Arc4Sports – Microcurrent Analysis : PAIN Section

February 2016

Professor Tim Watson

University of Hertfordshire

Overall :

27 papers were identified which related the use of Microcurrent based therapies to pain relief in a range of healthy and clinical populations

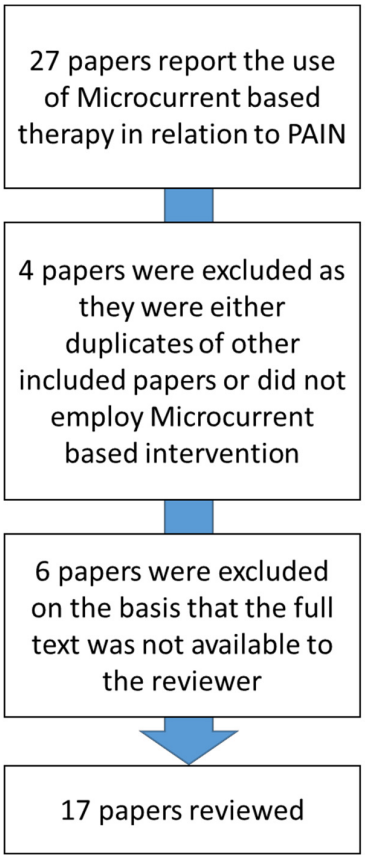
4 papers were excluded (Gabriel et al, 2013; Grief et al 2002; Jeong-Woo et al 2013; Rae Joon et al 2011) for the reason identified in the table below

Paper	Reason for Exclusion
Gabriel et al 2013	PEMF was employed to induce the Microcurrent in the tissue. This was an indirect Microcurrent application
Grief et al 2002	Electrical stimulation was employed in the mA range, and falls outwith the 1mA max taken to represent Microcurrent based therapy
Jeong-Woo et al 2013	This is a duplication of the Lee et al (2011). The reason relates to different database engines using different name based indexing systems
Rae Joon et al 2011	This is a duplication of the Park et al (2011). The reason relates to different database engines using different name based indexing systems

Of the remaining 23 papers, full versions of the paper were not available in n=6 instances

In 4 cases, there was not an abstract available (Boswell et al 1989; Sizer et al 2000; Shafer et al 2001; Katz, 2003) and these were excluded from further analysis

In 2 cases (Hochman 1988; Torres et al 2011), an abstract was available, but the full paper could not be obtained even when attempts were made to contact the authors. The results reported in the abstract were noted, but not included in the full analysis as it was not possible to determine the methodology, detailed results or statistical analysis methodology.



The remaining 17 papers were included in the analysis detailed below.

Of the 17 papers,

RCT	8
Case Studies/Series	3
Cohort Studies	2
Controlled Studies	2
Cross Over study	1
Retrospective analysis	1

The papers were divided into 2 groups based on overall outcome (MCT being determined to be effective / not effective)

MCT determined to be effective

13/17 papers (76%) employing 2335 patients out of 2462 (all trials) (95%)

Of the 2335 patients, 2205 received Microcurrent therapy (94%)

Of the 13 supportive papers, the study types were as follows:

RCT	5
Case Study/Series	3
Cohort Study	2
Controlled Study	2
Retrospective	1

The patient numbers were very heavily skewed by the retrospective analysis (Smith 2001) which reported on returns from 1949 manufacturer questionnaire returns based on device warranty card returns.

<u>Clinical conditions:</u>

The clinical conditions included in the supportive group covered a wide range

- Chronic low back pain (x2)
- Mixed chronic pain syndromes (x2)
- Pain secondary to radiotherapy or cancer surgery (x2)
- Mixed chronic neuromuscular back and neck pain
- Carpal Tunnel
- Diabetic Neuropathy
- Chronic periodontitis
- Orthodontic pain
- Groin strain

Stimulation Parameters

	From Reported Studies		Arc4Sports Device
Intensity	Range 25 - 600µA (4 papers parameter not reported)		50 - 400 µA
Pulsing (frequency)	Range 0.3 – 300Hz 1 report at 71.5kHz 6 papers provide no specific data		0 – 300Hz Predominantly 50-75Hz
Waveform	Not reported in 10 papers 1 reports biphasic 1 reports square wave 1 reports pulsed DC		Uni and Bipolar pulses
Total Treatment Time	Not reported, or reported as variable in 5 papers Reported Range: 12 minutes – 120 hours		Recommend 3 hours daily Total suggested at 60 – 130 hours

