Musculoskeletal Pain Management with a Commercially Available OTC PEMF Medical Device: A User Survey

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Running Title: Pulsed Electromagnetic Field Therapy for Pain

Objective
Musculoskeletal pain is widespread in society and is challenging to treat. To determine the effectiveness of a miniaturized, wearable PEMF device as a home-based, self-administered, musculoskeletal pain therapy an anonymous survey of customers who had bought the PEMF device for pain was conducted.

Design
The survey was created using Qualtrics web based survey software, and was included as a link in an email to customers who had previously ordered the PEMF medical device. The survey included questions on the condition, pain levels prior to and post PEMF treatment, using a 11 point visual analogue scale (VAS), a patient global impressions of change scale (PGIC), pain medication use and length of time of treatment.

Results
There were 260 responses from 2900 emailed, an 8.9% response rate. The PEMF device was used for an array of painful musculoskeletal conditions though predominantly back and knee pain. Prior to beginning PEMF therapy respondents reported an average pain level of 7.3 VAS points, whereas post PEMF use the reported pain level declined to an average 3.6 VAS points, a reported average drop of 3.7 VAS points. The results from the PGIC scale show that PEMF use had a positive effect on patient quality of life and 72% of those who indicated prior use of pain medication reported a reduction in use.

Conclusion
The survey data suggests that PEMF in this form is an effective self-administered pain therapy for an array of musculoskeletal pain conditions. There were no reports of significant adverse side effects.

Key words: Radiofrequency, electromagnetic, pain, back, knee

Introduction

Musculoskeletal pain is widespread and continues to increase in society. It is challenging to treat effectively and has a significant impact on a person's quality of life [1]. The loss of productivity as well as the costs to health care systems adds to the financial burden [2, 3]. The prevalence of back pain[4] is estimated at 5.6% in North America and prevalence of knee pain and symptomatic knee osteoarthritis have approximately doubled in women and tripled in men over 20 years[5]. While there are a number of conservative, commercially available therapies for musculoskeletal pain, widely available over the counter analgesics including nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen are a mainstay of therapy for many individuals. Although thought to be safe, these drugs have adverse side effects when taken for long periods, and increased risks of use are seen in the elderly[6]. NSAIDs are associated with a broad range of side effects, including renal toxicity, exacerbation of hypertension[7], fluid retention, gastrointestinal complications[8], and cardiovascular events[9, 10]. A serious side effect of regular use of the analgesics acetaminophen and ibuprofen, identified by epidemiological studies, is that of increased risk of hearing loss both in men [11], and women[12] who used acetaminophen or ibuprofen (but not aspirin) 2 or more days per week. At therapeutic doses acetaminophen is considered safe. However, at higher doses, acetaminophen can cause fatal liver damage and is responsible for approximately one-half of all cases of acute liver failure in the United States and Great Britain[13, 14].

Shortwave diathermy, originally a heating modality is used in medical applications for both acute and chronic pain. The therapy uses shortwave radiofrequency electromagnetic field energy, either at higher energy levels, as a thermal therapy, or at lower energy levels with pulsing of the signal, as a non-thermal therapy. The lower energy pulsed form of the therapy has been known as pulsed electromagnetic field therapy (PEMF). Clinical studies have shown it to be an effective therapy for musculoskeletal pain[15, 16]. Recently interest has been generated in medical devices that are based on the same technology but use significantly lower power levels, allowing them to be smaller, portable or battery powered , therefore used as a home based, self-administered therapy. These medical devices have shown success in clinical study including postoperative edema[17], postoperative pain [18-20], plantar fasciitis[21], osteoarthritis of the knee[22] and wound healing[23]

In this study, a commercially available miniaturized PEMF device, which has been shown to be a clinically effective treatment for plantar fasciitis[21] and postoperative pain [17, 18] was studied for effectiveness as a self-administered pain therapy . Customers who had purchased the PEMF device as a pain therapy, via a commercial website were surveyed to determine the effectiveness of the device.

