Paired Samples t-Test between Change_T and Change_V

Results

Descriptive Statistics

Introduction

Summary statistics were calculated for Age and Gender.

Summary Statistics

The observations for Age had an average of 58.15 (*SD* = 16.34, SE_M = 3.65, Min = 25.00, Max = 81.00, Skewness = -0.54, Kurtosis = -0.78). The observations for Gender had an average of 0.35 (*SD* = 0.49, SE_M = 0.11, Min = 0.00, Max = 1.00, Skewness = 0.63, Kurtosis = -1.60). When the skewness is greater than 2 in absolute value, the variable is considered to be asymmetrical about its mean. When the kurtosis is greater than or equal to 3, then the variable's distribution is markedly different than a normal distribution in its tendency to produce outliers (Westfall & Henning, 2013). The summary statistics can be found in Table 1.

Table 1

Summary Statistics Table for Interval and Ratio Variables

Variable	*M*	*SD*	*n*	SE_M	Min	Max	Skewness	Kurtosis
Age	58.15	16.34	20	3.65	25.00	81.00	-0.54	-0.78
Gender	0.35	0.49	20	0.11	0.00	1.00	0.63	-1.60

Note. '-' indicates the statistic is undefined due to constant data or an insufficient sample size.

Two-Tailed Paired Samples *t*-Test

Introduction

A two-tailed paired samples *t*-test was conducted to examine whether the mean difference of Change_T and Change_V was significantly different from zero.

Assumptions

Normality. A Shapiro-Wilk test was conducted to determine whether the differences in Change_T and Change_V could have been produced by a normal distribution (Razali & Wah, 2011). The results of the Shapiro-Wilk test were not significant based on an alpha value of .05, $W = 0.91$, $p = .064$. This result suggests the possibility that the differences in Change_T and Change_V were produced by a normal distribution cannot be ruled out, indicating the normality assumption is met.

Homogeneity of Variance. Levene's test was conducted to assess whether the variances of Change_T and Change_V were significantly different. The result of Levene's test was not significant based on an alpha value of .05, $F(1, 38) = 1.22$, $p = .276$. This result suggests it is possible that Change_T and Change_V were produced by distributions with equal variances, indicating the assumption of homogeneity of variance was met.

Results

The result of the two-tailed paired samples *t*-test was significant based on an alpha value of .05, $t(19) = -6.24$, $p < .001$, indicating the null hypothesis can be rejected. This finding suggests the difference in the mean of Change_T and the mean of Change_V was significantly different from zero. The mean of Change_T was significantly lower than the mean of Change_V. The results are presented in Table 2. A bar plot of the means is presented in Figure 1.

Table 2

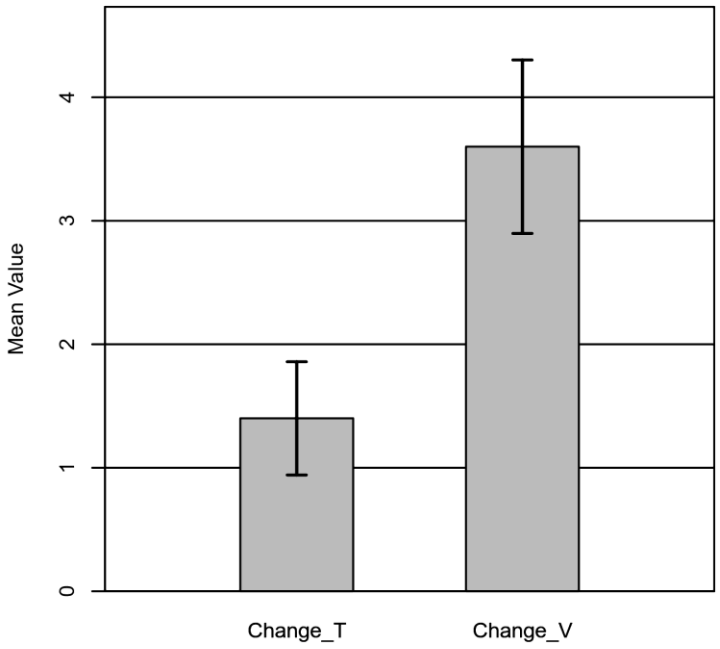
Two-Tailed Paired Samples t-Test for the Difference Between Change_T and Change_V

Change_T		Change_V				
M	*SD*	*M*	*SD*	*t*	*p*	*d*
1.40	1.05	3.60	1.60	-6.24	< .001	1.40

Note. N = 20. Degrees of Freedom for the *t*-statistic = 19. *d* represents Cohen's *d.*

Figure 1

The means of Change_T and Change_V with 95.00% CI Error Bars



References

Razali, N. M., & Wah, Y. B. (2011). Power comparisons of Shapiro-Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson-Darling tests. *Journal of Statistical Modeling and Analytics, 2*(1), 21-33.