Adverse effects reporting

No comment was made in 7 out of 13 papers

In 5/13 papers, it was specifically reported that there were no adverse events or responses

In 1 paper, it was reported that 6/10 patients reported skin irritation or itch (but this study involved patients wearing the electrodes 24/7 for 5 days)

MCT determined not to be effective

4/17 papers (24%) employing 127 patients out of 2462 (all trials) (5%)

Of the 127 patients, 90 received Microcurrent therapy (71%)

Of the 4 unsupportive papers, the study types were as follows:

RCT	3
Crossover	1

Clinical Conditions:

- Diabetic neuropathy
- Cold induced pain in healthy volunteers
- Induced skin inflammation (ultra violet)
- Mixed chronic musculoskeletal pain

Stimulation Parameters

	From Reported Studies		Arce4Sports Device
Intensity	Range 10 - 600µA		50 - 400 µA
Pulsing (frequency)	Range 0.5 – 100Hz		0 – 300Hz Predominantly 50-75Hz
Waveform	Not reported in 1 paper 1 reports bipolar 1 reports modified square wave with polarity reversal 1 reports rectangular monophasic		Uni and Bipolar pulses
Total Treatment Time	1 paper time not specified Reported Range: 20 min – 6hrs		Recommend 3 hours daily Total suggested at 60 – 130 hours

Adverse effects reporting

No comment was made in 3 out of 4 papers

In 1 paper, it was specifically reported that there were no adverse events or rasponses

Reviewer Commentary

The majority of the papers in the pain group (13/17 papers involving 2335 out of 2462 patients) report that Microcurrent based therapy has a significant beneficial effect in terms of pain relief. The papers providing supportive evidence are all clinical papers (2 of the 4 studies which fail to demonstrate benefit involve healthy volunteers in whom pain was induced).

There does not appear to be any obvious difference in the stimulation parameters employed in the effective vs the non-effective outcome studies, including Microcurrent intensity or pulsing, waveform. The most obvious (potential) difference between the effective and the ineffective Microcurrent treatments relates to the treatment times. Those in the ineffective group appear to have employed significantly shorter treatment times and total treatment hours than those in the effective group. The Arce4Sports device is recommended for use with treatment times and total treatment hours that fall within the 'effective' range. The ranges associated with these parameters are wide, and whilst it is likely that there are parameters which are more and less effective, the pain related research considered here does not appear to have identified any obvious therapeutic 'windows'. The reviewer is aware that research in this specific area is being undertaken at the present time.

The stimulation parameters are comparable with those employed by the Arce4Sports Device in that the Arce4Sports parameters fall within the range of effective parameters reported in this review.

The strength (quality) of some studies included is weak. Partly this relates to an historical / methodological shift. There are RCT's in both supportive and non supportive groups. The biggest factor which skews the group numbers is the inclusion of a retrospective review in the supportive group. The review (Smith, 2001) reports 93% of patients contacted following machine purchase indicate significant pain reduction following a minimum of 3 weeks use. This is informative, but a low quality retrospective analysis of manufacturer collated data.

There are no adverse events / reports other than skin irritation and/or itch in 6 patients involved in 1 trial. It is noteworthy that this trial involved the application of the adhesive patches 24 hours a day for 5 days, and therefore is quite unlike all the other trials considered in this section. From the available data (in both effective and non-effective groups) there are no reports of any serious adverse event, and thus the risks associated with Microcurrent use in the clinical environment appears to be very low (which would be consistent with predictions given the low magnitude of the applied current).

Overall, in relation to clinical pain issues, there is more supportive published evidence than evidence suggesting an ineffective treatment. Adverse events/effects reporting identifies no significant issues or risks. On balance, Microcurrent based therapy has supportive evidence of effectiveness across a wide range of clinical pain presentations. Optimal treatment parameters have yet to be determined.

References

Atkinson, M. Pain Ease microcurrent therapy treatment in subjects with period pain (dysmenorrhoea).

Bauer, W. (1983). "Electrical treatment of severe head and neck cancer pain." Arch Otolaryngol 109(6): 382-383.

Boswell, N. (1989). "Neuroelectric therapy eliminates xerostomia during radiotherapy-a case history." Med Electron 115: 105-107.

Gabriel, A., et al. (2013). "The use of Targeted MicroCurrent Therapy in postoperative pain management." Plast Surg Nurs 33(1): 6-8; quiz 9-10.

Gossrau, G., et al. (2011). "Microcurrent transcutaneous electric nerve stimulation in painful diabetic neuropathy: a randomized placebo-controlled study." Pain Med 12(6): 953-960.

