Clinical Evaluation Report

Efficacy of Microcurrent Therapy in the Treatment of Acute and Chronic Pain including Control of Postoperative Pain

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1. General

This Clinical Evaluation Report details clinical tests of the NOT FOR PUBLIC RELEASE 7500 microcurrent therapy device. The device is manufactured by Newmark, Inc. of Cheshire, CT and is cleared by the FDA for the intended use to reduce pain in soft tissue by the targeted application of pulsed direct current.

2. Description of the Device

The Newmark, Inc. Micro Current Therapy (MCT) Patch, Model 7500, consists of two electrodes mounted on adhesive material. The electrodes are connected on one side by a snap assembly containing the circuit and battery assembly and the other with an over-molded snap connector. They are joined together with a small diameter wire. The side with the circuit and battery contains an LED light.

- Electrode Pads – The electrodes are manufactured by Lead-Lok of Sandpoint, Idaho and contain a hydrogel and adhesive commonly used in standard electro cardiogram products. The products have received a United States FDA 510(k).
- Wire – Copper wire with insulation of extra-flexible PVC.
- Battery – 3 Volt Lithium battery, model CR1620, which has a nominal capacity of 70 mAh, standard discharge current of 1 mA. The weight of the battery is 1.2 grams.
- Backing layer – The top and cover layer is single coated Soft PET substrate, non-woven, and pressure sensitive adhesive tape.
- Circuit Board – is a .5mm thick two sided copper coated fiber board with standard electronic components.

The subject device is not supplied sterile and cannot be sterilized or disinfected. The subject device is to be discarded after use by one patient only. Recommendations on keeping the unit clean are included in the instructions for use. The product is marketed under the trade name NOT FOR PUBLIC RELEASE

3. How it works to achieve intended purpose

Research shows that ATP (adenosine triphosphate) levels increase with the application of microcurrent and diminish with current at milliamp levels. (Ngok Cheng, et al 1982). Cheng also observed that aminoisobutyric acid uptake increased dramatically beginning at 10 microamps. During electro stimulation, proton gradients are created across the mitochondrial membrane. The current produces a gradient when electrons at the cathode react with water to form hydroxyl ions while producing protons at the anodic side. As a result a proton and voltage gradient are established across the intervening tissues between the electrodes. The influence of the electrical field and the proton concentration difference produce a proton current that moves from anode to cathode. As the migrating protons cross the mitochondrial membrane-bound H+AT Pase, ATP is

formed. The increased ATP production stimulates amino acid transport, and these two factors both contribute to increased protein synthesis. (Cheng et al, 1982)

4. Intended Therapeutic indications for Use

The model 7500 Micro Current Device is intended to be used for the relief of chronic and acute intractable pain.

5. Developmental Context – Change of Existing Technology

In the mid 1980's, the focus of treatment of pain through electrical stimulation was the use of a transcutaneous electrical stimulation device commonly called TENS. These devices emitted current levels in the milliamp range at various frequency levels to short out the signal of pain to the brain. The devices offer no long term pain relief and, if used extensively, could cause cellular damage to the patient. In the 1990's, the use of microcurrent, defined as less than at 1 milliamp, was introduced as a treatment and proven to be safer and more effective than TENS. The TENS devices were large in size requiring a table to hold the equipment and available only at a licensed practitioner's office. As electronic components advanced shrinking in size and cost, Newmark, Inc. set out to produce a low cost microcurrent treatment device that could be personally used at home by a majority of the population.
In 1999, Newmark, Inc. produced a device that had the generator built into the back of the electrodes. By eliminating bulky controls, the generator could be made very small. The Model 7500 microcurrent therapy patch has a single non-programmable microcurrent mode that delivers pulses at a frequency of 0.5Hz with an average operating current of 42μA (microamps).

6. Summary of the clinical data

The Newmark, Inc. MCT device has been evaluated for efficacy to reduce pain in three (3) clinical trials.

1. Efficacy of Microcurrent Therapy in the Treatment of Chronic Nonspecific Back Pain by Joseph S. H.A. Koopman; Dorien H. Vrinten, MD; and Albert J.M. von Wijk, MD, PhD demonstrated positive trend in treatment of chronic low back pain reducing VAS scores 20% with a reduction analgesic use.
2. Microcurrent Skin Patches for Postoperative Pain Control in Total Knee Arthroplasty by Timour El-Husseini; and Mahmoud El-Sebai showed a progressive decrease in pain and a lower dose of tramadol.
3. Effect of Microcurrent Skin Patch on the Epidural Fentanyl Requirements for Postoperative Pain Relief of Total Hip Arthroplasty by Tarek M Sarhan; and Maher A Doghem conducted a similar study to #2 above and concluded the reduced requirement for fentanyl to reduce pain was statistically significant.

Copies of the studies are attached and made part of this evaluation report.

The Newmark, Inc. MCT device was used in a number of case studies for treatment of various pains. Six of the studies are summarized in the attached document.

7. Safety

There have been no reportable adverse events in the use of the product in the clinical or case studies. Additionally, over 400,000 units have been used by patients worldwide with no reportable adverse events. The device has been subjected to all applicable safety testing standards and passed.

8. Conclusions

The studies demonstrate consistent performance to meet its intended use in reducing pain and the results are statistically significant.

- The clinical evidence demonstrates conformity with relevant Essential Requirements.
- The performance and safety of the device have been established.
- The risks associated with the use of the device are acceptable when weighed against the benefits to the patient.

Efficacy of Microcurrent Therapy in the Treatment of Chronic Nonspecific Back Pain

A Pilot Study

Joseph S. H. A. Koopman, MD,† Dorien H. Vrinten, MD,* and Albert J. M. van Wijck, MD, PhD**

Objectives: Microcurrent therapy (MCT) is a novel treatment for pain syndromes. The MCT patch is hypothesized to produce stimuli that promote tissue healing by facilitating physiologic currents. Solid evidence from randomized clinical trials is lacking. To evaluate the efficacy of MCT in treating aspecific, chronic low-back pain, we conducted a double-blind, randomized, crossover, pilot trial.

Methods: Ten succeeding patients presenting with nonspecific, chronic low-back pain in our university hospital were included. Patients started with two, 9-day baseline period followed by a 5-day treatment periods. During the treatment periods, either a placebo or MCT (verum) patch was randomly assigned. Mean and worst pain scores were evaluated daily by a visual analog scale (VAS). Furthermore, analgesic use, side effects, and quality of life were assessed after each period. Differences between the last 4 days of a treatment period and the baseline period were calculated. Differences between verum and placebo periods per patient were compared using paired t tests. A 20-mm VAS score reduction was considered clinically relevant.

Results: The VAS score was lower during verum treatment, with a reduction [95% confidence interval (CI) of -0.43 (-1.74; 0.89) in mean and -1.07 (-2.85; 0.71) in worst pain. Analgesic use decreased during verum treatment, except for nonsteroid anti-inflammatory drug use, which increased. Quality of life improved during verum treatment. However, note of the findings were statistically significant.

Discussion: A positive trend in MCT use for aspecific, chronic low-back pain is reported. Further investigations are required to evaluate the significance and relevance of this.

Key Words: microcurrent therapy, chronic low-back pain, randomized, controlled trial, placebo, crossover design

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Chronic low-back pain is a serious problem affecting approximately 20% of the general population, with no specific diagnosis being made in more than 90% of these cases.[1,2] Despite the many available therapies, treatment of chronic low-back pain can be difficult and disappointing.

Microcurrent therapy (MCT) is a novel treatment for different pain disorders and is defined as a low-intensity, direct current that delivers monophasic or biphasic pulsed microamperage currents across the skin.[3–8] Patients do not perceive MCT currents, and the putative mechanism of action differs from conventional transcutaneous electrical nerve stimulation (TENS). Conventional TENS delivers a 10 to 100 Hz frequency, 1 to 2 mA current, whereas our device delivers a microcurrent of 25 μA, with a frequency of approximately 71.5 kHz.[9] Conventional TENS is hypothesized to "close the gate" in the spinal cord, thus suppressing nociceptive pain and stimulating endogenous opioid release.[9–11] MCT is hypothesized to increase the synthesis of adenosine triphosphate, amino-acid transportation, and protein synthesis to decrease inflammation and to promote tissue healing.[4,12,13]

Once or twice weekly, intermittent MCT treatment for 20 to 40 minutes with a 100-μA device provided a significant (3.8-fold) reduction in pain intensity in an uncontrolled trial with patients with intractable, chronic low-back pain.[14] The present pilot study evaluates the efficacy of continuous (24-h daily) intervention with the MCT patch, delivering a monophasic current, for the treatment of chronic low-back pain, using a randomized, placebo-controlled, double-blind, crossover design.

PATIENTS AND METHODS

To investigate the efficacy of continuous MCT-patch treatment, we included 10 otherwise healthy adults with aspecific, chronic low-back pain of more than 3 months' duration and an average intensity on a 0 to 100 mm visual analog scale (VAS) of above 40. Furthermore, participants were required to be out-patients, between 18 and 65 years of age, of normal weight and height, and able to comprehend the study design and give informed consent. Patients participating in other trials, undergoing other pain treatment (except escape medication), pregnant women, or patients with circulatory defects of their extremities, any connective tissue disease, any disease with a predisposition for, or with, seizures, a pacemaker, a skin infection at the site where the patch will be placed, or a neurologic disease leading to sensory disturbances were excluded from the trial. Patients were referred to our academic pain clinic after unsuccessful treatment by general practitioners and secondary care. An anesthesiologist specialized in pain treatment confirmed the diagnosis. We used a Pain Away patch (Newmark Inc, Cheshire, CT) delivering a 25 μA microcurrent, with a frequency of approximately 71.5 kHz and 3 V.