Westfall, P. H., & Henning, K. S. S. (2013). *Texts in statistical science: Understanding advanced statistical methods.* Taylor & Francis.

Raw Output

Descriptives

Included Variables:
Age and Gender

Sample Size (Complete Cases):
N = 20

Summary Statistics: Scale

Variable	M	SD	n	SE_M	Min	Max	Skewness	Kurtosis
Age	58.150	16.343	20	3.654	25.000	81.000	-0.539	-0.782
Gender	0.350	0.489	20	0.109	0.00000	1.000	0.629	-1.604

Quantiles:

	Age	Gender
10%	34.000	0.00000
20%	45.400	0.00000
25%	48.000	0.00000
30%	52.900	0.00000
40%	56.800	0.00000
50%	60.000	0.00000
60%	66.000	0.00000
70%	68.200	1.000
75%	71.250	1.000
80%	72.600	1.000
90%	76.100	1.000

Paired t-Test for Change_T and Change_V

Included Variables:
Change_T and Change_V

Sample Size (Complete Cases):
N = 20

Shapiro-Wilk Test:
W = 0.910, p = 0.0636

Levene's Test:
df_n = 1, df_d = 38, F = 1.221, p = 0.276

Results:

Change_T		Change_V				
M	SD	M	SD	t	p	d
1.400	1.046	3.600	1.603	-6.242	5.389×10^{-06}	1.396

Note. n = 20, df = 19.

Confidence Interval Based on α = 0.0500:
Lower Limit = -2.938, Mean Difference = -2.200, Upper Limit = -1.462

VibraCool®
« CRYOVIBRATION »

VibraCool® 2020 Literature Review

The human body is designed to adapt to motion. Below a mechanical strain threshold, muscles atrophy and bone is resorbed. Stressors exceeding the minimum strain threshold prompt growth at muscle, bone, and even cellular levels. Recent research on oscillatory mechanical strain proves that specific frequencies of vibration enhance physical therapy, improve post-surgical outcomes, increase training effectiveness, and reduce pain. We call this Mechanical Oscillatory Strain Therapy - MOST. We combine **evidence-based** MOST with cryotherapy (to address inflammation) and compression (to reduce edema). Our M-Stim® technology is proven to reduce pain up to 80%.

M-Stim® for Pain

Crossover trial of novel mechanical oscillatory vibration frequency device versus TENS for musculoskeletal pain. Tiziano M, 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.

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.

Effectiveness of vibratory stimulation on needle-related procedural pain in children: a systematic review. Ueki S, Yamagami Y, Makimoto K. JBI Database System Rev Implement Rep. 2019 Jul;17(7):1428-1463. Included Buzzy, Dental Vibe, Blaine Labs. "The effect size for the BUZZY tended to be higher than that for the other devices." "Overall, vibratory stimulation was significantly effective: self-rated pain: -0.55, 95% confidence interval [95% CI]: -0.92 to -0.18) observer-rated pain outcomes (SMD: -0.47, 95% CI: -0.76 to -0.18). [With Buzzy] the effect on the child's anxiety (SMD: -1.03, 95% CI: -1.85 to -0.20) was significant." PMID: 31021972

Pain Therapy Options for Home: a patient-based outcome review of at-home pain management devices, including Willow Curve, Quell, and VibraCool. Tiziano M, 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).

Why Vibration Instead of Electrostimulation

Mechnoreceptors 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, electrostim 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, electrical stimulation to twitch a muscle to twitch a motion nerve is less effective than actual motion.