Greif, R., et al. (2002). "Transcutaneous Electrical Stimulation of an Auricular Acupuncture Point Decreases Anesthetic Requirement." Anesthesiology 96(2): 306-312.

Hochman, R. (1988). "Neurotransmitter modulator (TENS) for control of dental operative pain." The Journal of the American Dental Association 116(2): 208-212.

Jeong-Woo, L., et al. (2011). "The Effects of Microcurrents on Inflammatory Reaction Induced by Ultraviolet Irradiation." Journal of Physical Therapy Science 23(4): 693-696.

Johnson, M. I., et al. (1997). "An examination of the analgesic effects of microcurrent electrical stimulation (MES) on cold-induced pain in healthy subjects." Physiotherapy Theory and Practice 13(4): 293-301.

Katz, M. A. (2003). "Treating lower back pain after back surgery: a combination of dry needle injection (acupuncture) and microcurrent stimulation." Pain-Clin---Bernardsville. 5(6): 23.

Koopman, J. S., et al. (2009). "Efficacy of microcurrent therapy in the treatment of chronic nonspecific back pain: a pilot study." Clin J Pain 25(6): 495-499.

Lee, J. W., et al. (2011). "The effects of microcurrents on inflammatory reaction induced by ultraviolet irradiation." Journal of Physical Therapy Science 23(4): 693-696.

Lennox, A. J., et al. (2002). "Pilot study of impedance-controlled microcurrent therapy for managing radiation-induced fibrosis in head-and-neck cancer patients." Int J Radiat Oncol Biol Phys 54(1): 23-34.

Lerner, F. N., et al. (1981). "A double blind comparative study of micro-stimulation and placebo effect in short term treatment of the chronic back pain patient." ACA Journal of Chiropractic 15: 101-106.

McMakin, C. R. (2004). "Microcurrent therapy: a novel treatment method for chronic low back myofascial pain." Journal of Bodywork & Movement Therapies 8(2): 143-153.

Naeser, M. A., et al. (2002). "Carpal tunnel syndrome pain treated with low-level laser and microamperes transcutaneous electric nerve stimulation: A controlled study." Arch Phys Med Rehabil 83(7): 978-988.

Noto, K., et al. (2009). "Comparative study of micro-amperage neural stimulation and conventional physical therapy modalities." online access.

Park, R. J., et al. (2011). "The effect of microcurrent electrical stimulation on the foot blood circulation and pain of diabetic neuropathy." Journal of Physical Therapy Science 23(3): 515-518.

Puhar, I., et al. (2011). "Efficacy of electrical neuromuscular stimulation in the treatment of chronic periodontitis." Journal of Periodontal and Implant Science 41(3): 117-122.

Rae Joon, P., et al. (2011). "The Effect of Microcurrent Electrical Stimulation on the Foot Blood Circulation and Pain of Diabetic Neuropathy." Journal of Physical Therapy Science 23(3): 515-518.

Roth, P. M., et al. (1986). "Effect of transcutaneous electrical nerve stimulation for controlling pain associated with orthodontic tooth movement." Am J Orthod Dentofacial Orthop 90(2): 132-138.

Shafer, J. P., et al. (2001). "Pilot study of impedance-controlled microcurrent therapy for managing xerostomia in head and neck cancer patients." Radiology 221: 334-335.

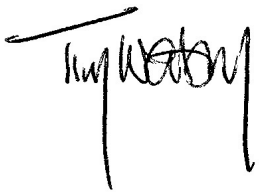
Sizer, P., et al. (2000). The effect of microcurrent stimulation on postoperative pain after patellar tendon-bone anterior cruciate ligament reconstruction. American Physical Therapy Association. Indianapolis, Indiana.

Smith, R. B. (2001). "Is microcurrent stimulation effective in pain management? An additional perspective." American Journal of Pain Management 11(2): 64-68.

Tan, G., et al. (2000). "Electromedicine. Efficacy of microcurrent electrical stimulation on pain severity, psychological distress, and disability." American Journal of Pain Management 10(1): 35-44.

Torres, R., et al. (2011). "Decrease in cervical pain using microcurrents." Disminución del dolor en cervicalgias mediante la aplicación de microcorrientes 14(2): 48-52.

Yuill, E. A., et al. (2012). "Conservative care of sports hernias within soccer players: a case series." J Bodyw Mov Ther 16(4): 540-548.



Professor Tim Watson

9th February 2016