

## Arc4Sports – Microcurrent Analysis : REPAIR Section

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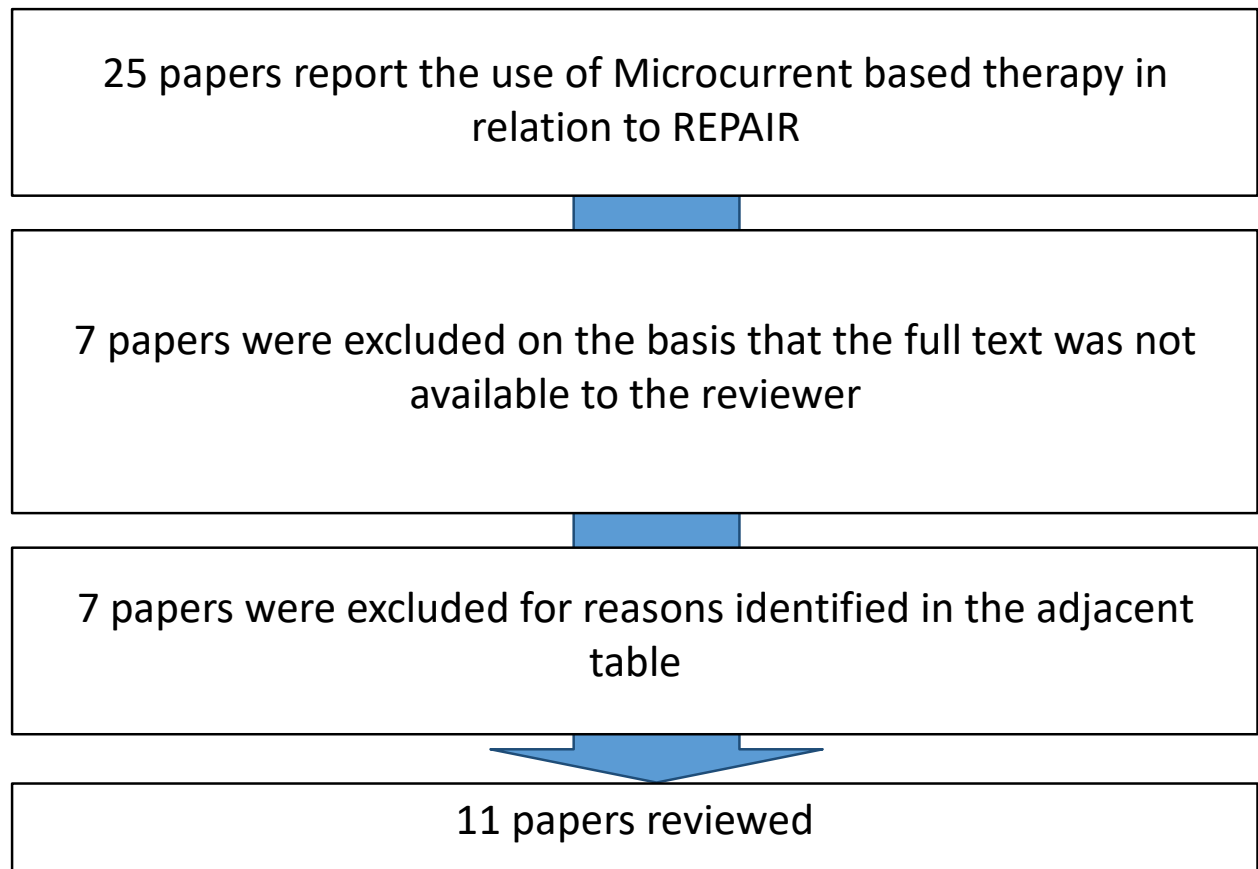
### Overall :

**25 papers** were identified which related the use of Microcurrent based therapies to have an effect on tissue repair / recovery in a range of healthy and clinical populations

**7 papers** were excluded as it was not possible to access the full paper in some cases even after contacting the author(s) : (Aliyev 2010; Aliyev and Geiger 2012; Bertolucci and Grey 1995; Lee et al 2006; Ohno 1982; Park et al 2006; Paul et al 2006)

**7 papers** were excluded for the reasons identified in the table below:

Paper	Reason for Exclusion
Jeong Woo et al 2011	This is a duplicate reference for Lee et al (2011) which is included in the main analysis
McMakin et al 2005	This paper was actually concerned with the treatment of fibromyalgia rather than post injury
Naeser et al 2002	This study did employ Microcurrent therapy but was primarily concerned with pain and nerve conduction issues rather than repair per se
Pajaczkowski 2007	Whilst Microcurrent was included as a treatment in this case study, no details were provided with regards treatment settings, machine or any other pertinent parameters
Perry et al 2010	This study employed a biofeedback based Microcurrent system (Fenzian) which is not equivalent to standard Microcurrent as employed in this analysis
Poltawski 2010	This is a PhD study, the main results of which are included in Poltawski et al 2012 and would constitute 'double counting' if included
Poltawski and Watson 2011	This was a conference poster and (as above). The salient data in included in Poltawski et al (2012) and would constitute 'double counting' if included



The remaining 11 papers were included in the analysis detailed below.

