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

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

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.

27 papers report the use of Microcurrent based therapy in relation to PAIN

4 papers were excluded as they were either duplicates of other included papers or did not employ Microcurrent based intervention

6 papers were excluded on the basis that the full text was not available to the reviewer

17 papers reviewed
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)

<table>
<thead>
<tr>
<th>MCT determined to be effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>13/17 papers (76%) employing 2335 patients out of 2462 (all trials) (95%)</td>
</tr>
<tr>
<td>Of the 2335 patients, 2205 received Microcurrent therapy (94%)</td>
</tr>
<tr>
<td>Of the 13 supportive papers, the study types were as follows:</td>
</tr>
<tr>
<td>RCT 5</td>
</tr>
<tr>
<td>Case Study/Series 3</td>
</tr>
<tr>
<td>Cohort Study 2</td>
</tr>
<tr>
<td>Controlled Study 2</td>
</tr>
<tr>
<td>Retrospective 1</td>
</tr>
</tbody>
</table>

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.

**Clinical conditions:**

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

<table>
<thead>
<tr>
<th></th>
<th>From Reported Studies</th>
<th>Arce4Sports Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intensity</strong></td>
<td>Range 25 - 600μA (4 papers parameter not reported)</td>
<td>50 - 400 μA</td>
</tr>
<tr>
<td><strong>Pulsing (frequency)</strong></td>
<td>Range 0.3 – 300Hz 1 report at 71.5kHz 6 papers provide no specific data</td>
<td>0 – 300Hz Predominantly 50-75Hz</td>
</tr>
<tr>
<td><strong>Waveform</strong></td>
<td>Not reported in 10 papers 1 reports biphasic 1 reports square wave 1 reports pulsed DC</td>
<td>Uni and Bipolar pulses</td>
</tr>
<tr>
<td><strong>Total Treatment Time</strong></td>
<td>Not reported, or reported as variable in 5 papers Reported Range: 12 minutes – 120 hours</td>
<td>Recommend 3 hours daily Total suggested at 60 – 130 hours</td>
</tr>
</tbody>
</table>

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

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

**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 responses

**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 (dysmenorrhea).


Professor Tim Watson
9th February 2016