The Benefits of Pulsed Electromagnetic Fields (P.E.M.F) and the Oska Pulse

Jeff Marksberry, MD

November 15, 2019

Plan for Our Discussion

- Discuss the history of PEMF in medicine
- Discuss some of the current uses of PEMF:
  - Healing
  - Bone stimulators
  - Mental Health
  - Pain management
- Discuss the integrative pain management approach and where the Oska Pulse fits into the landscape

Pioneers in PEMF Technology

FARADAY

Changing a magnetic field will create an electric current; changes in the field and field size were related to the amount of current created

EINSTEIN

Electricity and magnetism are not discrete phenomena, but different aspects of the same phenomenon

TESLA

Out of controversy with Edison about AC vs DC energy, built a large AC coil to demonstrate the safety of AC electricity, this amongst his expansive knowledge about electromagnetic fields, gave us PEMF

LAKHOVSKY

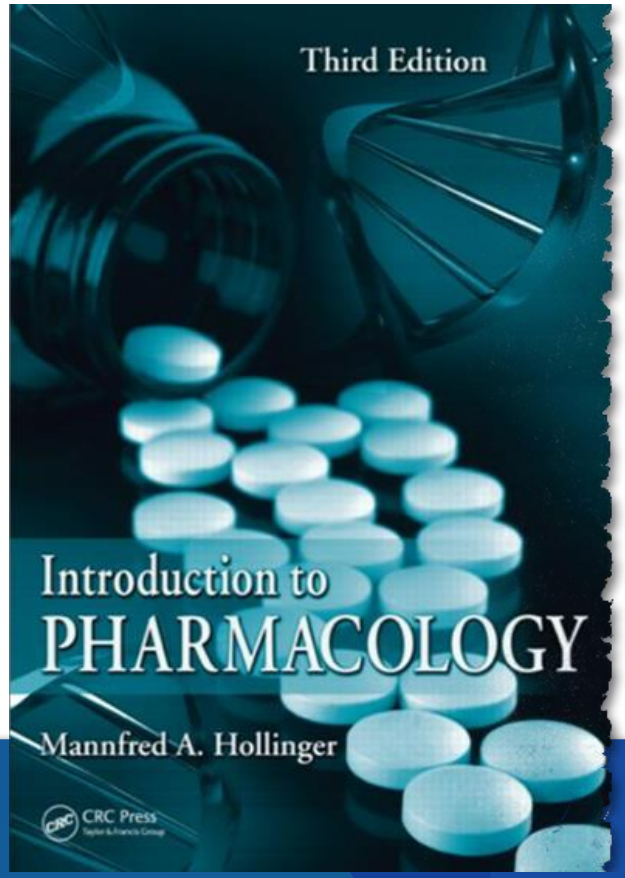
Russian scientist who that demonstrated living cells emit and receive electromagnetic radiations at their own frequencies

We knew all of this in the early 1900's

WHY DID IT TAKE 50 YEARS BEFORE PEMF DEVELOPMENT TOOK OFF?

The Flexner Report of 1910

Split the developmental paths of pharmacology
and electromedicine until the 1960's



U.S. Medicine | Electrotherapeutics Teaching Lab Europe

PEMF Historic Perspective

- Almost 190 years ago, Faraday discovered that a time-varying current creates a magnetic field that can induce another current in a nearby conductive medium.
- Around 60 years ago, Kolin et al. first demonstrated that an alternating magnetic field could stimulate a nerve in an animal model.
- In 1982, a group of researchers from the University of Sheffield were the first to report developing a practical magnetic peripheral stimulator and using it to stimulate human peripheral nerves.

