OSKA PULSE: A NEW METHOD OF PAIN MANAGEMENT

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Abstract

BACKGROUND Oska™ Pulse uses Pulse Electromagnetic Field Therapy to treat injured tissue, reduce pain, and improve range of motion.

OBJECTIVE The objective of this pilot study was to evaluate the effectiveness of the Oska Pulse device in reducing pain and improving perceived mobility in patients with chronic pain conditions.

METHODS Ten participants with chronic pain between the ages of 33 and 70 were recruited for this study. Participants were instructed to use Oska Pulse at home for one hour in the morning, afternoon, and night for four weeks. Participants used a Numeric Pain Rating Scale to log and report their pain levels in the morning before treatment and at night after treatments. Interviews with open-ended questions were conducted before and after the trial.

RESULTS Statistical analysis found the difference in the subjects' mean pain scores overtime to be 9.460 ($p<0.001$). Pain reduction ranged from 0% to 94%. Five participants experienced overall reduction in pain and improved perceived mobility. Three of the five participants who did not have overall reduction in pain reported having improved mobility. Two participants did not benefit from the device.

CONCLUSION The Oska Pulse device is an effective method in improving pain experience. More research studies with larger samples need to be done to evaluate the device.

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Chronic pain is one of the most common problems seen in clinical practice, affecting patients' daily activities and lives. While there are many options for pain management, some methods, such as medication, cause adverse side effects. Now there is the Oska Pulse, a pain management option that is less invasive and has minimal side effects. The Oska Pulse device uses Pulse Electromagnetic Field (PEMF) Therapy, a reparative technique that uses electromagnetic pulses to recover damaged cellular environments and ultimately improve pain experiences for patients. While many studies have found positive results with PEMF Therapy, a research study has yet to be conducted on the Oska Pulse device. The purpose of this pilot study is to evaluate the effectiveness of the Oska Pulse in reducing pain and improving mobility in patients with various chronic pain conditions.

BACKGROUND

Chronic pain is defined as pain that persists for a minimum of three months and often stems from an acute pain experience, such as trauma or a surgical procedure, or a result of a chronic illness. According to the Institute of Medicine (IOM) (2011) report on pain in the U.S., chronic pain affects approximately 100 million adults, posing a significant public health challenge. Ongoing chronic pain can result in sleep disturbances, fatigue, anxiety, depression, and a number of somatic complaints. This pain causes reduced mobility, loss of productivity, and diminished quality of life (Outcalt et al., 2015; Mudge, Meaume, Woo, Sibbald, & Price, 2008; Stubbs, Schofield, & Patchay, 2016; Rawe, 2014).

Pharmacological intervention has been the mainstream solution for pain in the past. Over-the-counter medications (OTC), such as acetaminophen and NSAIDs, are relatively safe but can cause serious adverse effects if taken too often or beyond its toxic limit. Acetaminophen overdose is common and can cause acute liver failure and death from liver damage (Bond, Ho, & Woodward, 2012). Long-term use of NSAIDs has been associated with kidney damage, hypertension, fluid retention, and adverse cardiovascular effects. At recommended doses, NSAIDs can cause gastrointestinal side effects, including pain and bleeding (Straube, Tramer, Moore, Derry, & McQuay, 2009). Medications, such as opioids, are still considered controversial since they are often not as effective as desired, have reduced efficacy when physical tolerance increases, produce undesirable side effects (i.e. constipation, sedation), and have a potential for abuse (Furlan, Sandoval, Mailis-Gagnon, & Tunks, 2006). There are other methods of pain reduction outside of pharmaceutical intervention that have shown to be beneficial with less adverse effects.