Vibration for Physical Therapy

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

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

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

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

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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

Additional Resources:

- **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
- **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
- **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
- **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

Vibration for Post-Surgical Rehabilitation

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

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

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

Additional Resources:

- **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
- **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

Vibration for Delayed Onset Muscle Soreness

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

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

Additional Resources:

- **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

Vibration for Pain Relief

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

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

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

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

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

Additional Resources:

- **Mechanisms of pain relief by vibration and movement.** J Neurol Neurosurg Psychiatry. 1992;55:282–286. Kakigi R, Shibasaki H. PMID: 1583512
- **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 for Muscle Strength and Athletic Training

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

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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

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

Additional Resources:

- **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

Why 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); vibration improves this stiffness.

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

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 makes revolutionary science-backed therapies that tap into the body's physiological pain response system to stop pain in its tracks, 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.

Crossover Trial of Novel Mechanical Oscillatory Vibration Frequency Device Versus TENS for **Musculoskeletal Pain**

PRESENTER: Amy Baxter MD

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).

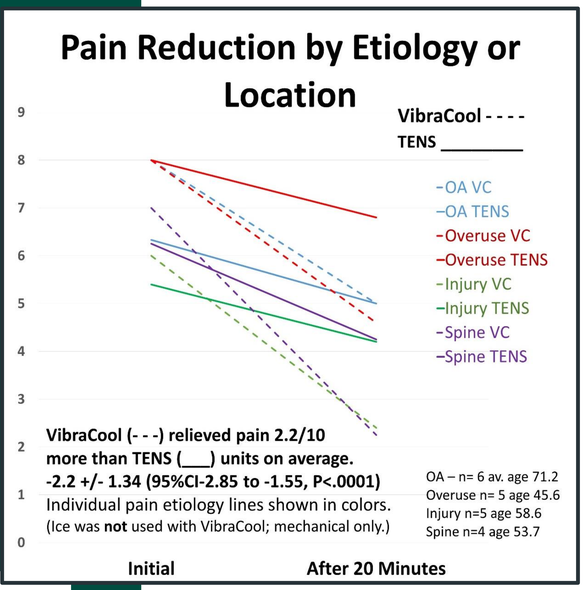
Interventions
Consented patients got a randomized 20-minute session of 180-200Hz mechanical oscillatory vibration, 0.1m/s2 amplitude (VibraCool (VC), Pain Care Labs, Atlanta, GA) or a generic model-TENS 3000 applied to pain. TENS units used 150Hz frequency with a pulse width of 200ms, asymmetrical biphasic 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.

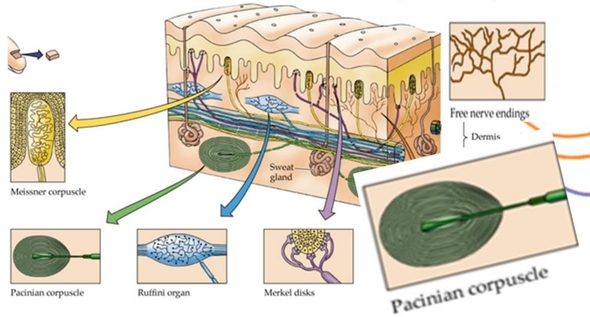
Specific mechanical **oscillation frequency relieved pain better than** electrical stimulation **(TENS).**

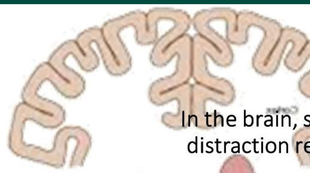


Why Mechanical Stimulation > Electrical

Gate Control Pain Relief

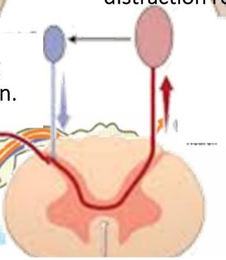
Mechanoreceptors fire at different mechanical frequency thresholds. Pacinian (180-250Hz)[1] block pain most.[2]





In the brain, self-efficacy and distraction reinterpret pain.

In the brain, annoying signals (cold) inhibit pain.