Methods

The PEMF device (RecoveryRx®, BioElectronics Corporation, Frederick, MD, USA), is a CE marked device and sold over-the counter in the European market, Canada and numerous countries around the world. The core technology of the PEMF device is a pulsed radiofrequency (RF) energy device, which emits a safe form of non-ionizing electromagnetic radiation. The carrier frequency is 27.12 MHz, and has a pulse rate of 1000 pulses per second and 100 microsecond burst width. Peak burst output power of the 12 cm antenna is approximately 0.0098 watts covering a surface area of approximate 100 cm^2. The circuitry consists of low voltage (3 V) digital/analog electronics that control all timing functions to produce the therapeutic RF field, where the antenna field is placed directly above the therapeutic site. This closed loop system of the antenna, low energy signal generator circuit, and battery power supply, transfers the RF energy to the tissue. The device is a battery powered device that allows operation for approximately 720 hours, with on/off capability. The device is recommended for use up to 24 hours per day.

To determine the effectiveness of the PEMF device as a home-based, self-administered, musculoskeletal pain therapy an anonymous survey was conducted of customers who had bought the PEMF device for pain within the last 3 months. Participation was voluntary. The survey was created using Qualtrics web based survey software (Qualtrics, Provo, UT), and was included as a link in an email to customers who had previously ordered the PEMF medical device through a website (www.RecoveryRx.ca), a Canadian based commercial website. There were no follow up emails after the first email.

The survey included questions on the musculoskeletal pain condition, the pain levels that customers were experiencing prior to and post PEMF treatment, using a 11 point (0-10) visual analogue scale (VAS), a patient global impressions of change (PGIC) scale, pain medication use and length of time of PEMF device use in hours per day, and days of use. There was also a comment field allowing input from the responder. The link within the email took responders to the survey site where the questions were laid out with clear response fields. Over a 10 day period a total of 260 responses were obtained, an 8.9% response rate. Results were outputted in, and analyzed with Excel 2010 (Microsoft Corporation, Redmond, WA).

Results

Of the 260 responses 7 were blank in all fields leaving 253 responses that could be analyzed. There were 234 responses for the first question focusing on the location of the pain that was treated with the PEMF device. The list of conditions that the PEMF device was used to treat are shown in table 1. The predominant conditions were back 84/253 (33%) and knee pain 87/253 (34%), with the remaining conditions totaling 82/253 (33%) including those with this field left blank. The analysis of the VAS, PGIC and medication use was performed on the total responses - group T, and three sub groups, these being responses for back pain - group B, knee pain – group K and the remaining treated conditions as one group – group R.

Table 1. The PEMF devices was used to treat an array of musculoskeletal pain conditions, with the most prominent being back (33%) and knee pain (34%).

Condition	Number
Back pain	84
Knee pain	87
Shoulder/neck pain	13
Ankle	3
Foot /toe	17
Wrist	9
Hand/fingers	7
Menstrual pain	1
Elbow	4
Hip	4
Fibromyalgia	2
Muscle pain	2
Mesh wound swelling	1
Unspecified	19
Total	253