PEMF therapy is an innovative method of pain management that uses safe levels of electrical energy to direct magnetic pulses through injured tissue to stimulate cellular repair. PEMF is commonly used in orthopedics for treatment of non-union fractures, failed fusions, and bone growth and has shown to cause biological changes. The treatment reaches the cellular membrane level, changing the cell environment and restoring integrity and function (Aktas, I., Akgun, K., & Cakmak, B., 2006). It helps to reduce pain and promote increased range of motion, as well as dilate blood vessels to reduce inflammation and increase oxygen-rich blood flow to support muscle recovery. Several clinical studies over the last 30 years have proven that PEMF therapy has minimal side effects and significantly reduces pain in patients with various chronic pain conditions. Oska Pulse is a device that utilizes a technology to optimize PEMF therapy to accelerate the body's ability to heal itself. Oska employs four frequencies of signals to target muscle ease, bone repair, capillary dilation, and pain reduction.

REVIEW OF LITERATURE

There are a number of research studies on PEMF therapy in patients with various chronic pain conditions. Most studies have found that PEMF is an effective method in reducing pain, with some studies showing improved function and decreased analgesic medication consumption as well.

In a systematic review by Andrade et al. (2016), the investigators studied the effectiveness of PEMF therapy on reducing pain and clinical symptoms in patients with lower back pain conditions. After a database search of studies from January 2005 to August 2015, a total of six studies were eligible for the review. All six studies reported a reduction in pain with an average reduction of pain of 2.1 to 6.4 points out of 10 on the VAS from baseline to end-point. All six studies in the review also found an improvement in functionality, with the Oswestry Disability Index as the most commonly used scale.

Many additional research studies have proven the efficacy of PEMF therapy as a method for patients with chronic disorders to reduce chronic pain (Table 1). In a study by Galace de Freitas et al. (2014), the researchers found that after three weeks of PEMF therapy, patients with shoulder impingement syndrome experienced higher levels of function, increased muscle strength, and reduced pain ($P<0.05$). Following treatment, patients were enrolled into a therapeutic exercise program to improve mobility and strength. Participants who received PEMF prior to the program showed increased strength while those who received placebo did not show any improvement ($P<0.05$). The results indicated that PEMF therapy is not only beneficial on its own but also effective when complemented with other interventions. Wuschech, von Hehn, & Funk (2015) studied a PEMF device, known as MAGCELL, on patients with pain from knee joint osteoarthritis. After 18 days of PEMF therapy with MAGCELL, patients showed reductions in pain ($P<0.001$), stiffness ($P=0.032$), and disability in daily activities ($P=0.005$). Twenty-nine percent of patients who received PEMF rated the effectiveness of the device as "very good" compared to a 0% rating from the placebo group.

PEMF therapy has also been shown to improve pain in patients post-surgery (Table 1). In a study of 30 patients with recurrent pain following back surgery who received PEMF twice a day for 45 days, it was found that approximately half of the participants experienced a reduction in back and leg pain intensity (PI) as well as decreased analgesic medication consumption. Sixty-seven percent of patients who responded to PEMF therapy reported an improvement in overall well-being (Harper, Schmidt, Kubat, & Isenberg, 2014). A study on postoperative pain in women recovering from Caesarean Section (C-Section) found that only 36% of the PEMF group experienced severe pain within 24 hours of the procedure compared to 72% in the control group. In addition to pain reduction, total analgesic use was 2.1 folds lower in the PEMF group than the control group during the seven postoperative days (Khooshideh, 2016). Heden & Pilla (2008) studied the effectiveness of PEMF therapy on women recovering from breast augmentation. They found that patients who received PEMF had a reduction in pain by a factor of three times that of the control group and a decrease in analgesic medication use three times faster than the control group. These three studies not only proved that PEMF therapy can reduce pain, but they also showed that the treatment can lead to a decrease in medication use, a treatment method that often comes with side effects.

METHODS

STUDY PARTICIPANTS

Participants were recruited using advertisements and word-of-mouth. Individuals of at least 18 years old and of either gender who experienced back, joint, or musculoskeletal pain for a period of three months or more were considered for the trial. Exclusion criteria included individuals who were pregnant, who were undergoing chemotherapy, and had implants or pacemakers. Respondents were interviewed and screened for eligibility. A total of 10 participants were accepted; seven females and three males, all Caucasian, and ranging in age from 33 to 70 years old. Each participant was given detailed information about the trial and written informed consent was obtained.