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The patches and the travel expenses of the participating patients were provided by the Benelux distributor of the patches TakeCare BV. The first and second authors have no conflicts of interest to declare, the third received compensation from the manufacturer. The first author is currently supported by an unrestricted grant from Pfizer for a totally unrelated research project.

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After obtaining informed consent and inclusion, a 9-day baseline period was started. Patients were randomly assigned to a 5-day treatment period with either verum (active MCT) patch or placebo followed by a 9-day wash-out period to eliminate any long-term effects of the MCT patch. During this 9-day period, no experimental intervention was given. Hereafter, patients crossed over to a second treatment period of 5 days with verum or placebo. The study design is further clarified in Figure 1. The patch was used continuously during both treatment periods. Patches were applied over the most painful spot with the positive electrode, marked by a LED light, closest to the spine (Fig. 2). Given the differences between TENS and MCT and the novelty of MCT, no uniform treatment regimen currently exists. We therefore chose to follow the manufacturer's recommendations. The placebo patch was indistinguishable from the active MCT patch in all aspects, owing to the fact that the microcurrent was below sensory threshold. Both patient and investigator were blinded to the assigned treatment.

The senior author numbered the placebo and verum patches from 1A and B to 10A and B. Each patient was given patch A during the first period and patch B during the second period by the first author, who was blinded to the treatment allocation. After the 2 treatment periods (1 active and 1 placebo), a 4-week open period began in which patients used an active MCT patch.

The primary end point was change in pain intensity between the treatment period and the placebo period. This was measured by daily VAS scores for average pain and for worst pain. Secondary end points were the use of analgesics in the treatment period, as compared with the placebo period, the scores on the short-form McGill Pain Questionnaire, Dutch Language Version (sf-MPQ-DLV), side effects, and global impression of the patients.[15] Quality of life was assessed by the European Quality of Life-5D (EQ-5D) at the end of each period.[16] These end points are all recommended as "core domains" by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT).[17] The EQ-5D was specifically designed for a nonspecific evaluation of health status.[16] During the open phase, the VAS score and the use of additional medication were recorded on a weekly basis. Side effects and sf-MPQ-DLV and EQ-5D questionnaires were recorded once at the end. All data collection and analyses were carried out by the first author. This study was approved by the medical ethics commission of the University Medical Center Utrecht. Informed consent was obtained before participation.

Analyses

The baseline VAS score was defined as the mean of the last 4 days before a treatment period (baseline period or wash-out period 1 or 2, Fig. 1) to eliminate a carry-over effect of the before-treatment period. The mean VAS score at the end of a treatment period (blinded period 1 or 2, Fig. 1) was calculated as the mean of the last 4 days to provide a wash-in period of treatment. The mean change in primary and secondary end points during the verum and placebo treatment was measured. The differences between these changes were compared with a paired t test and the 95% CI was calculated. A 20-mm VAS score difference between placebo and verum was considered to be clinically relevant.

EQ-5D and sf-MPQ-DLV were scored using published procedures.[18,19] The use of analgesics was recorded daily, and the mean use per period was compared between the different treatment periods using a Student t test. P values were derived using the Wilcoxon paired-sample tests. Mean use was calculated by multiplying strength by daily dosage, and dividing this sum by the number of patients (n = 10).

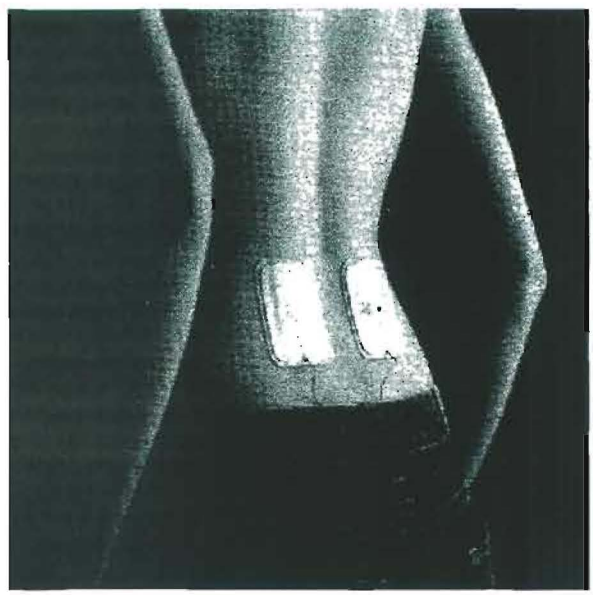

FIGURE 2. Disposable microcurrent therapy patch for continuous application.

RESULTS

Patient inclusion is displayed in Figure 3. During a 4-month period, 12 succeeding patients referred to our clinic with low-back pain were assessed for eligibility: 1 patient was excluded because she had a hip implantation; 1 patient refused informed consent; and 10 patients gave informed

Period 1: 9 days	Period 2: 5 days	Period 3: 9 days	Period 4: 5 days	Period 5: 9 days
Baseline period	Blinded period 1	Washout 1	Blinded period 2	Washout 2
V1	V2: randomization	V3	V4	V5
		Period 6		
Week 6	Week 7	Week 8	Week 9	Week 10
Open period				End of study
V6				V7

FIGURE 1. Study design. V1 to V7 denote data collection points 1 to 7. The last 4 days of the period before a "blinded period" were used to calculate baseline measures, whereas the last 4 days of the "blinded period" itself were used to calculate treatment effect.

consent. Patient characteristics are listed in Table 1. The mean and worst VAS scores during baseline, placebo, and verum treatment are described in Table 2. After treatment with an active patch, the VAS score was reduced by 0.09, in contrast to an increase of 0.34 during treatment with the placebo patch. The worst VAS score was decreased by 0.65 during verum treatment, whereas it increased by 0.41 during placebo treatment. The treatment effect of the verum patch can be described as small for the mean VAS score and as moderate for the worst VAS score, using the standardized nomenclature first introduced by Batterham and Hopkins.[20] The sf-MPQ-DLV and EQ-5D assessments and the use of additional pain medication improved during the use of the verum patch (Tables 2, 3). Paracetamol usage decreased during the verum period, whereas this increased during placebo treatment. Opioids were used less during treatment. Nonsteroid anti-inflammatory drug use increased during verum treatment, whereas this decreased during placebo treatment. The use of gabapentin remained constant.

The adverse events reported during this study were present in 6 patients during one or more of the treatment periods. These were pain (other than low-back pain), skin irritation, and itching (Table 4). None of the patients found these serious enough to withdraw from the study. All patients reported suboptimal adherence of verum and placebo patches at some time during the 3 treatment periods. Discontinuation of the continuous (24 h) application was prevented by the use of back-up patches. Back-up patches (either placebo or verum, depending on the allocated treatment) were available for use once the old patch had stopped adhering optimally.