Visual Analogue Scale Pain Score

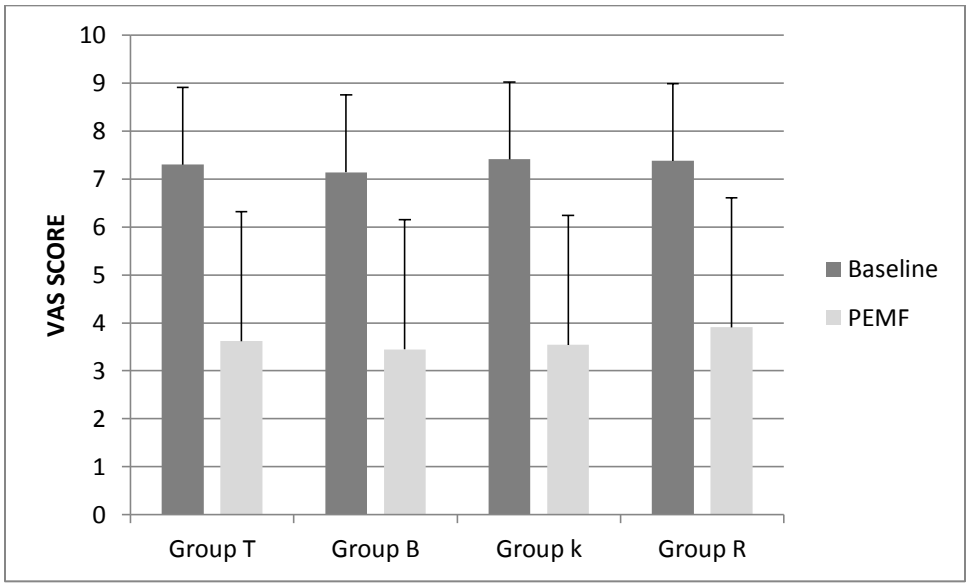
The average pain level on a 0-10 pain scale, before PEMF therapy and post PEMF device use was asked. A sliding bar on the questionnaire was used to register the VAS for both prior and post PEMF use. There were 248 complete responses in this field. The reported mean baseline VAS pain was 7.30 ±1.64, and the mean reported pain after use of the PEMF device was reduced to 3.62 ±2.73 (Figure 1 and Table 2). This represents, on average, a drop of 3.68 VAS points, or a 50% decrease after the PEMF device therapy was used. The mean baseline VAS pain specifically for group B, group K and group R are shown in Figure 1 and Table 2. The

mean baseline VAS, mean VAS score after PEMF device use was very closely matched in each of the four groups.

Table 2. The mean VAS score before PEMF use, and mean VAS score after PEMF use along with VAS point decrease and percentage decrease for the total responses (group T), and in the three sub groups of back (group B), knee (group K) and the remaining conditions group (group R).

	Group T	**Group B**	**Group K**	**Group R**
Mean VAS Baseline	7.30 ±1.64	7.14 ±1.71	7.41 ±1.76	7.38 ±1.50
Mean VAS PEMF	3.62 ±2.73	3.45 ±2.70	3.54 ±2.62	3.91±2.87
VAS score decrease	3.68	3.69	3.87	3.38
% decrease	50%	52%	52%	46%

Figure 1 The mean VAS score for the total responses (group T) decreases by 3.68 after use of the PEMF device. A similar decrease was also seen in the three sub groups of back (group B), knee (group K) and the remaining conditions group (group R).



A total of 56/248 (22.6%) responses reported no decline in VAS score. Of the 192/248 who reported a decrease the mean reported baseline VAS score prior to PEMF device use was 7.41 ± 1.62VAS and post PEMF device use a VAS of 2.56 ±1.98, or a 4.85 VAS point reduction equating to 63%. Of the responses for group B 22/84 (26%), group K 12/86 (14%), and group R 22/78 (28%) reported no VAS score decrease with the use of the PEMF device. Analysis of each group after omitting the responses that showed no pain reduction, were also similar in both the VAS score decrease and percent of decrease for each group (Table 3.).

Table 3. Seventy eight percent of responses reported a VAS decrease. The mean VAS score before PEMF use, and mean VAS score after PEMF use along with VAS point decrease and

percentage decrease for the total responses (group T), and in the three sub groups of back (group B), knee (group K) and the remaining conditions group (group R). Omitted are responses that reported no VAS decrease.