STUDY DESIGN AND INTERVENTION

This trial was a single-arm, pilot study of the Oska Pulse device. The 10 participants were treated with an at-home PEMF device, called the Oska Pulse. The compact device is battery-operated, poses no risk of thermal injury, and is ideally suited for home use. It is easily operated with a push of a button to turn it on, and it is worn at the pain site with adjustable bands. Once activated, the device automatically runs through the pre-programmed sequence over a 30-minute period, then turns itself off.

Participants were instructed to use the Oska Pulse device for two 30-minute sessions in the morning, afternoon, and before bed, totaling six sessions of three hours a day. The participants were to continue this treatment protocol for a total of four weeks.

OUTCOME MEASURES

Participants were asked to score and log their pain levels each morning prior to treatment and each evening after treatments. Pain was evaluated using a 0 to 10 numeric pain rating scale (NPRS) where 0 was "no pain at all," 5 was "moderate pain," and 10 was the "worst pain imaginable."

The participants were interviewed prior to beginning the trial and at the end of the protocol to assess their pain experiences and the treatment effects. Open-ended questions were designed to encourage participants to talk freely about their chronic pain and whether or not the treatment was beneficial in improving pain and sense of well-being.

RESULTS

A repeated measures ANOVA with a Greenhouse-Geisser correction determined a difference in subjects' mean pain scores overtime: $F(2.681, 308.286) = 9.460$ with $p<0.001$.

After four weeks of treatment with the Oska Pulse device, the overall pain reduction of the patients ranged from 0% to 94%. Five participants showed an overall decrease in pain with three participants remaining pain-free or nearly pain-free (score of 1 out of 10 on NPRS). Of the five participants, four reported that they perceived an improvement in mobility (Table 2). Subject #1, for example, was a 70-year-old male who had a history of bilateral knee pain for three years. He had a baseline pain of 4 out of 10, and after 12 days of using the Oska Pulse device as instructed, he consistently reported a pain level of 0 at morning and night for the rest of the trial (Figure 1). He also reported an improvement in mobility.