Early approvals of PEMF

Wolff in 1892

Observed that bone is reshaped in response to the forces acting on it

Wolff's Law

Becker in 1960s

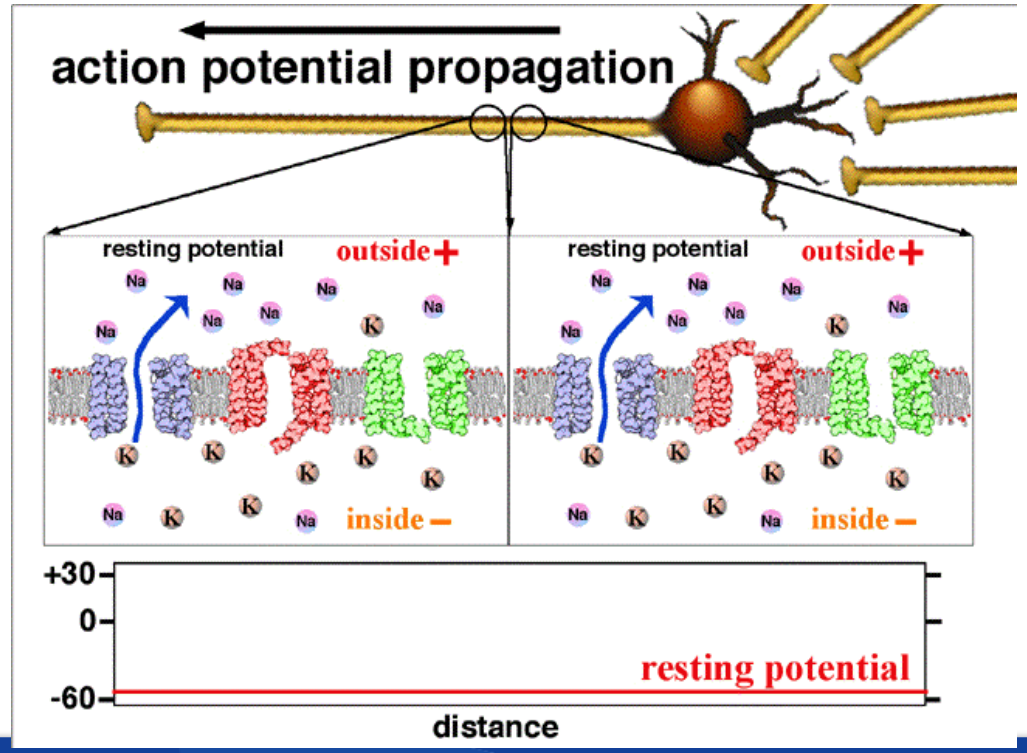
Applied the piezo electric effect principle by superimposing electromagnetic fields on amputated nematode limbs, causing them to regrow

Becker & Basset in 1970s

Published findings that PEMF provided a new approach to healing bone fractures

1979 FDA Approval for Nonunion of Bone and PEMF is reintroduced to American medical practice.

Cells create magnetic Fields specific to their type



Science Behind PEMF

- NIH database houses thousands of articles on PEMF and tissue specific applications

SPECIFIC FREQUENCIES = SPECIFIC TISSUES

- Examples include transcranial magnets that have been refined over time to work more effectively for patients' as treatments have become more frequency focused

Milestones in pemf approval by fda

1979

Approved PEMF Therapy for the healing of nonunion fractures.

1998

Approved PEMF Therapy for urinary incontinence and muscle stimulation.

2004

Approved PEMF Therapy for cervical fusion patients at high-risk of non-fusion.

2006

Approved PEMF Therapy for treatment of depression and anxiety.

2011

Approved PEMF Therapy for treatment of brain cancer.

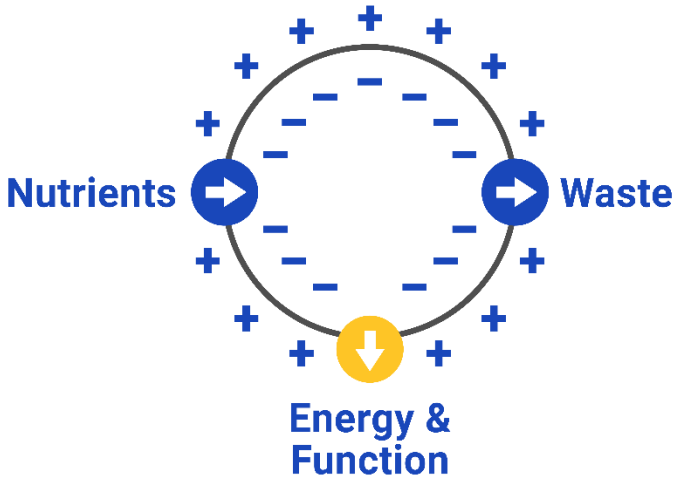
2015

On October 13th, the FDA reclassified PEMF devices from their existing Class 3 category to a Class 2 status, and most PEMF devices that are sold today in the United States are FDA registered as wellness devices.