	Group T	**Group B**	**Group K**	**Group R**
Mean VAS Baseline	7.41 ±1.62	7.23 ±1.67	7.45 ±1.77	7.63 ±1.34
Mean VAS PEMF	2.56 ±1.98	2.16 ±1.64	2.85 ±2.19	2.70 ±2.13
VAS score decrease	4.85	5.07	4.60	4.93
% decrease	63%	70%	62%	65%

Patient Global Expression of Change
To evaluate if the use of the PEMF device improved quality of life the following question was asked:

We would like you to describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS and OVERALL QUALITY OF LIFE related to your reason for using RecoveryRx. With the following response options. 1: No change or it got worse. 2: Almost the same, hardly any change at all. 3: A little better, but no noticeable change. 4: Somewhat better, but the change has not made any real difference. 5: Moderately better, a slight but noticeable change. 6: Better, and definite improvement that has made a real and worthwhile difference. 7: A great deal better, and a considerable improvement that has made all the difference

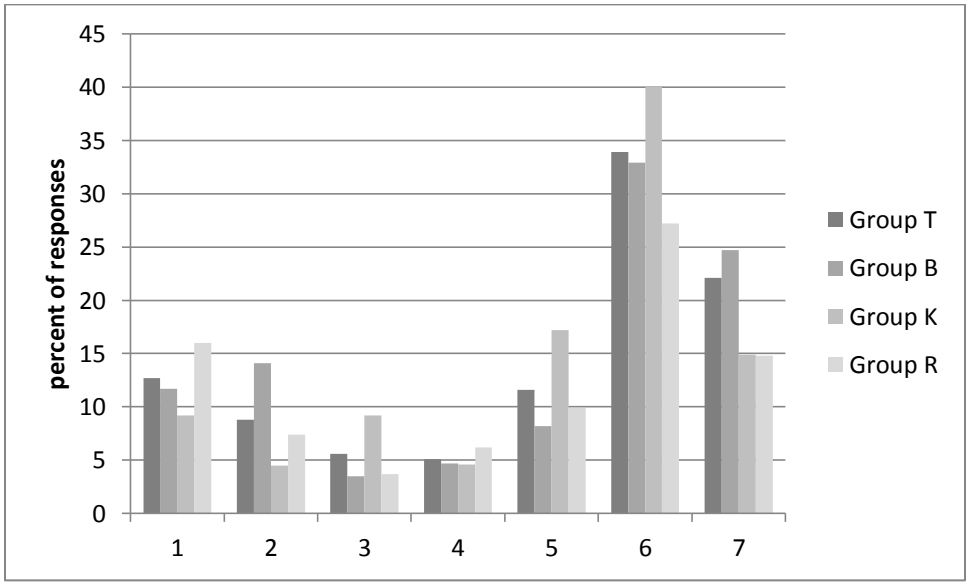
Over 66% of the total respondents indicated a noticeable change after using the PEMF medical device and 56% reported a definite to considerable improvement (Table 4 and Figure 2). These findings were slightly higher for sub groups B 65.8%, and K 72.1% over group R 51.9%. Another 14.6% of group T responses reported that they felt better, but there was little change in the quality of their life. Finally approximately 12.7% of group T reported no or negative improvement. Group K at 9.2% was the lowest sub group showing no improvement compared with group B reporting this 11.7% of the time and group R at 16%, which had the highest number reporting no or negative improvement.

Table 4. The use of the PEMF had a positive effect on patient quality of life with 66.6% of the total responses (group T) reporting a moderate to considerable improvement. The greatest improvement was seen in the knee pain group (group K) at 72.1 % reporting a moderate to considerable improvement, and lowest in the remaining conditions group (group R) at 51.9%.