RCT	7
Experimental, not controlled	2
Case Studies/Series	1
Comparative study	1

A total of 379 patients were involved in these trials with 251/379 (66%) being exposed to Microcurrent therapy.

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

**MCT determined to be effective**

10/11 papers (91%) employing 363 patients out of 379 (all trials) (96%)

Of the 363 patients, 243 received Microcurrent therapy (67%)

Clinical conditions:

The clinical conditions included in the supportive group (10 papers) covered a wide range

- Tennis Elbow (x2)
- Total Knee Arthroplasty (post operative) x 2
- Achilles Tendinopathy
- Groin strain
- Head/Neck fibrosis
- Inflammation (lab induced)
- Plantar Fasciitis
- Temporomandibular Disorder

Stimulation Parameters

	<b>From Reported Studies</b>		<b>Arc4Sports Device</b>
<b>Intensity</b>	Range 25 - 600µA (reported in all papers)		50 - 400 µA
<b>Pulsing (frequency)</b>	Range 0.3 – 400Hz 3 papers provide no specific data		0 – 300Hz Predominantly 50-75Hz
<b>Waveform</b>	Not reported in 7 papers 2 report monophasic square wave 1 reports monophasic rectangular with polarity reversal every 1 sec		Uni and Bipolar pulses
<b>Total Treatment Time</b>	Individual treatment session times vary from 20 min to continuous (24/7) Total treatment time ranges from 2 – 240 hours		Recommend 3 hours daily Total suggested at 60 – 130 hours

Adverse effects reporting

No comment was made in 7 out of 10 papers

In 3/10 papers, it was specifically reported that there were no adverse events or responses of significance. One patient in the Poltawski et al (2012) paper identified as machine fault, but this was not counted here as an adverse effect or event.

In no papers were clinically significant adverse events reported

**MCT determined not to be effective**

1/11 papers (9%) employing 16 patients out of 379 (all trials) (4%)

Of the 16 patients, 8 received Microcurrent therapy (50%)

The unsupportive paper was an RCT study

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Clinical Conditions:

- Tennis Elbow

Stimulation Parameters

	<b>From Reported Study</b>		<b>Arc4Sports Device</b>
<b>Intensity</b>	Authors do not identify current intensity		50 - 400 $\mu$ A
<b>Pulsing (frequency)</b>	Auto vary 0.3 – 300Hz		0 – 300Hz Predominantly 50-75Hz
<b>Waveform</b>	Reports square wave but does not identify whether monophasic or biphasic		Uni and Bipolar pulses
<b>Total Treatment Time</b>	Difficult to identify total treatment time, but individual sessions were for 40 minutes		Recommend 3 hours daily Total suggested at 60 – 130 hours

Adverse effects reporting

No comment was made in this paper

**Reviewer Commentary**

The majority of the papers in the pain group (10/11 papers involving 363 out of 379 patients) report that Microcurrent based therapy has a significant beneficial effect in terms of enhanced healing or repair of damaged tissue. Nine of the 10 papers providing supportive evidence are clinical papers (the one paper failing to provide supportive evidence was a clinical study). One paper in the supportive group involved a laboratory study in which an inflammatory response was instigated with an ultraviolet light exposure which was subsequently treated with Microcurrent therapy. This was carried out in otherwise healthy volunteers.

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, pulsing, waveform

or treatment times, though the treatment times in the less effective studies appear to be shorter, and total treatment hourage is possibly lower. The ranges associated with these parameters are wide, and whilst it is likely that there are parameters which are more and less effective, the repair 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 Arc4Sports Device in that the Arc4Sports parameters fall within the range of effective parameters reported in this review.

The strength (quality) of some studies included is weak though with 7/10 studies in the 'supportive' group being of an RCT design, there is a skew towards the higher quality studies in the repair section compared with the pain section.

There is a considerable range of clinical presentations included in this grouping, with Tennis elbow and post operative knee arthroplasty having 2 studies each. All 11 papers in this group do have common ground in that there is some tissue damage and the studies evaluated change in clinical status beyond pain.

The range of treatment protocols is extensive with (effective) treatments lasting as little as 20 minutes daily through to 24 hours a day. The frequencies employed in some studies are fixed (at 10 or 30Hz for example) whilst a number of studies used machines which automatically vary both the intensity and the frequency of the applied current. Given the ranges utilised in these (effective) studies are broad, it is likely that there are optimal, or more effective elements which have yet to be identified. It is anticipated that further research will enable these optimal treatment 'windows' to be more clearly identified.

There are no adverse events / reports other than minor skin irritation. The trial comparing different Microcurrent protocols (Poltawski et al 2012) did identify a machine malfunction which one patient reported. This is not an 'adverse effect' of treatment per se. 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 healing/repair 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 injury and repair presentations. Optimal treatment parameters have yet to be determined.

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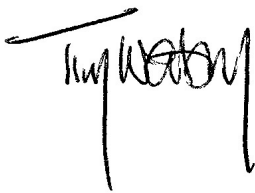
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A handwritten signature in black ink, appearing to read 'Tim Watson', with a horizontal line above the first few letters.

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9<sup>th</sup> February 2016