PEMF Technology

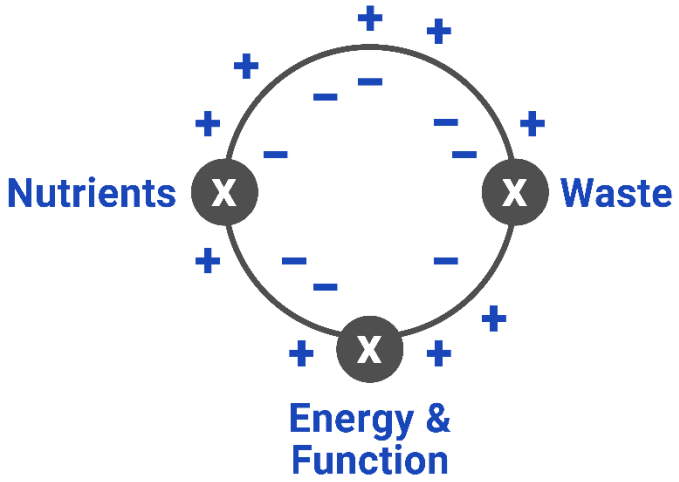
Healthy Cell

Healthy cells efficiently convert nutrients to function and stored energy. A cell's efficiency is based on the strength and consistency of the electrical potential across cellular and mitochondrial membranes.



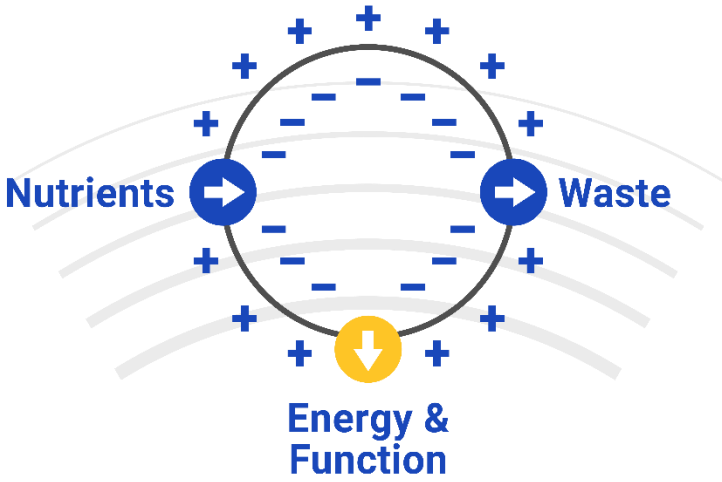
Distressed Cell

When cells are distressed from pathogens, trauma, starvation or toxins, their metabolic productivity is degraded.



Restored Cell

PEMF aids in the restoration of the electrical potential across the cellular and mitochondrial membranes restoring metabolic productivity and speeding tissue recovery.