Response	**Group T**	**Group B**	**Group K**	**Group R**
No change	12.7%	11.7%	9.2%	16%
Almost the same	8.8%	14.1%	4.5%	7.4%

A little better	5.6%	3.5%	9.2%	3.7%
Somewhat better	5.1%	4.7%	4.6%	6.2%
Moderately better	11.6%	8.2%	17.2%	9.9%
Definite improvement	33.9%	32.9%	40%	27.2%
Considerable improvement	22.1%	24.7%	14.9%	14.8%
Moderate to considerable improvement	**66.6%**	**65.8%**	**72.1%**	**51.9%**

Figure 2. The use of the PEMF device resulted in an increase in quality of life scores for the majority of users, with 66% of the total responses (group T) reporting a moderate to considerable improvement. A similar quality of life increase was also seen in the three sub groups of back (group B), knee (group K) but was lowest in the remaining conditions sub group (group R).



Medication Use

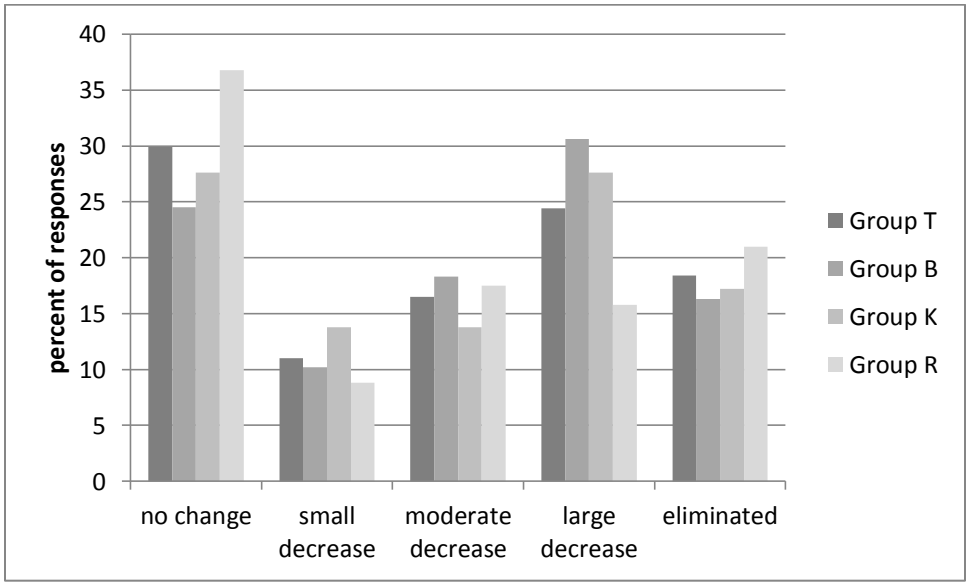
The change in medication use after PEMF device use is shown in figure 3. In group T 171/253 (68%) , group B 53/85 (62%) , group K 58/87 (67%) and group R 60/82 (73%) marked yes for the use of pain medication prior to the use of the PEMF device. This was followed by a question asking if their medication use had changed after using the PEMF device. The options were 1. Had no effect, 2. Reduced the use of pain medication a little, 3. Reduced the use of pain medication a moderate amount, 4. Reduced the use of pain medication a large amount, 5. Eliminated the need for using pain medication. Of those who responded yes, the average VAS score was 7.5, and those that responded no had an average VAS of 6.9. An indication that pain medication was taken by individuals with an overall higher pain level, and that the pain

medications they were taking had limited effect on their pain score. Seventy percent of the respondents who indicated prior use of pain medication reported a decrease in medication use after using the PEMF device, with 59% showing a moderate to complete elimination (Table 5). This percentage was highest for Group B and lowest for Group R.

Table 5. The use of the PEMF had an effect on pain medication use with 59% of the total responses (group T) reporting a moderate decrease to complete elimination. Similar reductions were seen in the three sub groups with back pain (group B) reporting a 65.2%, knee pain group (58.6%) and the remaining conditions group (group R) reporting a 54% moderate decrease to complete elimination of pain medication use.