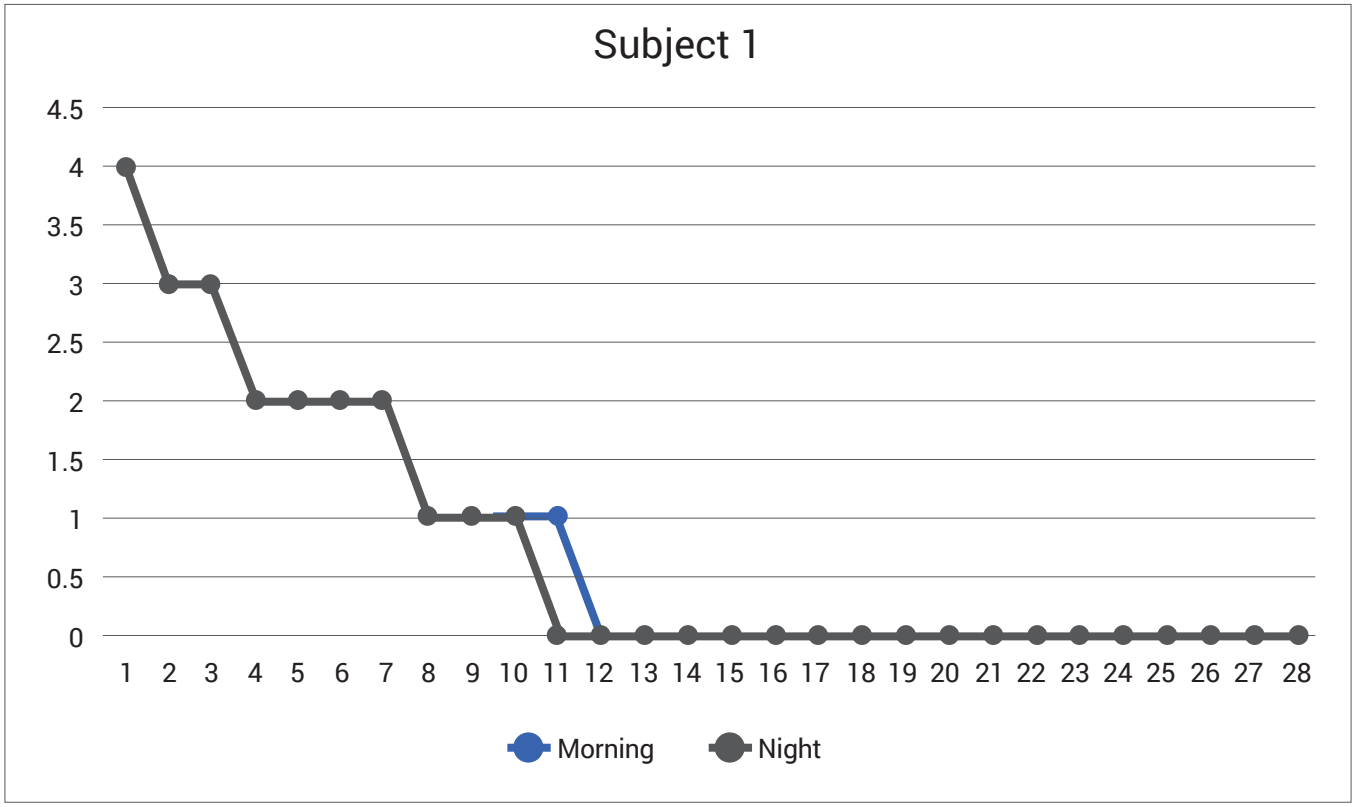

Figure 1. Morning and night pain levels of subject #1 during trial.

Subjects #4 and #7 showed overall reduction in pain but were not consistently pain-free by the end of the trial (Table 2). Subject #7 reported using the device for only two weeks total. Subject #4 had left knee pain and reported lower levels of pain with the device at night. The graph shows that he had an increase in pain during weeks to 3, but pain decreased from then until the end of the trial (Figure 2).