PEMF

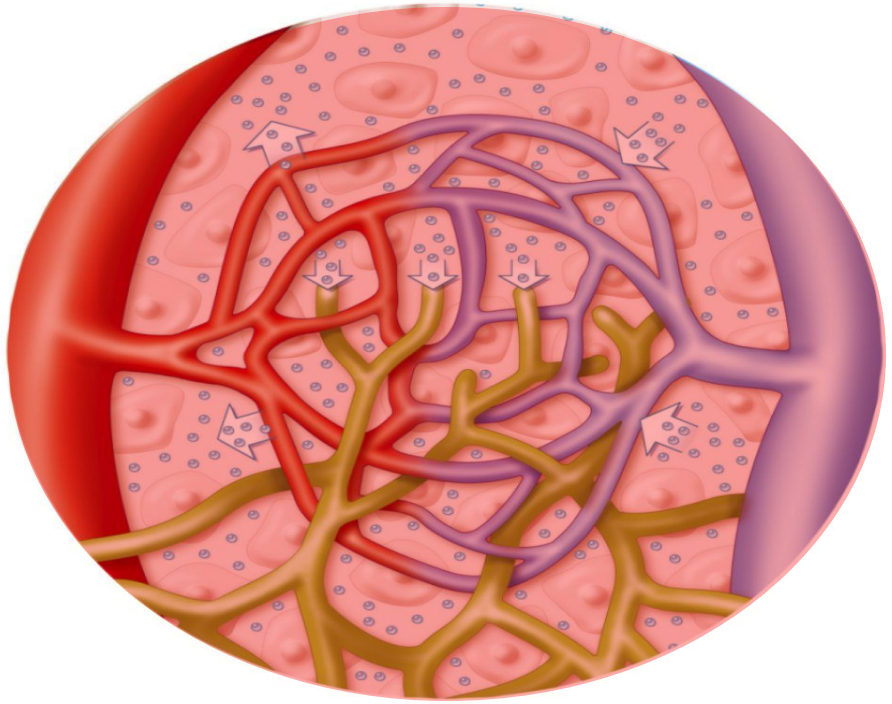
Tissue Mechanism of Action

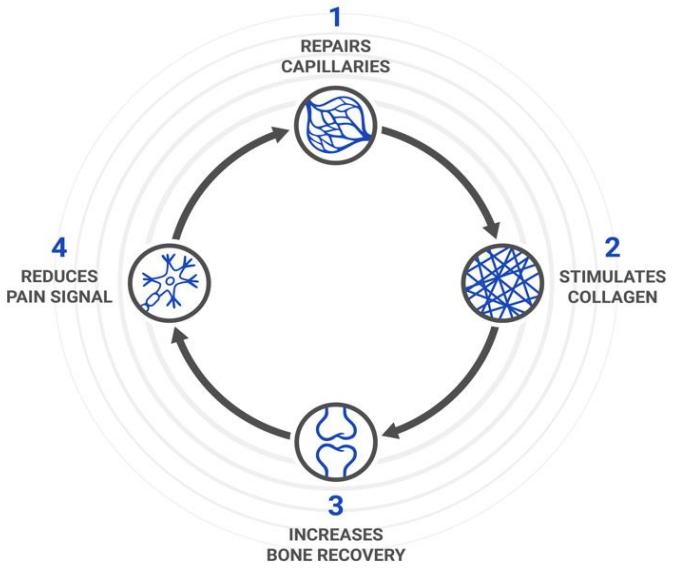
Protocol Targets Key Cell Types for Resolution and Recovery

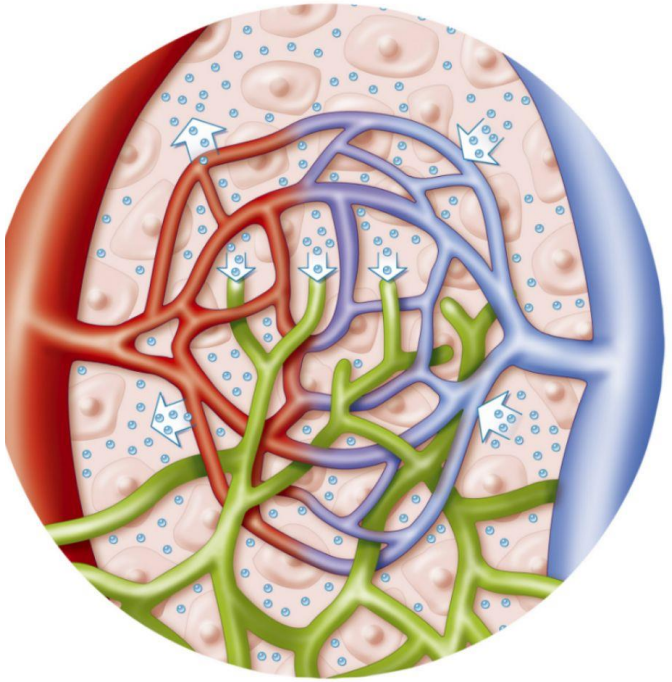
1. Stimulates endothelial cells which restore vascular and lymphatic tissue improving microcirculation, evacuating waste and reducing edema.
2. Stimulates fibroblasts repairing the proteoglycan cellular matrix, viscoelastic articular cartilage and other soft tissue.
3. Stimulates osteoblasts supporting bone growth and density as well as cartilage-bone interface.
4. Reduces the resting state of synaptic transmitters which has a temporary pain reduction effect.

Inflamed Tissue State

Tissue is saturated by plasma; edema compresses cells, constricts vascular and lymphatic circulation, slows delivery of nutrients and evacuation of waste resulting in pain and reduced mobility.







PEMF in Mental Health

Transcranial Magnetic Stimulation or TMS

- FDA approved in 2008 for the treatment of depression and in 2013 for pain associated with migraine headaches
- In Europe TMS is also approved to treat
  - Anxiety disorders such as OCD and PTSD
  - Stroke rehabilitation
  - Parkinson’s disease
  - Alzheimer’s disease
  - Chronic pain
  - Addiction

PEMF in Bone Repair

In 1979 the FDA approved PEMF for the use of non union fractures and bone repair.