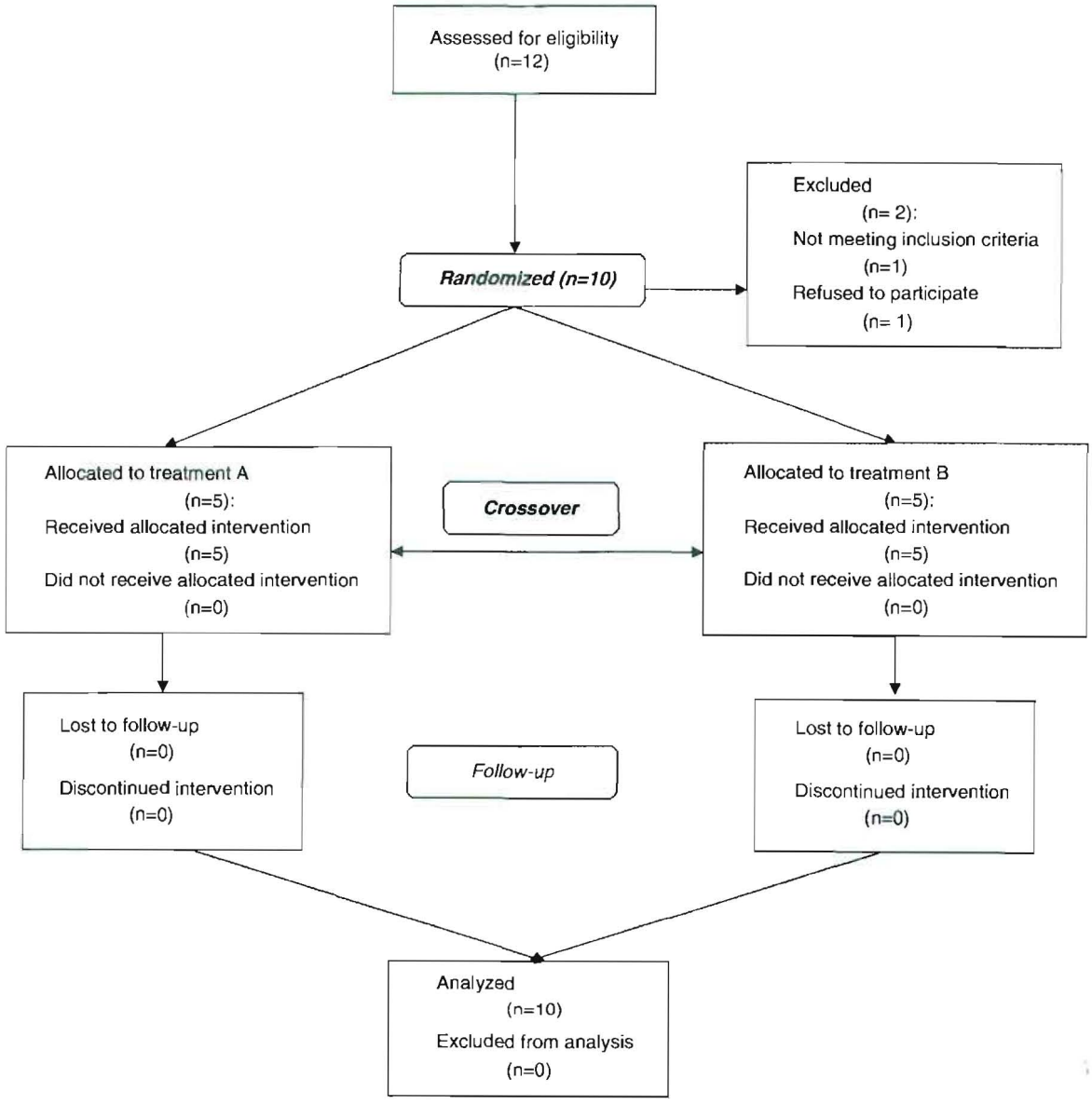

FIGURE 3. Consort diagram for patient inclusion.

TABLE 1. Baseline Characteristics of Patients

Patient	Sex	Age (y)	BMI (kg/m²)	Previous Invasive Pain Treatment	Months of Pain
1	Male	45	29.17	Yes	32
2	Female	61	29.73	No	360
3	Male	35	25.83	Yes	132
4	Female	58	28.09	Yes	156
5	Male	46	30.99	No	96
6	Female	39	30.48	Yes	36
7	Female	50	20.68	Yes	46
8	Female	52	25.64	Yes	144
9	Female	59	26.30	Yes	36
10	Male	60	31.01	Yes	32
Mean	40% male	50 (9.2)	27.79 (3.25)	80% yes	107.0 (102.0)
Placebo first	60% male	52 (7.1)	27.63 (4.34)	80% yes	48.4 (27.2)
Verum first	20% male	49 (11.5)	27.95 (2.20)	80% yes	165.6 (118.6)

The SD is displayed between ( ). Verum first means the first treatment period was with a verum patch.
BMI indicates body mass index.

TABLE 3. Additional Medication

	Paracetamol	Nonsteroid Anti-inflammatory Drug	Opioids	Gabapentin
Baseline 1	879 (1189)	390 (645)	179 (180)	270 (854)
Verum	566 (1136)	540 (884)	175 (179)	270 (854
Verum-baseline 1	−313	+150	−5	0
Baseline 2	481 (911)	450 (700)	180 (197)	270 (854)
Placebo	1014 (1523)	420 (703)	171 (198)	270 (854)
Placebo-baseline 2	+534	−30	−9	0
Baseline 3	696 (1143)	338 (549)	174 (178)	270 (854)
Open period	979 (1597)	226 (470)	165 (162)	270 (854)
Open period-baseline 3	+283	−112	−9	0
Difference verum/placebo	−847 [−2284; 591] $P = 0.50$	+180 [−191; 551] $P = 0.18$	+4 [−22; 31] $P = 0.79$	0 [0; 0] $P = 1.00$

The average daily dosage is given in milligrams, calculated by multiplying strength by dosage and dividing this sum by 10. The bold numbers represent the change in the measurements during one of the treatment periods. A negative number is, in general, an improvement whereas a positive number is a worsening. SDs are listed between ( ). The 95% confidence intervals are listed between [ ].

DISCUSSION

This is the first randomized trial to evaluate the efficacy of the continuous MCT patch and to find a reduction in mean and worst VAS scores in patients with nonspecific, chronic low-back pain. Our study has several limitations. First, the study population was small. Therefore, our parameters did not reach statistical significance and the results may not be robust. Second, we included patients in a tertiary pain clinic. These will be more complicated patients with larger medical histories including previously failed treatment, and thus harder to treat. Previous to this trial, 8 of 10 patients received unsuccessful invasive treatment. Therefore, treatment could, potentially, be more successful for patients presenting with nonspecific, chronic low-back pain in an earlier phase at a general practitioner's or a secondary pain clinic. The effect size might be larger in the latter patients as compared with our complicated study population. Thirdly, problem concerning the adherence of the patches was solved by providing multiple patches. Although this ensured continuous application, it lessened patient satisfaction and might influence quality of life.

Despite the above-mentioned points, we consider our results to be internally valid given our placebo-controlled, double-blind, randomized, crossover design and the absence of loss to follow-up.

TABLE 2. Primary and Secondary End Points

	VAS Score		EQ-5D		sf -MPQ-DLV				
	Mean	Worst	Question	VAS	NWC	Sum	Sen	Aff	Cog
Baseline 1	6.23 (1.45)	7.36 (0.68)	0.38 (0.34)	5.71 (2.19)	10 (3.16)	18.5 (7.23)	9.4 (4.84)	3.0 (2.26)	6.1 (2.23)
Verum	6.14 (1.42)	6.71 (1.58)	0.26 (0.35)	5.71 (1.82)	9.0 (3.27)	17.3 (7.78)	8.7 (4.76)	3.3 (2.87)	5.3 (2.11)
Verum-baseline 1	−0.09	−0.65	−0.12	−0.00	−1.0	−1.2	−0.7	+0.3	−0.8
Baseline 2	5.99 (1.37)	6.71 (1.48)	0.35 (0.39)	6.26 (1.97)	9.7 (3.59)	18.9 (8.06)	9.3 (4.83)	3.4 (2.95)	6.2 (1.40)
Placebo	6.33 (1.43)	7.12 (1.28)	0.33 (0.35)	5.42 (2.37)	10.6 (3.69)	20.8 (9.84)	10.7 (4.08)	3.8 (3.77)	6.3 (3.09)
Placebo-baseline 2	+0.34	+0.41	−0.02	−0.84	+0.9	+1.9	+1.4	+0.4	+0.1
Baseline 3	6.29 (1.30)	6.89 (1.18)	0.34 (0.37)	5.33 (1.73)	10 (3.23)	18.8 (6.53)	9.3 (3.65)	6.3 (2.26)	3.2 (2.53)
Open period	6.32 (1.26)	7.11 (0.79)	0.28 (0.33)	5.05 (1.51)	10.2 (2.94)	20.4 (6.04)	9.70 (4.79)	6.9 (2.33)	3.8 (2.39)
Open period-baseline 3	+0.03	+0.22	−0.06	−0.28	+0.2	+1.6	+0.4	+0.6	+0.6
Difference verum/placebo	−0.43 [−1.74; 0.89] $P = 0.29$	−1.07 [−2.85; 0.71] $P = 0.39$	−0.09 [−0.50; 0.31] $P = 0.21$	−0.85 [−1.31; 3.00] $P = 0.28$	−1.9 [−4.22; 0.42] $P = 0.09$	−3.1 [−11.49; 5.29] $P = 0.67$	−2.1 [−5.31; 1.11] $P = 0.18$	−0.1 [−3.38; 3.18] $P = 0.40$	−0.9 [−3.65; 1.85] $P = 0.45$

The second and third column displays the average (of all 10 patients) mean daily pain score and worst daily pain score per period. The bold numbers represent the change in the measurements during one of the treatment periods. A negative number is, in general, an improvement whereas a positive number is a worsening. An exception is the European Quality of life-5D (EQ-5D) Visual Analogue Scale (VAS) score, where a negative number means a worsened situation. The SD is between ( ).The 95% confidence intervals are listed between [ ]. sf-MPQ-DLV is the short form McGill Pain Questionnaire—Dutch Language Version.
Aff indicates focus on affinity of pain; Cog, focus on cognition of pain; NWC, net word count; Sen, focus on sensitivity of pain; Sum, summation.

Microcurrent skin patches for postoperative pain control in total knee arthroplasty: A pilot study

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Abstract:

Pain control following painful orthopedic procedures such as total knee arthroplasty is an ongoing challenge, as current pain management techniques often result in undermedication and/or complications, clinical research investigating alternative or hybrid methods becomes a major interest for the orthopaedic surgeon.
This pilot study included 24 patients who underwent Total Knee Arthroplasty (TKA). Patients were randomly allocated into 2 groups of 12 patients each. Group 1 used micro-current skin patch (MCT) with tramadol hydrochloride SOS for pain relief (MCT Group). Group 2 received tramadol hydrochloride SOS without application of MCT which served as a control group. tramadol was given IM in increment doses of 100 mg and both groups were observed for 10 days postoperatively.
The main endpoint was pain assessment using a Visual Analog Score (VAS) that was measured daily. Other endpoints included dose of tramadol needed for pain relief, degree of wound healing measured at he end of the follow up period and categorized into grade 1, 2, and 3; and total drain fluid volume in ml.
Results showed progressive decrease in pain VAS. MCT group showed lower VAS throughout the observation period, most marked at follow-up days with highest pain scores in control group. This effect was achieved using a lower dose of tramadol that averaged 200.0±7.0 mg/day in control group and 63.3±15.8 mg/day in MCT group. Wound healing was better with MCT patch application. Grade 1 was observed in 50% of patients of MCT group as compared to 8.3% in control group. The total drain volume was lower in MCT group compared to controls (1020.8±211.6 and 1170.8±243.5 in the 2 groups respectively). None of the patients showed and indication for discontinuation of patch application.