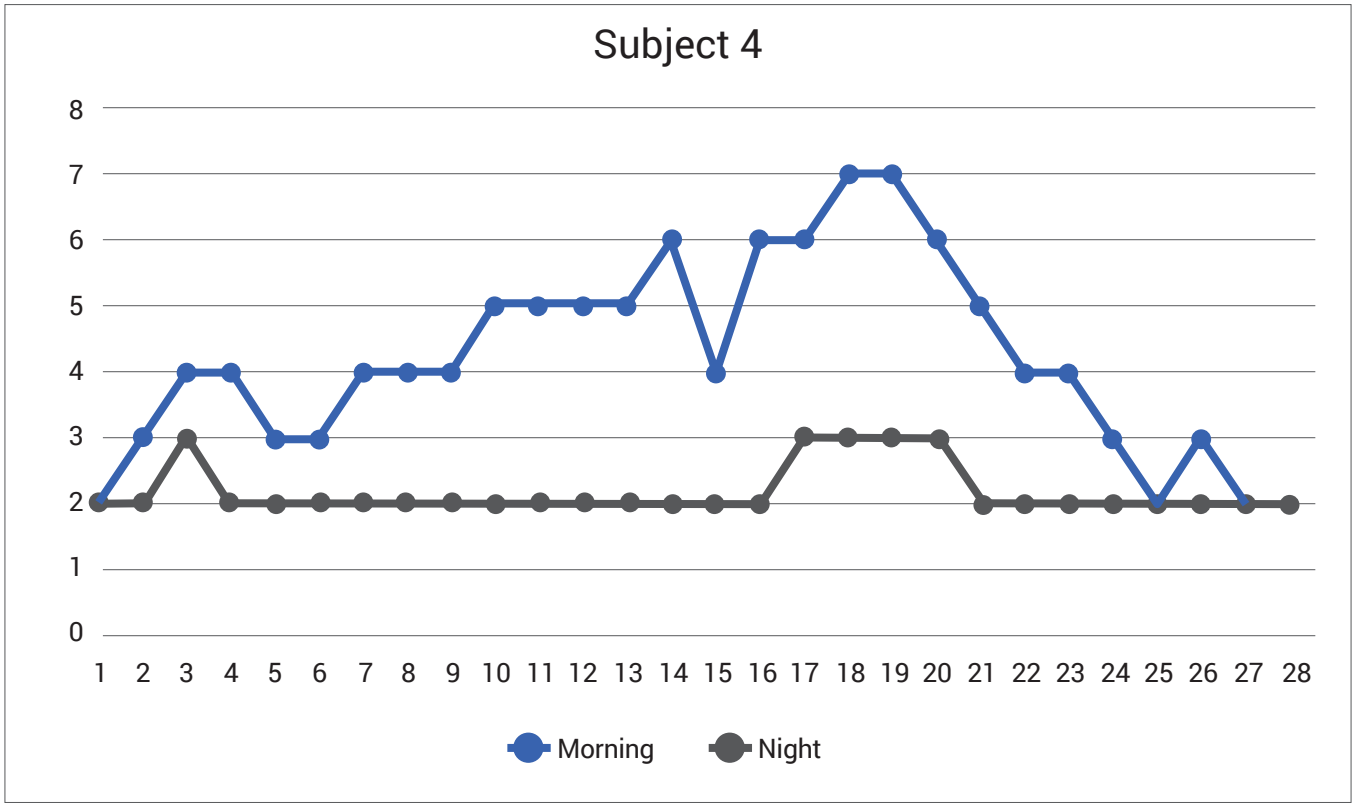

Figure 2. Morning and night pain levels of subject #4 during trial.

While half of the participants did not show an overall reduction in pain from their reports, subjects #2, #9, and #10 still perceived an improvement in mobility. Subject #9, for example, was a 69 year old female with lower back pain from a herniated disc. She reported a baseline pain level of 10 and stated that the device not only made her back feel better, but also allowed her to be more active. While she perceived improvements, the graph of her reported pain levels throughout the four weeks illustrates her levels as variable in the mornings and nights with some days better than others (Figure 3).