- Selvamurugan et. al. 2017 used PEMF to regulate gene expression in bone marrow stromal cells to enhance osteoblasts differentiation
  - Reported significant increase in number of preosteoblasts in bone marrow and that PEMF regulated a range of genes in the cells which stimulated cell proliferation, differentiation and mineralization.
- Li et. al. 2017 used PEMF to reduce osteoporosis in diabetic bone
  - Study showed significant improvement in cortical microarchitecture along with a significant promotion of bone formation and mineralization
  - This further supported previous studies which showed PEMF to be useful in the treatment of osteoporosis secondary to estrogen deficiency or disuse

PEMF in Bone Repair

- Galli et. al. 2018 published a review article looking at the effects of PEMF to promote bone response to biomaterials used in orthopedic and dental prosthesis
  - The group looked at several factors including effects on osteoblasts, calcium phosphate scaffolds, orthopedic metals and polymer scaffolds
  - The reviewers concluded by calling PEMF a “powerful technology” as they had seen increase in bone volume and density in the presence of biomaterials. The number of cells significantly increased on both calcium phosphate and polymer scaffolds as well.

PEMF in Healing

- Istique et. al. 2013 exposed Staph Aureus colonies to various frequencies of PEMF for 90 minutes
  - Found 150 – 300 Hz to be most effective
  - Showed a reduction in CFU's (colony forming units) by 20% after only one 90 minute treatment
- Seelinger et. al. 2014 used low frequency PEMF to improve closure time and proliferation of fibroblasts
  - Scrapes were placed into patellar tendon fibroblasts cultures and were treated with PEMF for 90 minutes
  - Measured for closure time and cell proliferation against controls
  - Closure time for controls was 5 days vs. 3.3 days for treated tissue
  - There was also significant increase in health cell proliferation

Effective Non-Drug Treatment Options for Pain

What's the Science?

Effective Non-Drug Treatment Options


Acupuncture


Massage

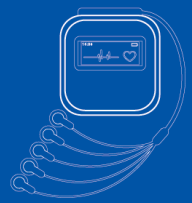

Manipulative Therapy


CBT

All of these treatments have shown some effectiveness at treating pain.


Pain Patches

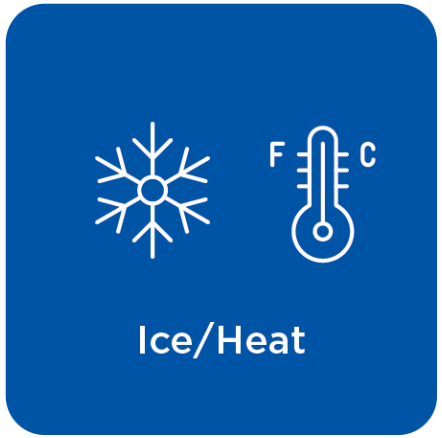

Ultrasound


TENS


PEMF

So What Distinguishes One from the Other?

Patient Centered Treatments



In addition to education, the list above should be encouraged in every chronic pain patient as one way of having a locus of control over their pain.

