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

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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

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<th><strong>FARADAY</strong></th>
<th><strong>EINSTEIN</strong></th>
<th><strong>TESLA</strong></th>
<th><strong>LAKHOVSKY</strong></th>
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<td>Changing a magnetic field will create an electric current; changes in the field and field size were related to the amount of current created.</td>
<td>Electricity and magnetism are not discrete phenomena, but different aspects of the same phenomenon.</td>
<td>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.</td>
<td>Russian scientist who that demonstrated living cells emit and receive electromagnetic radiations at their own frequencies.</td>
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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
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
<table>
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<td>1979</td>
<td>Approved PEMF Therapy for the healing of nonunion fractures.</td>
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<td>1998</td>
<td>Approved PEMF Therapy for urinary incontinence and muscle stimulation.</td>
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<td>2004</td>
<td>Approved PEMF Therapy for cervical fusion patients at high-risk of non-fusion.</td>
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<td>2006</td>
<td>Approved PEMF Therapy for treatment of depression and anxiety.</td>
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<td>2011</td>
<td>Approved PEMF Therapy for treatment of brain cancer.</td>
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<td>2015</td>
<td>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.</td>
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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.
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
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

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

So What Distinguishes One from the Other?
Patient Centered Treatments

- Diet
- Exercise/Stretching
- Ice/Heat
- Tai Chi
- Meditation
- Yoga

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

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
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.

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

14 Day Change in Pain

\[ n = 30 \quad p = .03^* \]

- Placebo
- Oska Pulse

*Statistically significant
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!