Key words:
Micro current therapy, pain assessment, total knee artroplasty

Introduction:

Postoperative pain management is critical for optimal care of orthopaedic surgery patients especially after operations that cause considerable pain like total knee arthroplasty. Opioids, administered intramuscularly, as epidurals, or IV as patient-controlled analgesia, are effective for severe pain[1].

Adjunctive therapy and preemptive analgesia such as nerve blocks, and methods of delivery such as infusion pumps are recognised but are not used as standard practice. Oral opioids are effective for moderate to severe pain, and tramadol, with efficacy comparable to morphine but with fewer severe side effects, is selected for moderate to moderately severe pain [2]. Opioid-sparing NSAIDs, such as ketorolac, and COX-2-specific NSAIDS are also widely used. These current current pain management techniques often result in undermedication and/or complications[3,4].

Nonpharmacologic treatments and alternative approaches are less widely accepted, they span over physical therapy, cryotherapy, continuous passive motion, transcutaneous electrical nerve stimulation (TENS) and patient education, an individualised approach of one or more of the above mentioned approaches[2,5].

Reports on the effectiveness of microcurrent therapy (MCT) in the management of pain[6] may offer a new nonpharmacologic approach which, to our knowledge, has not been investigated for postoperative pain following total knee arthroplasty

Aim of work:

Main objective of the study was postoperative pain assessment after total knee arthroplasty, with and without MCT patch application. Secondary objectives included dose of tramadol hydrochloride needed for pain relief, degree of wound healing, and total drain fluid volume.

Patients and method:

This pilot case-control study included 24 patients who underwent Total Knee Arthroplasty (TKA). Patients were randomly allocated into 2 groups of 12 patients each. Group 1 used micro-current therapy (MCT) applied through the electrodes –which did not interfere with the wound or its dressing (figure 1), with tramadol SOS for pain relief (MCT Group). Group 2 received tramadol SOS without application of MCT and served as a control group. tramadol was given IM in increment doses of 100 mg to a maximum of 400 mg/day and both groups were observed for 10 days postoperatively. All patients gave an informed consent to participate in the study.

The main endpoint was pain assessment using a Visual Analog Score (VAS) that was measured daily. Other endpoints included dose of tramadol needed for pain relief, degree of wound healing measured at he end of the follow up period and categorized into grade 1, 2, and 3 (grade 1: dry suture line, no redness around suture line, normal skin texture around suture line, grade 2: wet suture line, no or minimal redness, normal skin, grade 3: wet or draining suture line, redness and surrounding skin changes of oedema or bullae); and total drain fluid volume in ml.

Data are summarized using means $\pm$ standard deviations for quantitative variables and percentages for categorical variables. Nonparametric tests were used for analysis due to the limited number of patients in this pilot study. The threshold of significance was fixed at the 5% level.

Results:

Effect on pain control:

The VAS was lower under MCT throughout the 10 days of the study. This lower VAS was achieved starting first day postoperatively. (Table 1 and Figure 2).

Effect on dose of tramadol hydrochloride:

The lower pain VAS in MCT group was achieved using a significantly lower dose of tramadol as compared to controls. The average daily dose was 200.0±7.0 mg/day in control group and 63.3±15.8 mg/day in MCT group; a difference proved to be significant at $p<0.001$ (Table 2 and Figure 3). All through the observation period, patients of MCT group needed lower doses of tramadol (Table 3 and Figure 4).

The need for lower dose of tramadol was evident in MCT group. Throughout the observation period, there was no need for the drug in almost 60% of patients at day 1 in MCT group. In control group, about 80% of patients were in need of 300 mg of tramadol. In day 10, more than 90% of patients were not in need of the drug in MCT group as compared to 40% in control group (Tables 4 and 5)

Effect on wound healing:

As shown in table 6, wound healing was better in MCT group. They had higher frequency of grade 1 (50.0% compared to 8.3%). Grades 2 and 3 were more frequent in control group. Ridit analysis proved significance of higher frequency of lower grades under MCT ($p<0.001$). This was accompanied by less drain volume in MCT group

Effect on drain volume:

The lower pain VAS and better wound healing in MCT group were accompanied by a less drain volume compared to controls. The drain volume was 1020.8+211.6 in MCT group and 1170.8±243.5 in control group (Table 2). The difference was proved to be statistically significant ($p <0.05$).

Side effects and discontinuation of treatment:

During the entire observation period, none of the patients had any side effects from patch application. None of them requested discontinuation of MCT treatment.

Discussion

Pain control following painful orthopedic procedures such as total knee arthroplasty is an ongoing challenge, as current pain management techniques often result in undermedication and/or complications[1,2]. The standard approach depends on systemic opioids given in bolus IV or IM or in patient controlled analgesia (PCA) self administration pumps. Preemptive analgesia in the form of epidural pumps, several techniques of regional nerve blocks also depend on opioids and local anaesthetic agents. Oral pharmacologic postoperative pain therapy similarly depends on opioids, but non opioid agents as tramadol hydrochloride are widely used due to their relative safety and known potency. The use of NSAIDs and the new COX-2-specifics is widely practiced despite the scope of side effects associated with its administration in higher doses required in such operations [1,2,4].

Nonpharmacologic methods are less widely accepted in the management of sever pain induced by this group of operations, they include physical therapy, cryotherapy, continuous passive motion (CPM), transcutaneous electrical nerve stimulation (TENS) and patient education[4]. Reports on the efficacy of cryotherapy[7,8,9] and TENS[10] are generally disappointing, while the use of CPM to control pain is controversial[11].

Several reports support a favourable effect of MCT as related to pain control and tissue healing through the modification and recruitment of cell membrane ATP (adenosine triphosphate)[6,12,13,14,15], but this was mostly reported in chronic painful conditions.

If MCT can proves to be a reliable and effective method to control pain postoperatively while avoiding the side effects associated with pharmacologically based methods, a new approach for postoperative pain management would be available to the orthopaedic surgeon.

This pilot study was designed to investigate such an approach, in our small number of patients it was evident that in the group which used the MCT the need for tramadol to control pain has markedly decreased indicating better pain control. Their was also evidence that the use of MCT may improve local wound healing which may be of major importance in total knee arthroplasty, and other operations with major surgical approaches.

Conclusion:

1. This pilot study showed that MCT led to better pain control with markedly lower need for tramadol as compared to control group.
2. This better pain control was accompanied by better wound healing and lesser drain volume.
3. There were no adverse effects or need for discontinuation of MCT application.

Further formal clinical trials with larger numbers are required to establish the validity of this pilot study

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Tables and figures

Table 1: Pain visual analog score (mean ± Standard Deviation) during the 10-day observation period in the 2 groups.

Days	Control Group	MCT Group
1	84.2±4.2	63.7±19.4
2	86.3±4.8	81.3±14.6
3	82.1±7.2	55.8±18.3
4	77.1±9.6	77.5±17.4
5	76.7±8.1	78.8±26.8
6	68.8±7.4	62.1±15.9
7	60.0±12.1	46.1±19.8
8	55.4±10.9	35.4±11.9
9	43.8±7.4	37.9±17.8
10	38.8±10.9	34.2±13.8

Table 2: Total dose of tramodol in mg/patient and average drain volume

Grade	Control Group	MCT Group
Dose	200.0±7.0	63.3±15.8
Drain	1170.8±243.5	1020.8±211.6

Table 3: Daily dose of tramadol (mean ± standard deviation) in the 2 groups during the 10-day observation period.

Days	Control Group	MCT Group
1	291.7±66.9	50.0±67.4
2	325.0±45.2	125.0±75.4
3	283.3±71.8	41.7±66.9
4	250.0±67.4	15.0±90.5
5	258.3±108.4	133.3±49.2
6	183.3±71.8	66.7±65.1
7	158.3±90.0	25.0±45.2
8	125.0±86.6	8.3±28.9
9	66.7±65.1	25.0±45.2
10	58.3±51.5	8.3±28.9

Table 4: The overall distribution of dosage of the 12 patients of each group during the 10-day observation period

Dose (mg)	MCT Group	Control Group
Not needed	52.5%	10.7%
100	33.3%	23.7%
200	12.5%	28.7%
300	1.7%	25.4%
400	0.0%	11.5%

Table 5: Distribution of dose of tramadol in the 2 groups during the 10-day observation period.