PEMF in Pain Management

PEMF

Magnetic fields penetrate body

60+ years of literature show healing effects

Body of knowledge match frequencies to effects

Effects tissue and cell specific

NO REPORTED SIGNIFICANT SIDE EFFECTS

Effects endure post treatment

Wide range of potential

TENS

More widely known electro treatment pain

Treats pain by interference with nerve conduction

Requires electrodes or direct contact

Little to no healing effect

Little to no enduring impact

Wide variance in frequencies

Local conditions impact effect

General PEMF Trials

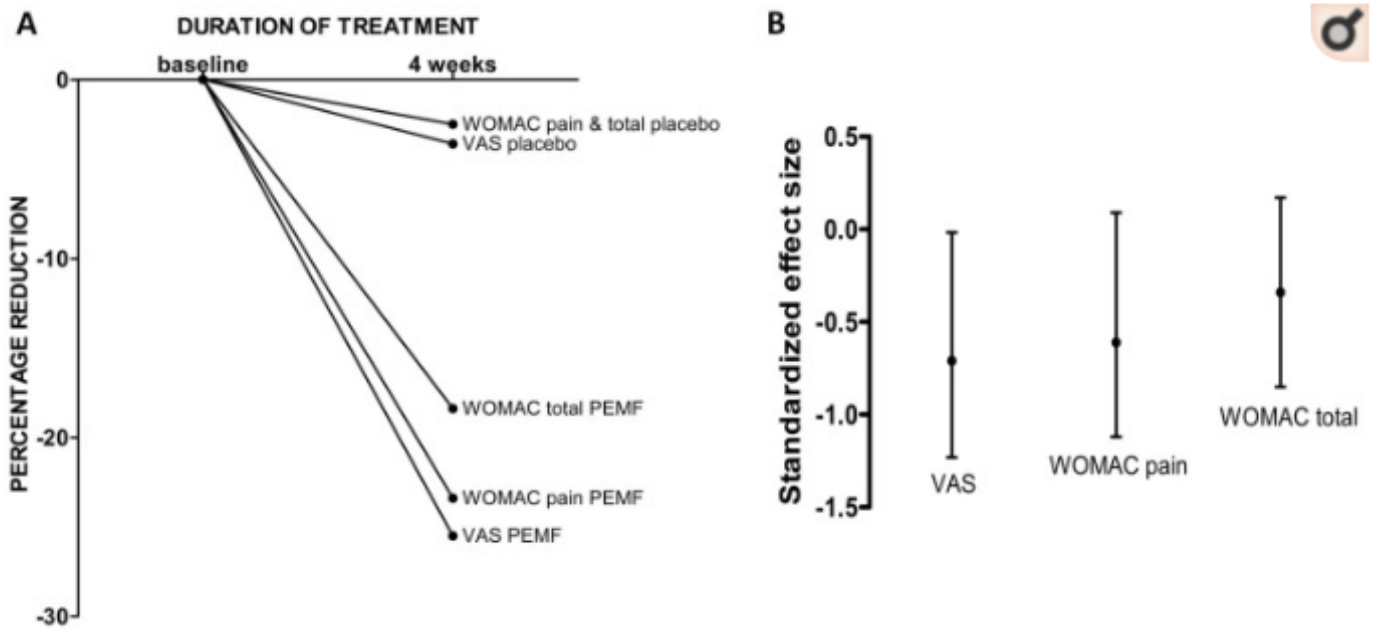
Pulsed electromagnetic fields in knee osteoarthritis: a double blind, placebo-controlled, randomized clinical trial

- Device: The carrier **frequency is 27.12 MHz**, has a pulse rate of 1000 Hz
- Knee OA and persistent pain higher than 40 mm on the visual analog scale (VAS) were recruited
- **2 hour daily treatment for 1 month in 60 knee OA patients**
- Secondary outcomes included **quality of life assessment** through the 36-item Medical Outcomes Study Short-Form version 2
- 66 patients were included, and 60 completed the study
- After **1 month, PEMF induced a significant reduction in VAS pain and WOMAC scores compared with placebo**
- Mean treatment effect of -0.73 (95% CI - 1.24 to - 0.19) was seen in VAS score, while the effect size was -0.34 (95% CI - 0.85 to 0.17) for WOMAC score
- **26% of patients in the PEMF group stopped NSAID/analgesic therapy**

Bagnanto, et. Al. Rheumatology (Oxford). 2016 Apr;55(4):755-62. doi: 10.1093/rheumatology/kev426. Epub 2015 Dec 24.

PMC full text: Rheumatology (Oxford). 2016 Apr; 55(4): 755–762.
Published online 2015 Dec 24. doi: [10.1093/rheumatology/kev426]

FIG. 2



Changes over time and standardized effect size of VAS pain, WOMAC pain and WOMAC total score

(**A**) The percentage reduction in VAS pain, WOMAC pain and WOMAC total in knee OA participants according to the group of treatment. (**B**) The standardized size effect induced by PEMF treatment is higher for the parameters evaluating pain (VAS score: −0.73 (95% CI −1.24 to −0.19); WOMAC pain: 0.61, 95% CI − 1.12 to − 0.09), while the effect size associated with an improvement in WOMAC, considering all the subscales, is −0.34 (95% CI − 0.85 to −0.17). PEMF: pulsed electromagnetic fields; VAS: visual analog scale.