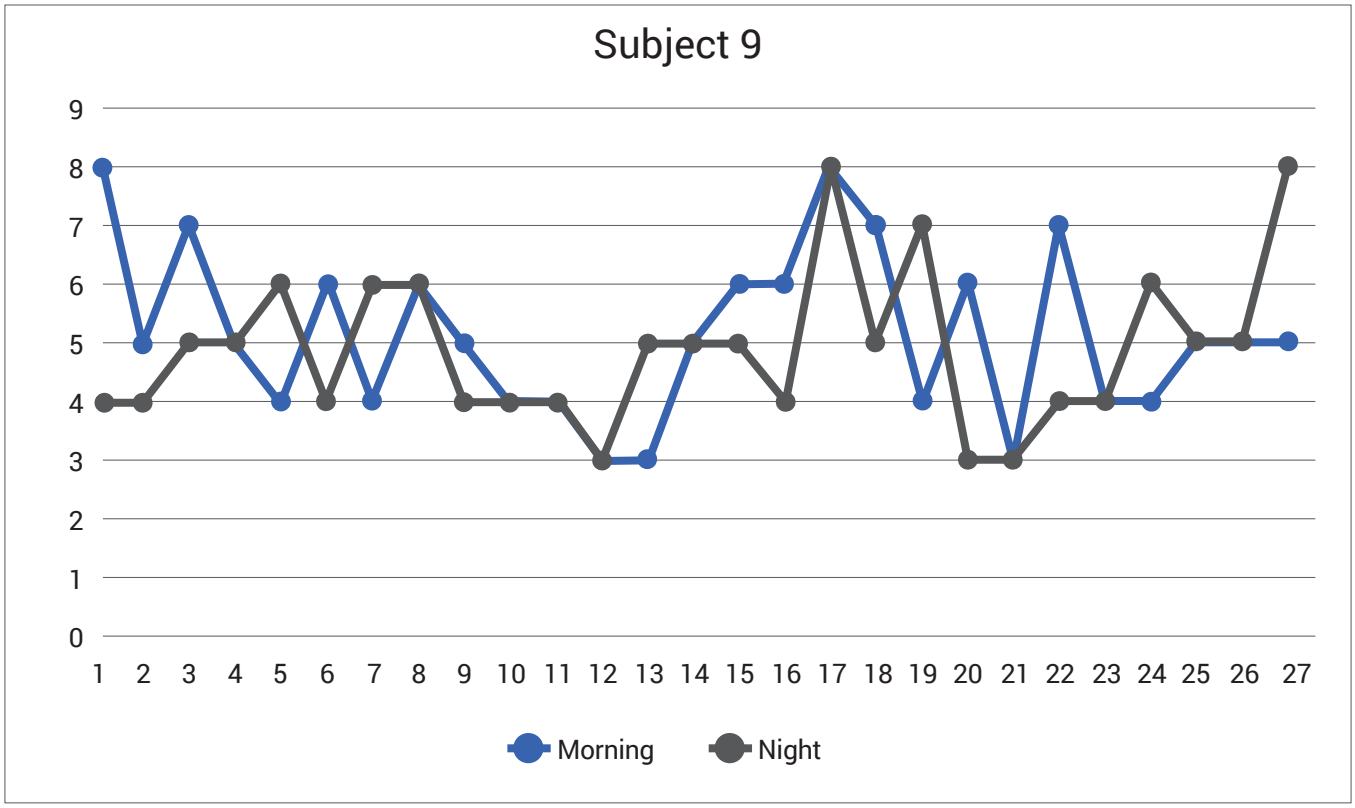

Figure 3. Morning and night pain levels of subject #9 during trial.

Subjects #6 and #8 did not show any overall improvements with the Oska Pulse device, as there were neither reduction in pain nor perceived improvement in mobility (Table 2). Subject #6, who had back pain, reported that the device slid off the area of pain often. Subject #8 was noncompliant with the treatment, as he often forgot to follow the schedule and only used the device two to three sessions a day.

DISCUSSION

The results of this research study found that the Oska Pulse device is an effective method of pain management for patients with chronic pain. Statistical analysis found a significant difference in the subjects' mean pain scores overtime, indicating that regular use of the device reduced pain for the group as a whole. Similar to other research studies on PEMF therapy that were mentioned in the literature review, this study found that PEMF can both reduce pain and improve perceived mobility. Fifty percent of the subjects showed overall pain reduction from the device, while three became either pain-free or nearly pain-free, proving that the Oska Pulse can be effective.

Although five out of the 10 participants showed improvements based on the data, eight out of the 10 reported that the Oska Pulse was helping their pain and mobility during the four-week trial. It can be assumed that there were some benefits from the device for these subjects but more time was needed to see significant effects. Additionally, although the NPRS is a highly reliable tool, it only measures pain intensity at a given point in time and does not capture the complex nature of the pain experience or subtle changes that may occur. This could also explain why the data is not consistent with the patients' perception of their pain experiences.

In addition, there were variances in the results because some subjects did not follow protocol or use the device properly. Both subjects #7 and #8 did not follow protocol or use the device long enough to see its full effects. Subject #7 showed overall reduction in pain, while subject #8 did not have improvements. Subject #6 simply did not gain benefits from the Oska Pulse because the device was not worn properly during sessions.