Days and Group		0	100	200	300	400
1	Control	0	0	3	7	4
	MCT	7	4	1	0	0
2	Control	0	0	0	9	3
	MCT	1	8	2	1	0
3	Control	0	0	4	6	2
	MCT	8	3	1	0	0
4	Control	0	0	7	4	1
	MCT	2	3	6	1	0
5	Control	0	1	7	0	4
	MCT	0	8	4	0	0
6	Control	0	4	6	2	0
	MCT	5	6	1	0	0
7	Control	1	5	4	2	0
	MCT	9	3	0	0	0
8	Control	2	6	3	1	0
	MCT	11	1	0	0	0
9	Control	5	6	1	0	0
	MCT	9	3	0	0	0
10	Control	5	7	0	0	0
	MCT	11	1	0	0	0

Table 6: Grade of wound healing

Grade	Control	MCT
1	8.3%	50.0%
2	66.7%	41.7%
3	25.0%	8.3%

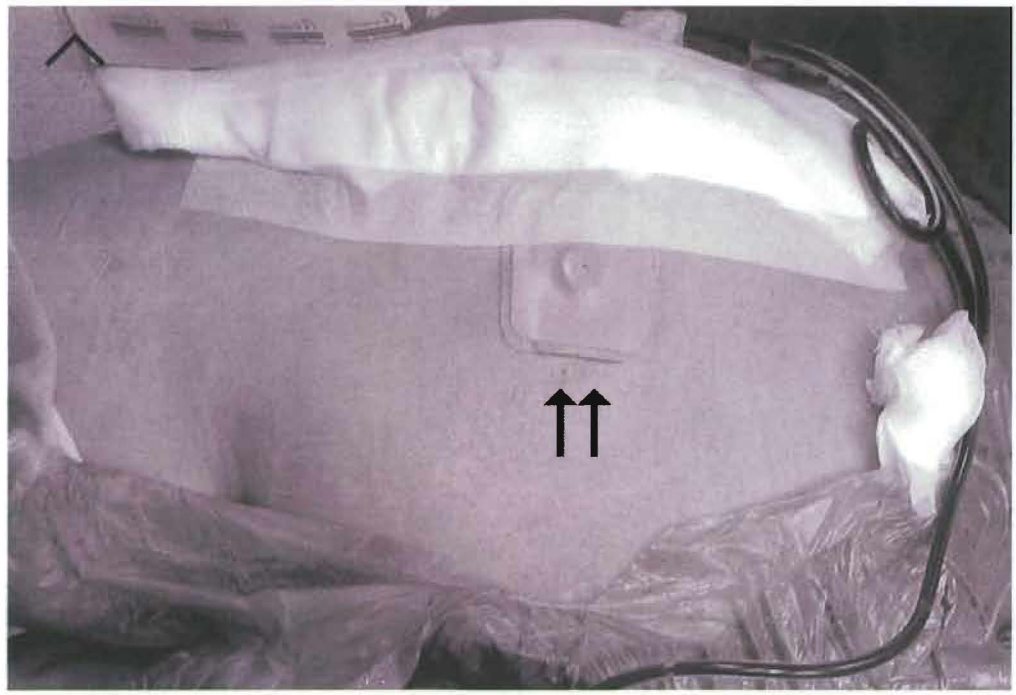

Figure 1: Microcurrent adhesive skin patch in situ (arrows) during postoperative dressing, the other patch is applied on opposite side of the knee at the level of the patella.

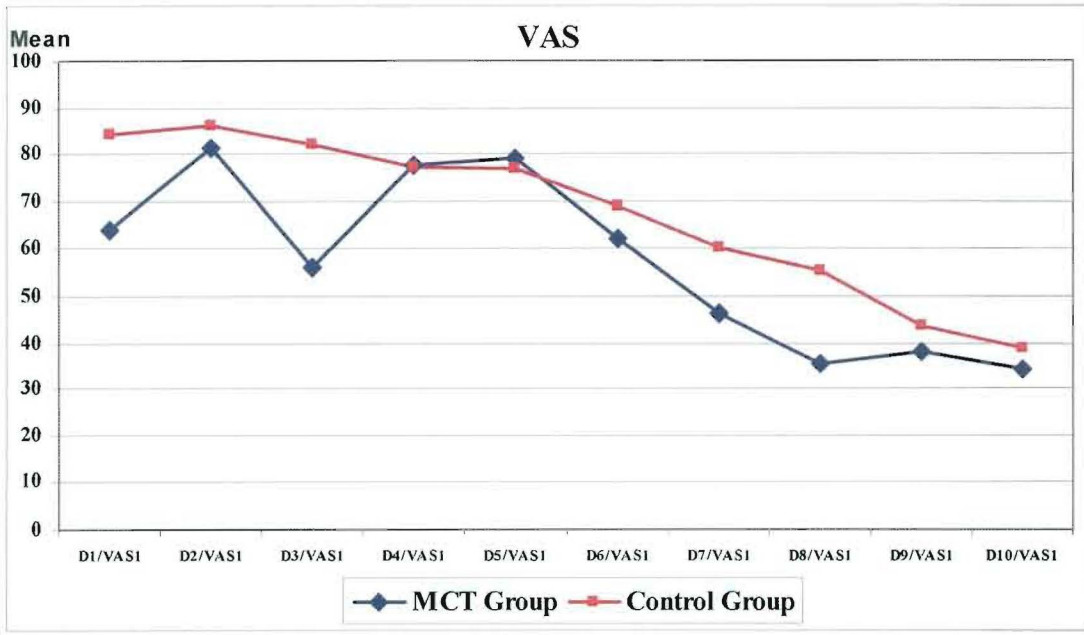

Figure 2: Change in Visual Analog Score in the 2 groups during the 10-day observation period

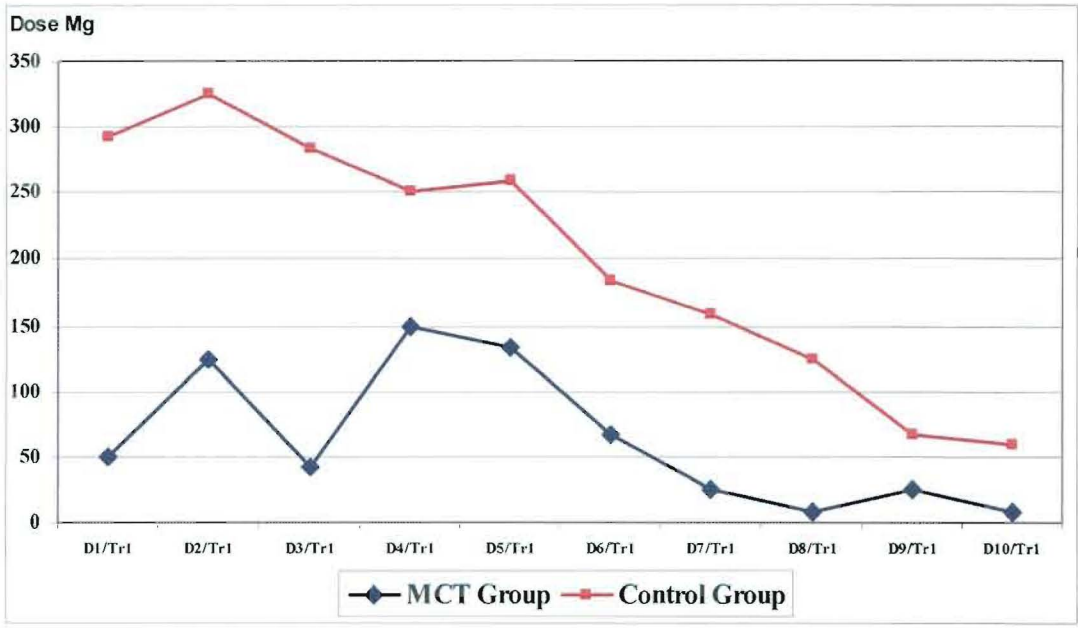

Figure 3: Average daily dose of tramadol needed by patients in the 2 groups during the 10-day observation period

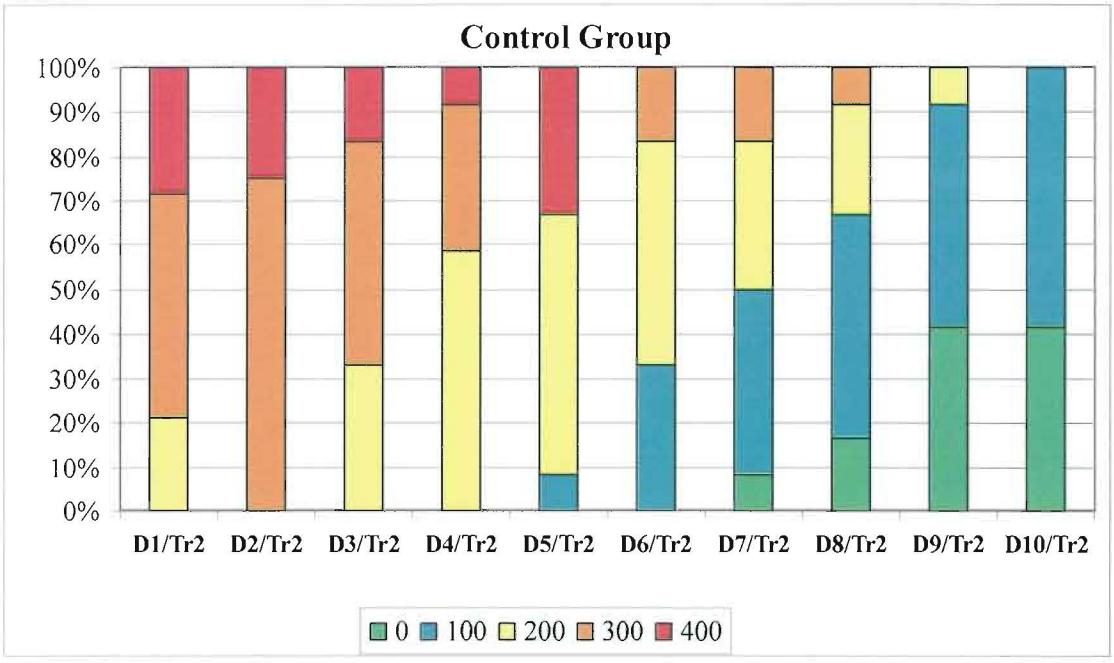

Figure 4: Frequency of different daily doses of tramadol needed after Total Knee Arthroplasty (TKA) for patients in control group during the 10-day observation period