Pain Medication Use	**Group T**	**Group B**	**Group K**	**Group R**
No change	29.9%	24.5%	27.6%	36.8%
Small decrease	11%	10.2%	13.8%	8.8%
Moderate decrease	16.5%	18.3%	13.8%	17.5%
Large decrease	24.4%	30.6%	27.6%	15.8%
Eliminated	18.4%	16.3%	17.2%	21%
Moderate to complete elimination	**59%**	**65.2%**	**58.6%**	**54%**

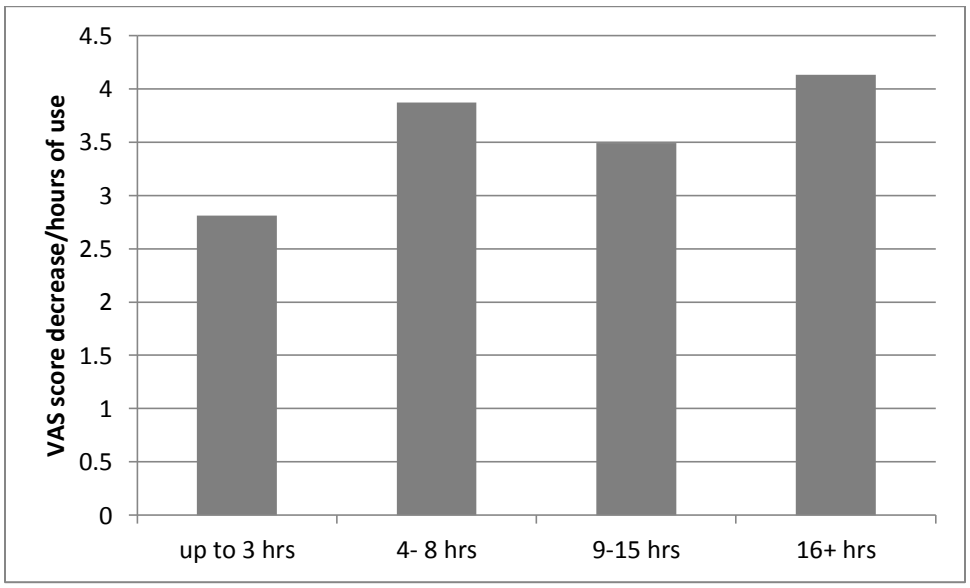
Figure 3. Sixty eight percent of responses reported a use of pain medication before PEMF device use. The amount of pain medication use decreased in the majority of those surveyed after the PEMF device was introduced with over 50% in each group showing a moderate decrease to complete elimination of pain medication use.



Time of Use - Hours

To determine if there was a correlation between hours of use the question, How many hours per day do you use the PEMF device was asked with the following response options: 1) Up to 3hrs, 2) 4-8 hours, 3) 9-15hrs and 4) 16 hrs plus. The average VAS score decrease was calculated for each response. The results appear to show a correlation in the number of hours used and VAS reduction. The lowest VAS score reduction was seen with the shortest amount of hourly use, up to 3 hours which had a mean VAS decrease of 2.81 and the highest response for hours of use, 16 plus, showed a 4.13 mean VAS point decrease. These results indicate a dose response effect but it is only appears significant when the device is used 3 hours or less per day.