In the spine, mechanical signals override pain signals' transmission to the brain.[7]

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]

Scan to link to the poster

Link to more research

References

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4. Serrano-Munoz D et al. Intensity matters: Therapist-dependent dose of spinal transcutaneous electrical nerve stimulation. PloS one. 2017;**12**(12):e0189734.
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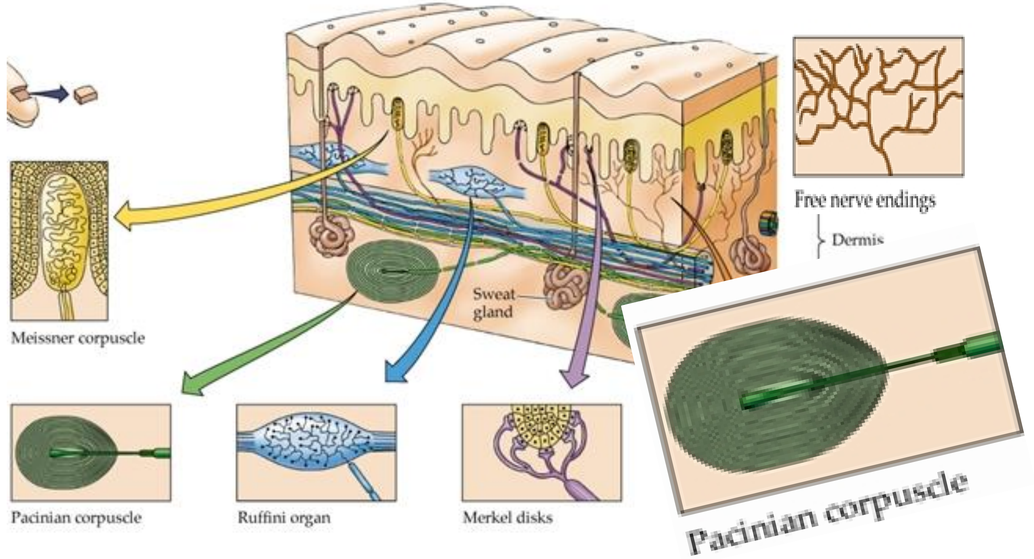

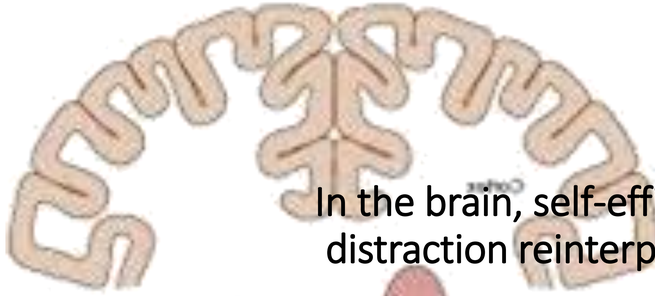

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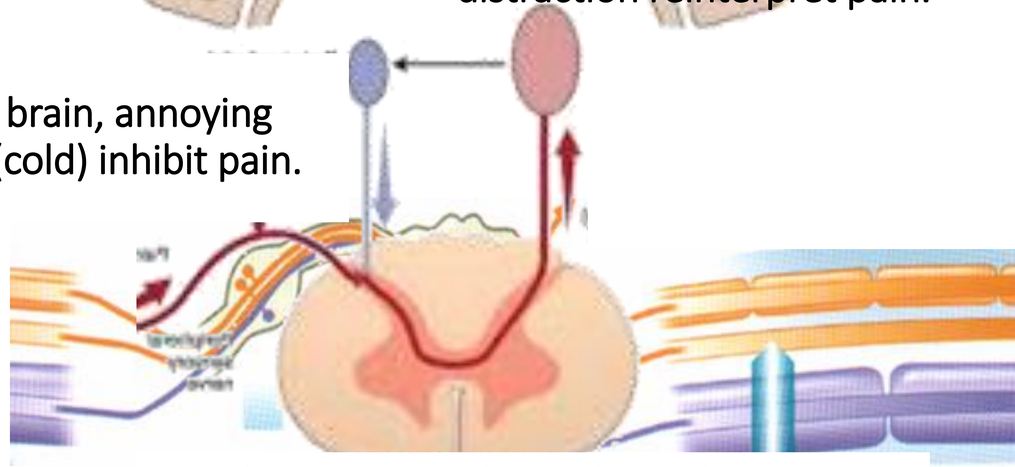