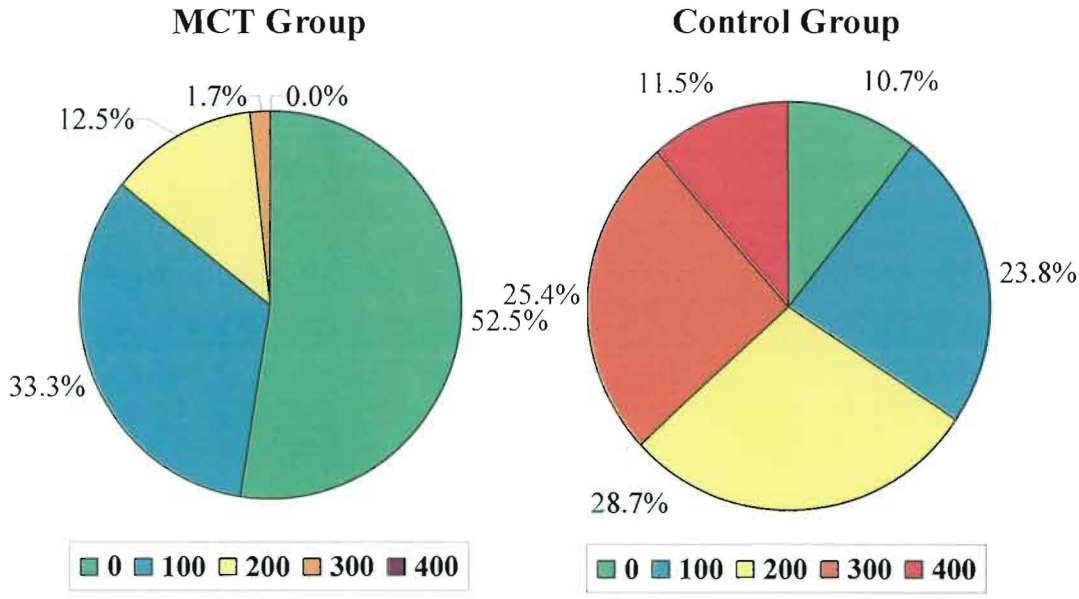

Figure 5: Frequency of different doses of Tramadol needed after Total Knee Arthroplasty (TKA) for patients who received MCT and control group during the 10-day observation period

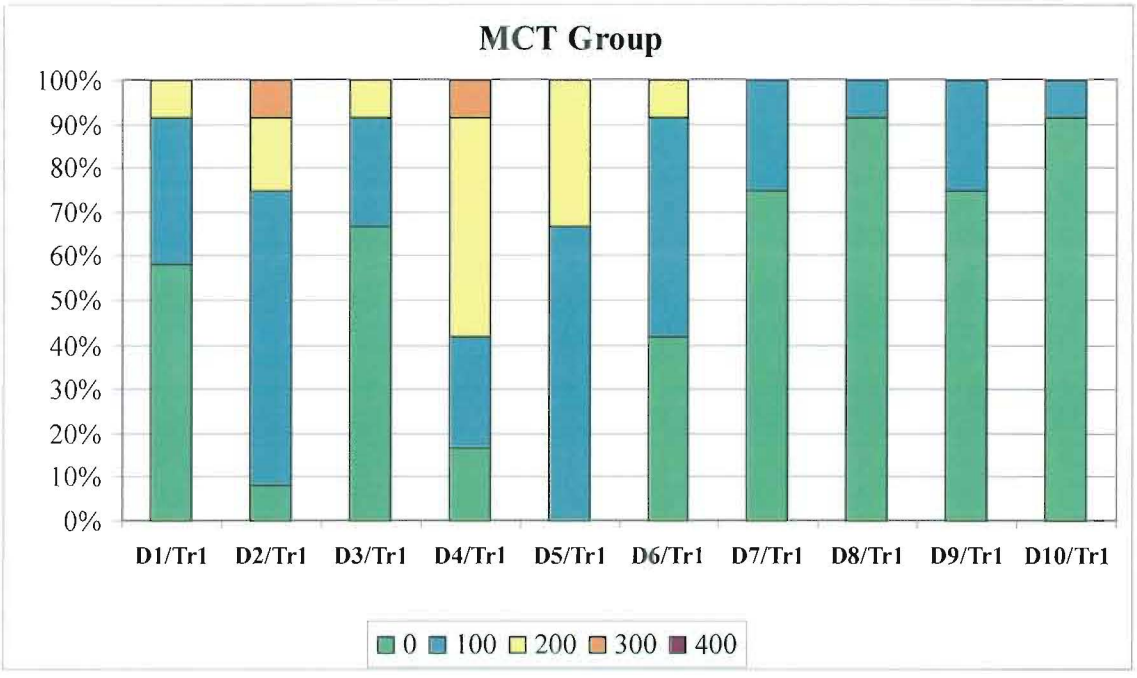

Figure 6: Frequency of different doses of tramadol needed after Total Knee Arthroplasty (TKA) for patients who received MCT and control group during the 10-day observation period

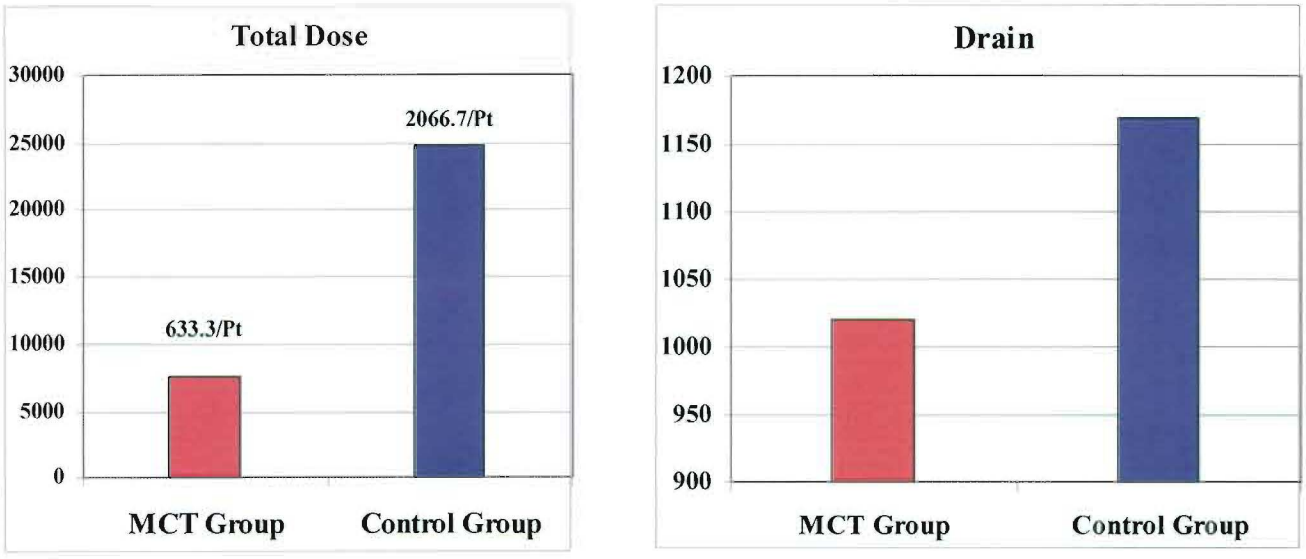

Figure 7: Total dose of tramadol needed during the study period and drain volume in each group