PEMF Clinical Trials

- Using PEMF therapy Sutbeyaz et al. tested low-frequency PEMF on 56 women with fibromyalgia
  - Random group assignment placed 28 women in a PEMF treatment group, while the 28-patient placebo group received a sham therapy
- After receiving two 30-minute treatments per day for 3 weeks, researchers reported 52% reduction in life interference in the PEMF group, compared to 11% reduction in the sham group

PEMF Clinical Trials

- In an exploratory study of PEMF therapy's effects on postoperative pain, Hedèn reports a **three-fold decrease** in subjective pain by the PEMF group compared to a placebo after only three days.
- A 2014 study evaluated the effects of PEMF and exercise on pain, muscle functioning, and muscle strength in patients with shoulder impingement syndrome (SIS). These 56 patients, randomly assigned to a PEMF plus exercise condition or placebo plus exercise condition, completed a three-week trial. Results indicated significantly higher levels of functioning and reduced pain in the PEMF group. The PEMF group also exhibited greater strength.

Why isn’t PEMF More Widespread?

- Flexner Report of 1910 paved the way for pharma
- Electroceuticals aren’t taught in medical school
- PEMF was cost prohibitive and could only be used in office
- PEMF and microcurrent studies vary greatly
  - Over a thousand studies but vary in frequency used, shape of waveform, intensity used and duration of the treatment
  - There are very few substantially tested frequencies

OSKA Pulse represents an advance at multiple levels

Over 14,000
Oska Pulse users

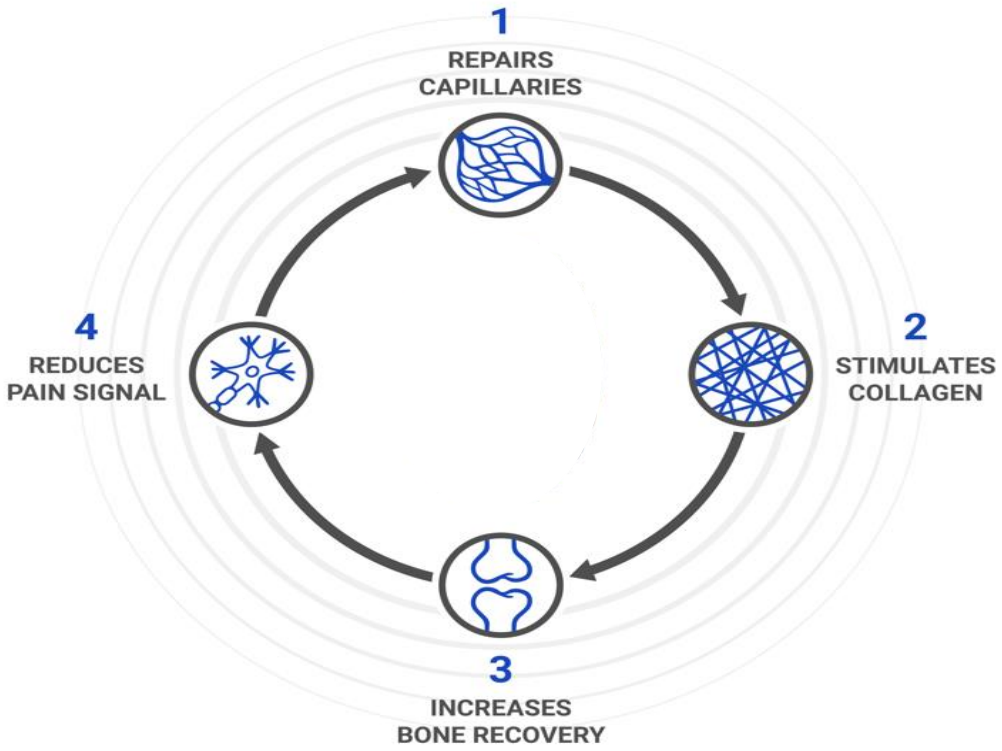
Costs much less than
large, single frequency
commercial devices

Restructures tissue
and speeds healing

The frequencies selected are known
to be specific to multiple tissue types

PEMF Therapy Protocol

Much of the pain we experience is a result of tissue inflammation. When tissue is distressed from pathogens, toxins, trauma, ruptures, temperature or other damage, the body's inflammatory response results in heat, redness, pain and edema reducing function and/or mobility.



During each 30 minute session, pulse cycles through four precise frequencies targeted at key cell types designed to accelerate the resolution of the tissue's inflammatory response, improve micro-circulation, degrade pain signals and stimulate tissue regeneration.