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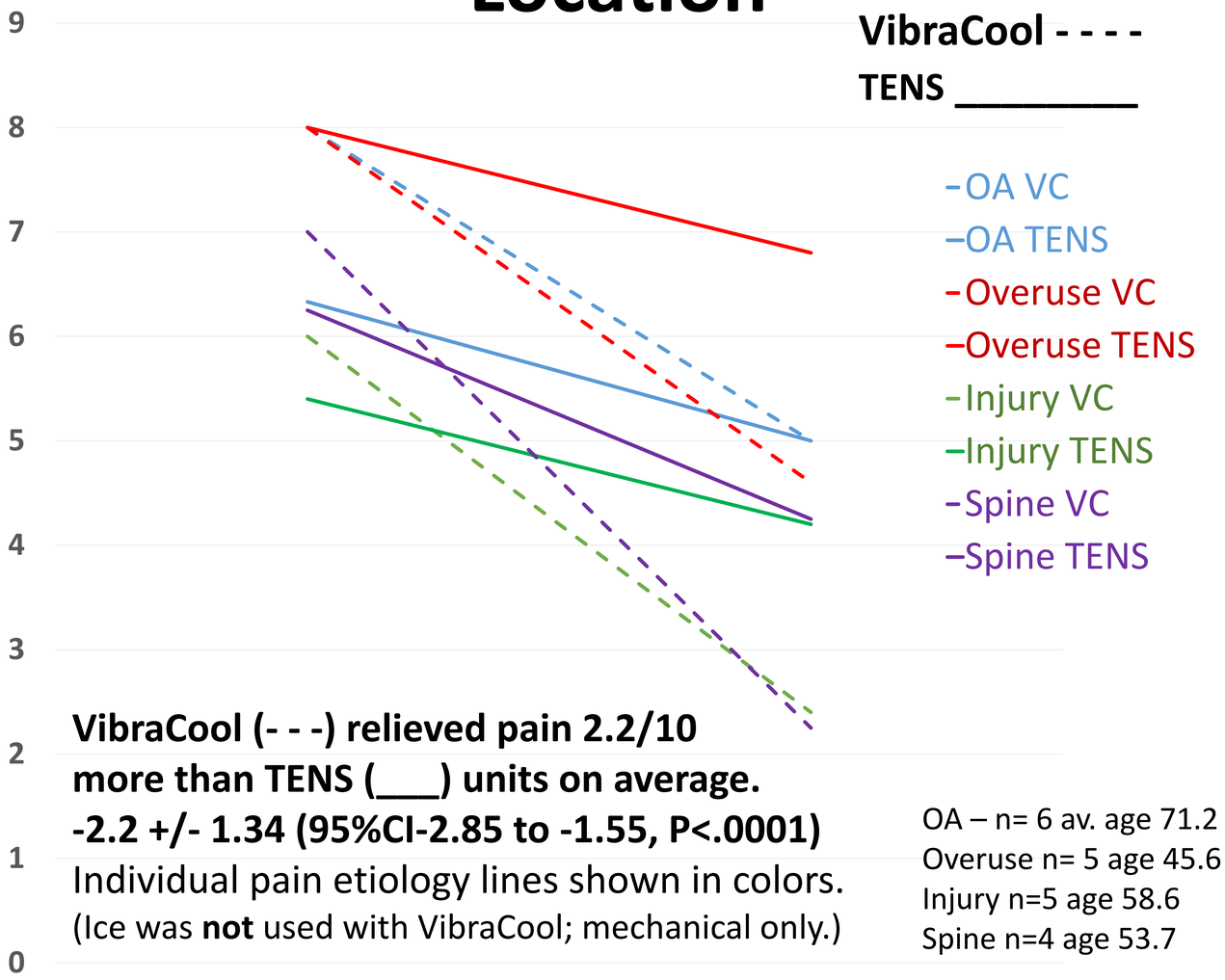
Pain Reduction by Etiology or Location



VibraCool (- - -) relieved pain 2.2/10 more than TENS (___) units on average.
-2.2 +/- 1.34 (95%CI-2.85 to -1.55, P<.0001)
Individual pain etiology lines shown in colors.
(Ice was **not** used with VibraCool; mechanical only.)