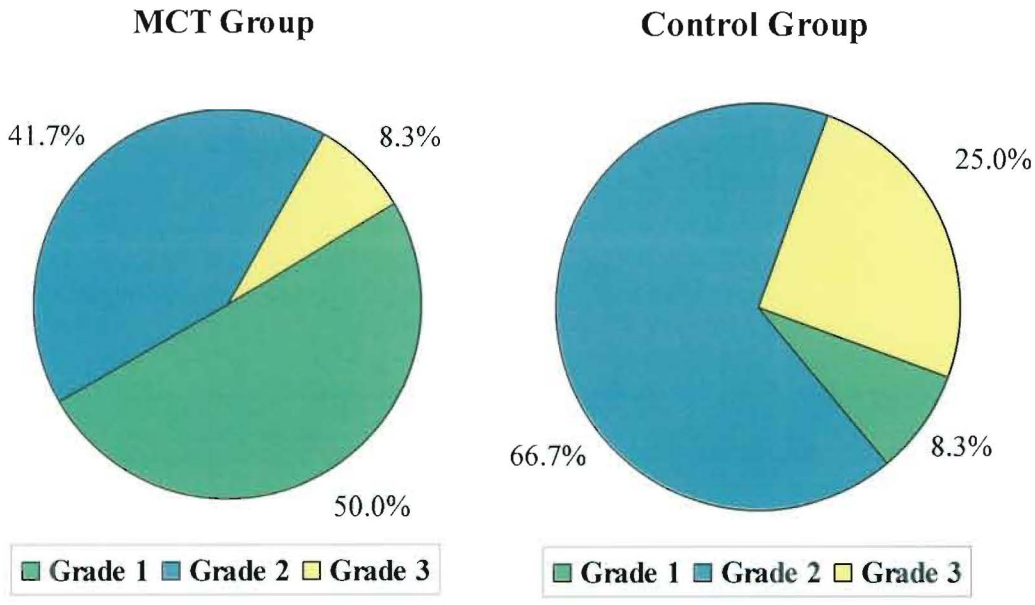

Figure 8: Distribution of grades of wound healing after Total Knee Arthroplasty (TKA) among MCT and control groups

EFFECT OF MICROCURRENT SKIN PATCH ON THE EPIDURAL FENTANYL REQUIREMENTS FOR POST OPERATIVE PAIN RELIEF OF TOTAL HIP ARTHROPLASTY

TAREK M SARHAN*, AND MAHER A DOGHEM*

Abstract

Introduction: Major orthopedic surgery that cause considerable pain like total hip arthroplasty, requires good post operative pain management. Microcurrent therapy (MCT) is a new therapy whereby electric current is provided in literally millionth of an ampere. MCT comes as two self adherent active electrode patches linked by a cable Efficacy of MCT in the management of musculoskeletal pain and enhancement of wound healing has been reported.

Aim of the work: To study the effect of microcurrent therapy (MCT) on the epidural fentanyl requirements and degree of wound healing after total hip arthroplasty.

Materials and Methods: Twenty eight patients undergoing total hip replacement (THR) were randomly allocated into two groups.

Group I: had micro current skin patches (two adhesive electrode) attached above the site of operation in addition to the lumbar epidural catheter. Post operative epidural fentanyl infusion with a syringe pump given at a rate ranged between 25 and 75 microgram per hour to keep visual analogue pain score (VAS) less than 3/10. Group II had only continuous epidural infusion with fentanyl at the same range to keep VAS less than 3/10 without MCT.

Results: There was statistically significant lower mean epidural fentanyl requirement in Group I (23.24 microgram) when compared to Group II (58.36 microgram).

There was 23% incidence of dermatitis in Group I due to application of micro- current skin patch which resolved by treatment.

There was statistically significant higher frequency of grade 1 of wound healing in the microcurrent group (41.3 %) when compared to Group 11 (7.2%). Grade 2 and 3 were more frequent in Group II)

Conclusion: The microcurrent skin therapy lead to reduction in the requirements of the post operative epidural fentanyl with improvement of degrees of wound healing but with considerable incidence of skin dermatitis after total hip arthroplasty.

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Introduction

Major orthopedic surgery that cause considerable pain like total hip arthroplasty requires good post operative pain management. Several techniques have been used for that purpose such as: intermittent injection of systemic opioids, epidural opioids and or local analgesia drugs, non steroidal anti-inflammatory drugs ($NSAID_S$), patients controlled analgesia (PCA) with opioids with different reports of efficacy and adverse effects[1,2,3,4,5].

Non pharmacological treatments and alternative approaches are less widely accepted, they span over physical therapy, cryotherapy, continuous passive motion, transcutaneous electric nerve stimulation (TENS) and patient education, an individualized approach of one or more of the above mentioned approaches[6,7,8,9,10].

Microcurrent therapy (MCT) is a totally new physical treatment method for electrotherapy[11]. It is a therapy used whereby electric current is provided in literally millionth of an ampere. It works on a cellular level to help stimulate the healing process. It is based upon the theory that the body's electrical balance is disrupted when one is injured, so that the natural electrical current of the body changes course. Microcurrent stimulation restores this balance[12].

In fact, microcurrent therapy can relieve pain, stimulate wound healing, help stimulate the regeneration of injured tissue, provide relief to myofascial trigger points, increase protein synthesis, and stimulate lymphatic flow. Microcurrent stimulation is produced in therapy at literally one millionth of an ampere, because this is believed to be the body's own natural current strength. This therefore restores the body's own natural current[11].

When microcurrent stimulation is provided, it cannot be felt, because the sensory receptors are not stimulated. Other electrotherapy pain relief methods, such as TENS, are provided at higher occurrence in milliamps, thereby causing muscle contraction[12].

With microcurrent therapy, ATP production increases by 500%. ATP is the primary molecule our bodies use to produce energy and is found in every cell of the body. In fact, it has been found that ATP production increased fivefold after microcurrent therapy was administered. As stated previously, protein synthesis also increased, and so did amino acid transport[11].

When microcurrent therapy is used to help heal injured tissue, it restores the natural current flow to the tissue. This in turn allows the cells to regain their own natural energy flow. When injury occurs, the area that has been injured has a higher electrical resistance than the surrounding tissue does. This in turn decreases and perhaps even stops electrical flow through the injured area, which impedes the healing process and promotes inflammation. When microcurrent therapy is used, this resistance is reduced, which allows electricity to flow through and therefore restore normal function. This, in turn, helps stimulate natural healing[12].

In addition, microcurrent therapy can be used at specific frequencies for a variety of tissues and conditions. This can often soften tissue and decrease pain, which provides long-lasting pain relief that may even be permanent. This has some promising benefits that may be applicable to current chronic pain conditions as well[13].

MCT comes as a two self adherent active electrode patches linked by a cable, self generate the necessary current of approximately 10 micro amber required for stable galvanism.. The treatment however lasts 100 times longer than usual. Crucial for galvanic treatment is the quantity of charge carries Q (ions), which are being moved in the body tissues in the electrical field between the therapeutic electrodes as a measure of the degree of stimulation of electric active body structures (Gillert), in accordance with the equation for the physiologic galvanization effect:

Q(carrier) = I (current)x t(times).

An equal quantity of ions are moved during the course of 24 to 48 hours treatment with the microcurrent skin patch as with the more usual electrotherapy involving approximately an I (current) of I m A for a t (time) of 15 to 20 minutes[13].

Recent reports on the efficacy of micro current therapy (MCT) in the management of musculoskeletal pain may offer a new non pharmacological approach for post operative pain relief of major orthopedic surgery.

Aim of the work

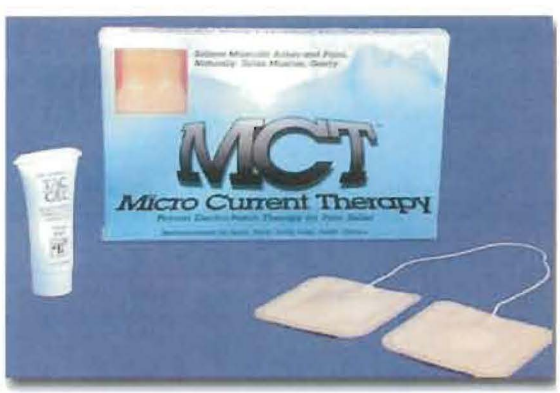
To study the effect of micro current therapy (MCT) on the requirements of epidural fentanyl for post operative pain relief of total hip arthroplasty.

Patients and Methods

This study was a prospective randomized study included 28 patients who underwent total hip replacement (THR). After approval by local Ethical Committee, informed written consent were taken from all patients included in the study, they were randomly allocated into 2 groups of 14 patients each.

Group I: had micro current skin patches (Fig. I) (two adhesive electrode) attached above the site of operation just away from the wound, in addition to the epidural catheter that was inserted at L4-L5 lumbar interspace. Post operative fentanyl infusion was given at a rate ranged between 25 and 75 microgram per hour, using a syringe pump to keep visual analogue pain score (VAS) less than 3/10.

Fig. 1
Micro current skin Patches



Group II. had only continuous epidural infusion with fentanyl at the same rate and range to keep VAS less than 3/10 without MCT.

Measurements

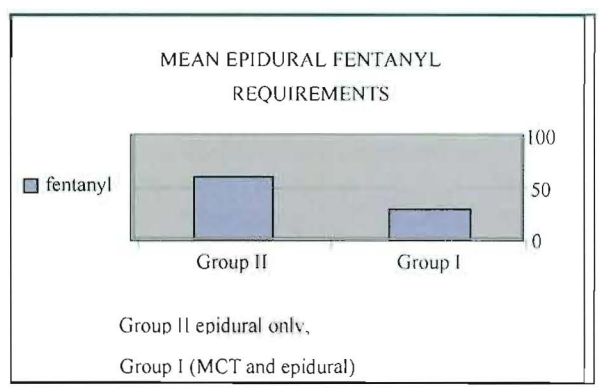
1 -Visual Analogue Scale (VAS) before starting post operative pain treatment and every one hour for the first 36 hours.
2 -The mean dose of epidural fentanyl in both groups after 36 hours of post operative period.
3 Side effects and complications.
4 Degree of wound healing measured at the end of follow up period and categorized into grade 1,2 and 3 (grade 1: dry suture line, no redness around suture line, normal skin texture around suture line, grade 2: wet suture line, no or minimal redness, normal skin, grade 3: wet or draining suture line, redness and surrounding skin changes of edema or bullae).