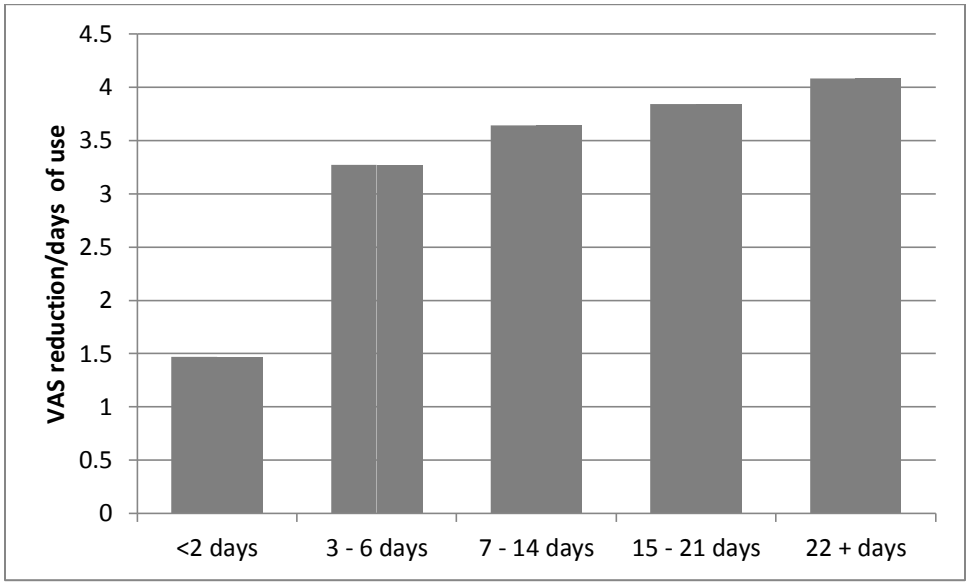
Figure 4. Increasing the hours of use of the PEMF is beneficial in that the amount of pain (mean VAS) decrease that was reported.



Time of Use - Days

A second dose response was assessed through determining the reduction of VAS score to the length of time in days the PEMF therapy was used. The question, How many total days have you used the PEMF device as asked, with the following response options, 1) 2 days or less, 2) 3 to 6 days, 3) 7 to 14 days, 4) 15 to 21 days, 5) 22 days or more. There were 245 responses in this field with 11/245 (4.5%) reporting 2 days of less, 42/245 (17.1%) reporting 3 to 6 days, 47/245 (19.2%) reporting 7 to 14 days, 38/245 (15.5%) reporting 15 to 21 days and 107/245 (43.7%) reporting 21 days or more. The results indicate a positive trend with the greater time of use in days showing the greatest VAS point decrease (Figure 5). This result, coupled with the hours of use per day indicate that the greatest reductions are obtained when the pain sufferer uses the product over long time periods and for at least 4 hours per day.

Figure 5. Increasing the days of use of the PEMF is beneficial in that the amount of pain (mean VAS) decrease that was reported.



Discussion

Musculoskeletal pain is wide spread in society, negatively impacts quality of life and is currently inadequately treated. The results from this study, of the use of a self-administered PEMF device for musculoskeletal pain, indicate that it is an effective pain therapy for a wide range of conditions, including back and knee pain. An average reduction of 3.68 VAS points or 50% indicates a level of pain reduction that is clinically significant. It has been previously shown that a decrease of 1.3 points is the minimal change needed to show clinical significance[24]. The decrease in mean pain was similar in the sub groups analyzed. With a 52% decrease for back pain, 52% decrease for knee pain and a 46% decrease in the group encompassing the other conditions including shoulder, neck, ankle, foot, toes, wrists, hand and finger/thumb pain. This level of pain reduction of 50%, is similar to that reported in a double blind placebo controlled trial using a battery powered PEMF device on osteoarthritis of the knee[22], and a 40% pain reduction was reported in a placebo controlled double blind study on plantar fasciitis[21].

Of the survey responders 22% reported no pain reduction. Comparing the sub groups, the percent reporting no reduction was 13.8% for the knee pain sub group, which was nearly half that of the back pain sub group 26%, and also the remaining sub group 27%. The lack of response in pain reduction from 22% of the users maybe be related to the complexity of the underlying cause of their pain. But a clear conclusion cannot be made at this time. However, there was a clear trend in level of pain reduction and the hours the PEMF device was used per day, and association with the level of pain reduction with time of use in days. This data strongly suggest that maximum benefit can be obtained with extended hours of use per day along with continued daily use.