OA – n= 6 av. age 71.2
Overuse n= 5 age 45.6
Injury n=5 age 58.6
Spine n=4 age 53.7

Initial **After 20 Minutes**

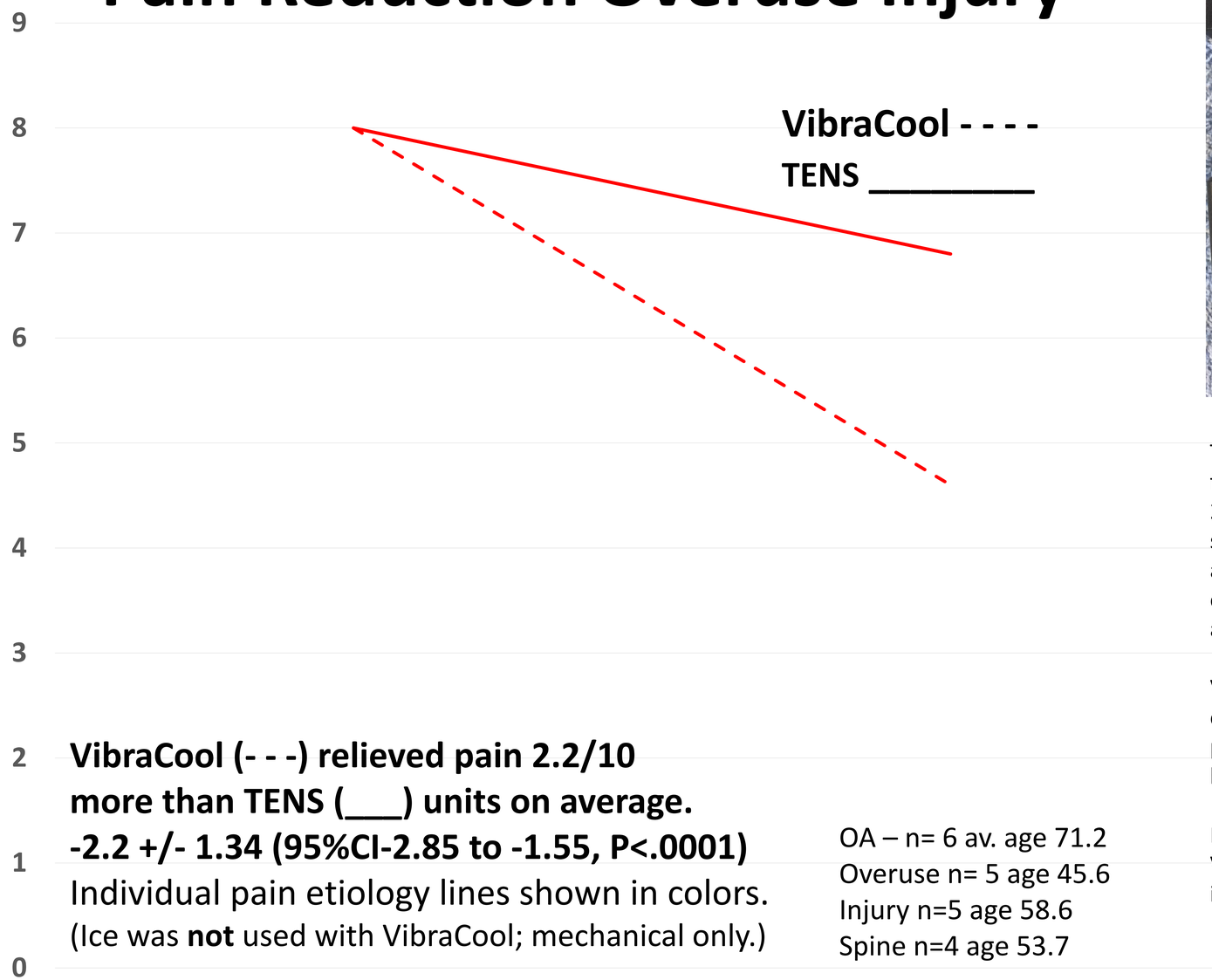
The TENS unit used 150Hz frequency with a pulse width of 200ms, asymmetrical biphasic square pulse waveform, and amplitude as high as comfortable on a 0-80mA using a 500 ohm load per channel

VibraCool® has an MSRP of $90, compression strap, reusable ice pack, and is powered by 2 AAA batteries which can be replaced.