Two subjects reported that they used the device on other painful parts of the body that were not included in the study. They saidJa that they experienced positive results.

LIMITATIONS

The fact that this was a convenience sample and the sample size was extremely small were certainly limitations. There was also a lack of a control arm and some results were anecdotal. The demographics were limitations to the study, as there was not an equal number of males and females and all the participants were Caucasian. There may be gender and ethnic differences in pain perception that should be considered. In addition, the NPRS may not have truly reflected the multidimensional pain experience of each of the subjects.

FUTURE STUDIES

While this study found positive results from using the Oska Pulse, its limitations and variable results indicate that more research studies need to be conducted on the device. Future research studies should have a larger sample size and include a control arm. A sample population with greater diversity would be preferable. Additional outcome measures of pain experiences should be utilized to fully assess any effects from using the device.

CONCLUSION

With chronic pain as a common problem seen in clinical practice, patients and providers are seeking alternatives to pain management that are safe and effective. Oska Pulse is a non-invasive and safe device that uses PEMF to heal the body. In this pilot study, the Oska Pulse device improved pain experiences for most of the patients with chronic pain problems, indicating that the device is effective. Larger studies need to be conducted to assess the full potential of this device.

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Table 1. Research studies on PEMF therapy for patients with chronic pain.

Authors and Date	Study Objective	Study Population	Intervention	Variables	Results
Galace de Freitas, D., Marcondes, F.B., Monteiro, R.L., Rosa, S.G., Maria de Moraes Barros Fucs, P., & Fukuda, T.Y., 2014	To evaluate the effectiveness of PEMF and exercises in reducing pain, improving function, and improving muscle strength in patients with shoulder impingement syndrome (SIS).	56 patients, ages 40-60 years old with a diagnosis of SIS	Intervention group (n=26) = patients received PEMF; Control group (n=30) = patients received placebo PEMF; After 3 weeks of PEMF/ placebo, both groups started a 6 week therapeutic exercise program to increase shoulder mobility and strength.	Pain (VAS), function (UCLA shoulder rating scale, Constant-Murley shoulder score), muscle strength (handheld dynamometry)	The PEMF group had a higher level of function and reduced pain at all follow-ups ($P<0.05$), while the placebo PEMF group only had increased function and reduced pain after exercise therapy. The PEMF group had increased strength in lateral and medial rotation ($P<0.05$), whereas the placebo PEMF group showed no significant changes in strength.
Wuschech, H., von Hehn, U., Mikus, E., & Funk, R.H., 2015	To evaluate the effects of PEMF (MAGCELL device) on patients with pain from knee joint osteoarthritis.	57 patients with an average age of 61.6 years	Intervention group = PEMF for 5 min twice a day for 18 days; Control group = placebo PEMF for 5 min twice a day for 18 days	Pain, stiffness, and disability in daily activities with Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scales	Treatment with the MAGCELL device showed a significant reduction in pain ($P<0.001$), significant reduction in stiffness ($P=0.032$), and a significant reduction in disability in daily activities ($P=0.005$). The placebo group did not show significant change in any of the above variables. Patient ratings of the "effectiveness" of MAGCELL was 29.5% very good and 27.3% good compared to 0% and 15.4%, respectively, in the placebo group.