- ✓Increased Micro-Circulation
- ✓Reduced Inflammation
- ✓Increased Analgesia
- ✓Improved Mobility

Proof of Concept Trial

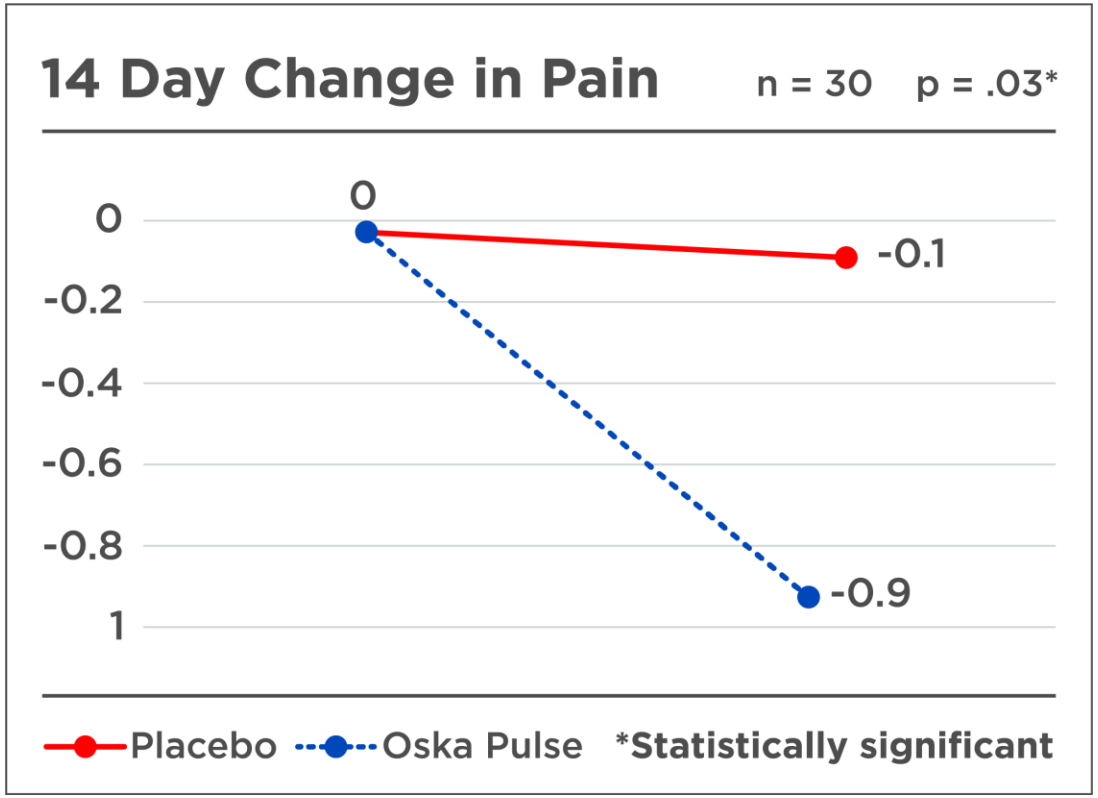
In a randomized, double-blind placebo clinical study, the majority of patients achieved significant pain reduction with wearable PEMF device.

- A 2-week trial was conducted with 30 patients (diagnosed with chronic knee, shoulder, or back pain) recruited at two San Diego area chronic pain clinics
- These were typical patients with few exclusions
- Results were dramatic in that the placebo group had little or no response
- PEMF group was substantially improved
- Each participant was provided a daily log to report their pain, stress, and daily use of PEMF. Pain and stress scores in the daily logs were based on a 10 point scale.

† Shurman, J., Wiederhold, BK., Kasendorf, R., Qian, J., Miller, I., Wiederhold, MD. Treating Chronic Pain Using the Oska Pulse Device: A Double Blind Clinical Trial Using Placebo. www.practicalpainmanagement.com. 2018 Feb.

Randomized Double-blind placebo controlled

- 39 patients with hip, back and knee pain meeting diagnosis for chronicity- 30 completed
- Used original technology; 30 minute cycles 4x daily Current tech is 3 hours



OSKA Pulse represents an advance at multiple levels

Anecdotal evidence for decreased medication use (including opioids)

Preparing to launch app for direct physician monitoring/supervision
Our technology is evolving and being refined

Early trials show good separation and pain reduction

Research programs being proposed with NIH and strategic partner

Thank You!