Results

There was no statistically significant differences on the Visual Analogue Scale (VAS) on both groups at all time of measurements.

There was statiscally significant lower mean epidural fentanyl dose in Group I (micro current skin therapy group) (23.24 microgram) when compared to Group II (58.36 microgram) (Fig. 2).

Fig. 2
Mean post operative epidural fentanyl requirements in both Groups



There was 23% incidence of dermatitis in Group I due to application of micro- current skin patch which resolved by treatment.

There was statistically significant higher frequency of grade 1 of wound healing in the microcurrent Group (41.3 %) when compared to Group 11 (7.2%). Grade 2 and 3 were more frequent in Group 11 (Table 1).

Table 1
Healing in both groups Wound

Grade	MCT	Group II
1	41.3%	7.2%
2	47.7%	58.8%
3	12%	34%

Discussion

Orthopedic procedures such as total hip arthroplasty (THA) is an ongoing challenge regarding post operative pain control, as current pain management techniques often result in undermedication and/or complications[1,2].

The standard approach depends on systemic opioids given in bolus IV or IM or in patient controlled analgesia (PCA), epidural analgesia with narcotics with or without local analgesia and $NSAID_S$.

Non pharmacological methods are less widely accepted in the management of severe pain induced by this group of operations, they include physical therapy, cryotherapy, continuous passive motion (CPM), transcutaneous electric nerve stimulation (TENS) and patient education[8]. Reports on the efficacy of cryotherapy[5,6,7] and TENS[8] are generally disappointing, while the use of CPM to control pain is controversial[9].

Several reports support a favourable effect of MCT as related to pain control and tissue healing, through the modification and recruitment of cell membrane ATP (adenosine triphosphate)[11,12,,14,15,16,17], but this was mostly reported in chronic painful conditions.

Microcurrent stimulation to the body causes radically increased production of adenosine triphosphate (ATP) levels. This allows the body to perform whatever healing process it has undertaken in an accelerated fashion. It may even allow one to get over the proverbial "hump" that was unachievable, due to insufficient ATP concentrations to perform the changes needed.

The result of the present study showed efficacy of MCT patches in reduction of the epidural fenatnyl requirements after THR, demonstrating its efficacy in contribution of post operative pain relief. The present study shows that reduction of analgesic dose post operatively goes with that of El-Husseini et al[18] during their study of the effect of microcurrent skin patches (MCT) for post operative pain relief in total knee arthroplasty which demonstrated reduction in the post operative tramadol dose with MCT patches.

Result of our study showed marked acceleration of wound healing with the microcurrent therapy which goes also with that of El-Husseini et al[18].

Microcurrent therapy, which is used from one to 600 uA clinically, is the modality of choice for increased tissue healing. Research and clinical trials[19] have shown that the microcurrent stimulation, there is a 40-50% reduction in healing time of ulcers and sprain/strains ; fracture heal faster and stronger; that bad scarring (keloid scars) remodel to become a healthier, stronger scar. Other ATP related microcurrent stimulatory effects include decrease inflammation ,edema and swelling[20].

Conclusion

The microcurrent skin therapy lead to reduction in the requirements of the post operative epidural fentanyl with improvement of degrees of wound healing but with considerable incidence of skin dermatitis.

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Case Studies

Newmark, Inc

NOT FOR PUBLIC RELEASE

MCT Patch Case Studies

Effectiveness with ailments of the Knee

Case 1.

A 70-year-old male suffering from severe pain from knee replacement surgery. Prior to treatment using Newmark MCT patches, treatments with an anti-inflammatory provided temporary, short-term relief. Patient's treatment consisted of 24-hour treatment of 25μA of direct current utilizing Newmark MCT patches placed on the right and left side of knee. After 48 hours of continuous treatment patient experienced a 75% reduction of pain. Subsequent weekly treatments over three months have reduced the level of pain 90%.

Case 2.

A 65-year-old male suffering from chronic knee pain. Prior to treatment using Newmark MCT patches patient was using Celebrex, which gave some relief from the pain. During the four (4) weeks of treatment with Newmark MCT patches the patient discontinued the use of Celebrex and reported that the Newmark MCT offered an equal amount of pain relief, without the side effects associated with Celebrex. Treatment and patch placement was the same as case 1.

Case 3.

A 73-year-old male suffering from chronic knee pain. Prior to treatment using Newmark MCT patches patient was using over-the-counter pain relief medications with some success. Being an avid golfer, this individual seemed to suffer most pain during and immediately following exercise. Treatment consisted of application of Newmark MCT patches several hours prior to any exercise. Patient reported an immediate improvement in mobility and a complete reduction of pain during and after exercise.

Newmark case studies of effectiveness with Chronic Back Pain

Case 4.

A 64-year-old female (Ex-Wimbledon Champion) suffering from chronic back pain linked to years of strenuous exercise associated with tennis. Individual has been under

several treatment protocols ranging from over-the-counter pain relievers to TENS treatment with very little success. Treatment consisted of continuous treatment at 25μA using the Newmark MCT patches periodically for one week and subsequent treatments during and after strenuous exercise. Patches were placed in the small (dimple area) of the lower back. Patient reported a 65% reduction in pain after exercise and continues to improve with additional treatment. Treatment and use have been ongoing for five (5) months.

Case 5.

A 50-year-old female suffering from chronic lower back pain. Patient has had surgery to repair rupture and has suffered from post operative pain for the last five (5) years. Prescription pain relievers have offered only minor relief. Treatment consisted of application of Newmark MCT patches prior to sleep, allowing for treatment of up to eight (8) hours of continuous treatment with very little movement or strenuous activity. After four (4) nights of treatment patient has reported an 80% reduction in pain. After two (2) months of treatment consisting of approximately 36 hours of treatment per week patient reports a 90 to 95% reduction. Treatment has been ongoing for six (6) months. Patch placement was the same as case 4.

Newmark case studies of effectiveness with Chronic Neck Pain

Case 6.

A 35-year-old male suffering from chronic neck pain stemming from an automobile accident. Individual has suffered from chronic pain for five (5) years following the accident. Numerous treatment protocols have been used including Transcutaneous Nerve Stimulation (TENS), physical therapy and various prescription drugs commonly used for pain relief. Individual was treated on a continuous basis for two (2) weeks and subsequently every other day for an additional one (1) month. Early results showed a reduction of approximately 55% while long-term results are approaching 75%. MCT patches were placed on the lower neck area at the intersection of the shoulder and upper back. To date patient has been using Newmark MCT patches for eight (8) months and continues to improve. Recent results have allowed for a reduction of treatment to once or twice weekly for 24 hour periods.

Case 7.

A 60-year-old female suffering from chronic pain stemming from an automobile accident. Individual has been suffering from neck pain for approximately six months following injury. Traditional treatments of pain medication have been unsuccessful. Newmark MCT patches were applied to the lower neck area for 48 hours. Results showed a reduction in pain of 70%. After three (3) weeks of treatment individual reported a reduction of 85%.

Literature Search Report

Efficacy of Microcurrent Therapy in the Treatment of Acute and Chronic Pain

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1. General

This Literature Search Report details published articles using microcurrent levels similar to the NOT FOR PUBLIC RELEASE 7500 microcurrent therapy device for the treatment of pain. . The device is manufactured by Newmark, Inc. of Cheshire, CT and is cleared by the FDA for the intended use to reduce pain in soft tissue by the targeted application of pulsed direct current.

2. Scope of the Literature Search

Method: A literature search using Medline, Cinahl, and Google Scholar was performed. The following search terms with common synonyms were used: *microcurrent, electrical stimulation and pain therapy.* In addition, *microampere, soft tissue, and pain scale* were used to broaden the search. The limits of *English Language* and *humans* were applied when applicable to help focus the search. Articles were screened by title, abstract, and/or review of the full test for relevance

Results: Eight articles were found that addressed the criteria. Two of the articles were studies conducted with the model 7500 MCT device. All studies found microcurrent therapy more efficacious than placebo.

3. Discussion

The available research on the efficacy of microcurrent therapy in reducing pain as compared to placebo is sparse. Two of the studies showed the microcurrent therapy significantly reduced pain as measured against the placebo but one was not more efficacious than the other. Microcurrent therapy is imperceptible to humans because it cannot cause nerves to fire or muscles to contract. The fact that microcurrent therapy is indistinguishable from a placebo treatment makes it an excellent candidate for large RCT's. Such a study would determine the efficacy with certainty and carry considerable weight given the small number of studies performed to date.

4. Conclusions

There is significant evidence to show that microcurrent therapy is more effective in reducing pain than placebo. There are virtually no adverse side effects associated with microcurrent therapy. In the studies reviewed in this analysis most patients received significant benefit from using microcurrent therapy and placebo therapy. The value of this perceived affect should not be discounted, particularly in patients who are resistant to other treatments or who may suffer severe side effects from medications.

SUPPORTING ARTICLES - EFFECTIVENESS OF MICROCURRENT THERAPY

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