Table 1 continues on next page

Table 1. Research studies on PEMF therapy for patients with chronic pain. (cont.)					
Harper, W.L., Schmidt, W.K., Kubat, N.J., & Isenberg, R.A., 2014	To evaluate the effectiveness of PEMF in patients with recurrent pain following back surgery.	30 patients	All participants received PEMF twice a day for 45 days.	Pain intensity (PI), physical function (Oswestry Disability Index), analgesic consumption, overall well-being (Patient Global Impression of Change)	33% of participants reported a clinically meaningful reduction in PI overall. Participants reported an average of 44% and 55% reduction in back PI and leg PI, respectively, and 13% improvement in physical function. 50% of responders and 12% of nonresponders used less analgesia consumption following treatment. 67% of responders and 0% of nonresponders reported improvement in overall well-being.
Khooshideh, M., Latifi Rostami, S.S., Sheikh, M., Ghorbani Yakta, B., & Shahriari, A., 2016	To evaluate the effectiveness of PEMF on postoperative pain reduction, wound healing, and analgesic use in patients recovering from Caesarian Section (C-Section).	72 women, who underwent elective C-Section	Intervention group (n-36) = active PEMF; Control group (n=36) = sham PEMF	Pain (VAS), analgesic use, wound healing	Fewer women in the active PEMF group experienced severe pain within 24 hr postoperative (36% vs 72%, P=0.002). Analgesic use was 1.9 folds lower in the active PEMF group within 24 hr postoperative (1.6+/-0.7 vs 3.1+/-1.2, P<0.001), while total analgesic use was 2.1 folds lower in the active PEMF group during the 7 postoperative days (1.7+/-0.7 vs 3.7+/-1.1, P<0.001). At 7 days postoperative, the active PEMF group had better wound healing, with no exudate, erythema, or edema, than the sham group.
Heden, P. & Pilla, A.A., 2008	To evaluate the ability of PEMF to control pain after breast augmentation.	42 healthy females undergoing breast augmentation	Group 1 (n=14) = bilateral PEMF treatment; Group 2 (n=14) = bilateral sham treatment; Group 3 (n=14) = one breast with PEMF and one with sham	Pain (VAS), analgesic medication consumption	Participants who had active PEMF had a decrease in pain by a factor of 3 times that of the sham cohort by postoperative day 3 (P<0.001) and persisted until postoperative day 7. Use of analgesic medication also decreased 3 times faster in the active versus sham groups by postoperative day 3 (P<0.001).

Table 1 shows the various studies on PEMF. Studies have shown that PEMF therapy is effective in reducing pain and improving function.

Table 2. Results of Oska Pulse device trial.

SUBJECT	GENDER - AGE	CHRONIC PAIN LOCATION (CONDITION)	LENGTH OF TIME OF CHRONIC PAIN	BASELINE PAIN LEVEL	LOWEST PAIN LEVEL	PAIN REDUCTION (%)	WAS PAIN REDUCED WITH OSKA? (Y/N)	NUMBER OF DAYS TILL PAIN FREE	DID PERCEIVED MOBILITY IMPROVE WITH OSKA? (Y/N)
#1	M - 70 yo	Bilateral knee pain	3 years	4	0	94%	Y	12	Y
#2	F - 42 yo	Lower back pain	Several years	2.5	1	None	N	Not pain free	Y
#3	F - 70 yo	Back pain (compression fraction of L2),	Several years	4	1	50%	Y	12 days till pain level 1, but not pain free	Y
#4	M - 54 yo	Left knee pain (removal of meniscus)	"Couple" of years	2	1	32%	Y	Not pain free	Y
#5	F - 52 yo	Shoulder pain (arthritis in the neck)	1 year	5	0	43%	Y	24	Y
#6	F - 70 yo	Back pain (post-surgery)	5 years	5.5	5	None	N	Not pain free	N
#7	F - 34 yo	Right ankle pain (tendonitis)	9 years	2.5	1	42%	Y	Not pain free	Y
#8	M - 69 yo	Back pain (trauma)	3 years	6.5	5	None	N	Not pain free	N
#9	F - 69 yo	Lower back pain (herniated disc)	1 year	6	3	None	N	Not pain free	Y
#10	F - 33 yo	Shoulder pain	6 months	6	4	None	N	Not pain free	Y

Table 2 illustrates the pain experiences of the ten subjects. Pain reduction ranged from 0% to 94% with five subjects experiencing overall pain reduction. Three patients became either pain free or nearly pain free by the end of the trial.