For this Crossover Trial, VibraCool was used without the ice component.

VibraCool FDA 510(k) K130631
“Temporary relief of minor injuries…also intended to treat myofascial pain caused by trigger points, restricted motion and muscle tension” www.PainCareLabs.com

Pain Reduction Overuse Injury



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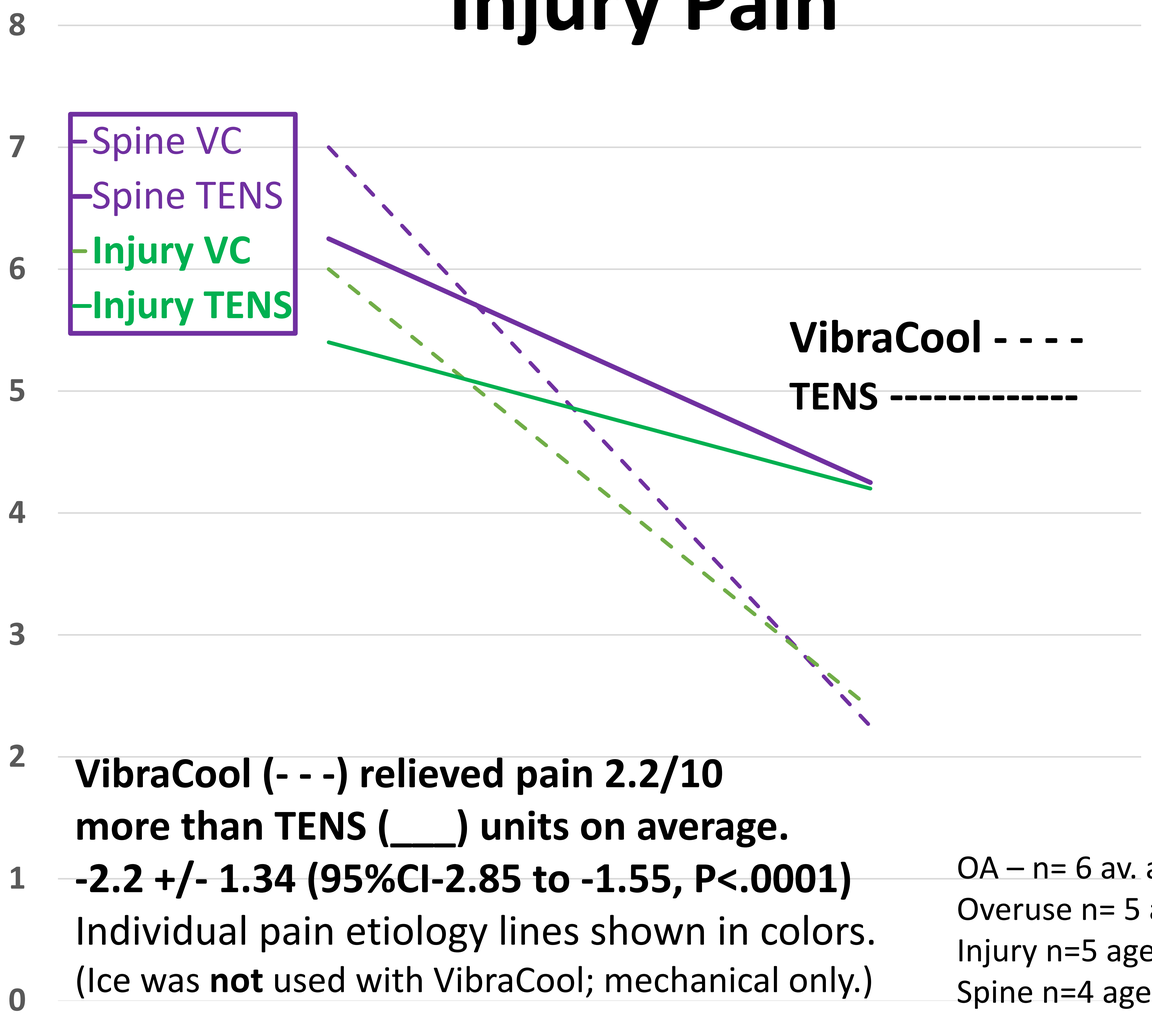
Pain Reduction for Spinal and Injury Pain



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