Inadequately controlled pain has a detrimental effect on quality of life, and there is a proven association that decreasing pain will increase quality of life [25-28]. This effect, a decrease in pain score resulting in an increase in quality of life was seen in this survey. Of the survey responses, 66.6% reporting a noticeable to considerable improvement in quality of life score after use of the PEMF device for pain. This compares closely to the 68% who reported a reduction in VAS score. In sub group K, which had the highest percent reporting a VAS decrease at 86% and the greatest mean VAS reduction of 3.87 points. Also had the highest number, reporting a moderate to considerable improvement, in quality of life at 72%. Conversely the sub group R had the lowest number reporting a VAS reduction at 72% along with the lowest mean VAS point reduction at 3.38. The reported moderate to considerable improvement in this group was 51.9%. These results confirm the close association between the reported pain decrease and improved quality of life. A decreased reliance on pain medications also contributes to an increased quality of life, lowering the risk of undesirable side effects. A significant advantage of PEMF as a pain therapy is the lack of undesirable adverse side effects[15], and that it is non-invasive localized treatment. This allows it to be used as a stand-alone, or as an adjunct therapy option.

The responses to this survey clearly indicate that pain is inadequately treated in many individuals as the mean pain reported was 7.3 VAS points, a level of pain that would be considered as severe. Of the responders, 68% indicated use of pain medications for their pain, and there was a correlation of pain medications users having a slightly higher mean baseline pain, 7.5 compared to non-pain medication users of 6.9. This data suggests that pain medications alone are an inadequate therapy for these common pain conditions. There are also serious drawbacks to use of pain medications, especially with long term use with both over the counter and narcotic pain medications [6-14, 29, 30]. With the increasing prescription of opioid based medications for pain contributing to serious social problems including addiction and death due to drug overdose [31]. After the introduction of the PEMF device, as well as a decrease in

mean baseline VAS pain score, there was also a reported decrease in use of pain medication. With 11% reporting a small, 41% reporting a moderate to large decrease, and 18% indicating a complete elimination of pain medication use. In total 70% reported a decrease in pain medication use, suggesting that introduction of the PEMF device had the important benefit of decreasing the reliance on pain medications.

Overall PEMF therapy, in a meta-analysis review has been shown to significantly reduce postoperative pain, orthopedic pain, reduce edema and promote wound healing[16]. And PEMF has been reported to be effective for osteoarthritis of the knee in a meta-analysis of randomized control trials[32].

The mechanism of action of PEMF therapy is not well understood, though it has been postulated to involve activation of a CaM-dependent NO/cGMP signaling pathway[22, 33], and PEMF have been shown to decrease the expression of the pro-inflammatory cytokine interleukin 1β[20]. *In vitro* cell studies using gene array, have demonstrated that PEMF treatment effects all phases of the wound healing cycle[34], including the inflammatory phase[35]. The increased expression of endogenous opioid peptide has also been reported in the same *in vitro* cell culture system exposed to a PEMF[36]. Taken together the evidence suggests that PEMF therapy is therapeutic through a combination of an anti-inflammatory effect and a localized analgesic effect through an up-regulation of endogenous opioid peptide.

While there are clearly limitations on the conclusions that can be drawn from this user survey, there is supporting evidence from double blind randomized controlled trials that used the identical PEMF device. As a treatment for plantar fasciitis, overnight therapy significantly reduce morning heel pain compared to placebo ($p = 0.03$) in seven days[21]. Postoperative pain, in a double blind, randomized control trial was also significantly reduced, as was the amount of narcotic pain medication required during the recovery period[18]. The three main assessment tools used in this survey, VAS scores, PGIC and medication use, strongly suggest that this form of self-administered therapy could play a significant part in reducing pain, improving quality of life and reducing pain medication use for a significant percentage of the population suffering from common musculoskeletal pain conditions. Another significant advantage with this medical device is the very low economic cost, with the potential for significant health care cost savings. The results presented here show the need that further clinical study is warranted to fully assess the clinical effects of this PEMF device. Back pain and knee pain would clearly be excellent targets for clinical study.

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