MICROCURRENT TREATMENT OF CHRONIC TENNIS ELBOW – AN EXPLORATORY STUDY

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Summary of investigation

Two studies were conducted to investigate the effects of microcurrent on signs and symptoms of chronic tennis elbow. In each study, two forms of treatment were compared through a randomised or partially-randomised parallel arm clinical trial methodology. The first study used one device to deliver the same form of microcurrent but two different current amplitudes; the second study involved two devices delivering microcurrent that differed on several parameters. Treatment was applied at home by the patient over three weeks. Patients had symptoms of tennis elbow for at least three months, and were diagnosed with tendinopathy on the basis of clinical tests and sonographic examination. Outcomes were pain-free grip strength, the Patient-Rated Tennis Elbow Evaluation of pain and function, patient-rate global impression of change and sonographic features. These were measured at baseline, end of treatment, and at 3 weeks and 3 months after treatment. Separate analyses were conducted for each study, but data were also compared between studies as all groups did not differ significantly on main prognostic indicators.

Sixty-two people were recruited and divided amongst the four comparison groups, and 61 completed treatment. Statistical tests suggested that 50µA microcurrent was more effective than 500µA. Statistically non-significant trends suggested that a monophasic, low frequency form of microcurrent was the produced the best outcomes, and there is limited evidence to suggest that extending treatment duration may improve outcomes. The limited sample size is likely to have been a factor in the non-significance of statistical test results. Two significant adverse events were recorded using one device. Comparisons of outcomes with data obtained from other studies suggests that these forms of microcurrent treatment may be effective in the treatment of less severe cases of chronic tennis elbow. Further analysis of data is planned.

INTRODUCTION

Microcurrent therapy (MCT) involves the direct application of electric currents in the microampere (µA) range to the body for therapeutic purposes. There is a substantial body of evidence to suggest that it can promote healing in various types of tissue, particularly where natural repair processes are dysfunctional[1]. Most of the clinical trial evidence is concerned with bone and skin tissue, however, and there is very little data specifically relating to soft connective tissues such as tendons. The capacity of MCT to treat tendinopathies is of interest because these are relatively common, prone to chronicity, and many existing

therapies have only limited success in their treatment[2, 3]. Three trials of MCT with tendinopathy have provided mixed results[4-6] but they are difficult to compare because they use very different microcurrent parameters. In fact, reviews of the effectiveness of MCT for a variety of conditions have been unable to synthesise evidence effectively either because the types of microcurrent used in studies are very different, or because they are poorly reported[7-9]. Hence, there is little consensus over which microcurrent parameters are likely to be the most beneficial, and there is a need to investigate the relative effectiveness of different types of MCT for particular conditions.

A preliminary survey amongst physiotherapists[10] concluded that tennis elbow, or lateral elbow tendinopathy, was particularly problematic in terms of prevalence, impact and resistance to treatment, so this was chosen as the condition to treat in this investigation. A variety of proprietary microcurrent devices are available, many claiming to promote healing and/or reduce symptoms in musculoskeletal disorders, including the tendinopathies. A number of these were selected for use in this investigation. The choice was based on their capacity to deliver microcurrent parameters that approximate those found effective in studies with other tissue types, and on their portability and ease of use by patients. Parameters such as current intensity, waveform and treatment duration varied substantially between them. The variety of waveforms used in published studies is wide, and little is known about much this influences effectiveness: constant direct current, varying monophasic and biphasic waveforms all appear capable of producing produced beneficial effects. Current intensity and treatment duration appear to be critical variables, however: currents in the range of a few tens to a few hundred μA, and durations of at least tens of hours, appear most beneficial. The aim of this study was to investigate the effects of MCT on chronic tennis elbow, and whether effects depend on the parameters used. Since microcurrent appears capable of promoting tissue healing in some tissue forms, the impact of the treatment both on the signs and symptoms of tennis elbow, and on the status of the tendon itself, was considered.

METHODS AND MATERIALS

A prospective randomised comparative clinical trial design was selected for the investigation. Since the main focus was to compare the effects of different microcurrent parameters, a no-treatment or placebo treatment group was not used. This maximised the sample size available for each study group, so increasing the chances of detecting significant differences between them. The data could then be used to inform the protocol and sample size calculations for a full randomised controlled trial at a later date.

Participants

Participants were recruited by publicity in the investigators' university, in local sports clubs and in local media. Expressions of interest were sought from people with typical symptoms of tennis elbow that had been present for at least three months. Respondents were sent an information sheet about the study and asked to complete a preliminary screening questionnaire. Those appearing to meet the eligibility criteria were invited to an initial assessment where they provided informed written consent to participate and, if suitable, began treatment.

Included participants were over 18 years old, with lateral elbow pain exacerbated by gripping or twisting movement for at least 3 months, and diagnosed with the condition on assessment. Diagnosis required positive findings from both clinical tests and sonographic examination of the common extensor tendon. Clinical tests were pain on palpation at the lateral epicondyle, and pain on resisted wrist extension, middle finger extension or a chair lift test. Sonographic signs were tendon thickening, hypoechoic patches, fibrillar disruption, calcification and hyperaemia. Observation of any of these features was taken to indicate the presence of tendinopathy. Sonography was used for differential diagnosis, since clinical tests are of unproven sensitivity and specificity. Those receiving some other form of treatment currently or within the previous month were excluded. Nerve entrapment in the cervical spine or upper limb can contribute to the symptoms of tennis elbow and so screening tests were included in the assessment, but their presence was not an exclusion criterion so long as there were sonographic signs of tendinopathy.

During initial assessment information was sought from the participant on the history of the problem, demographic, lifestyle and medical data that might have a bearing on its development and prognosis, and a description of any previous treatment received. In addition to the physical tests described, the neck and upper limbs were screened for restricted movement, muscle weakness and mechanical problems with the elbow.

Treatment protocols

Because of uncertainties about the numbers that could be recruited, two separate trials were conducted sequentially using similar protocols: one used the same device delivering the same form of microcurrent but at two different current intensities; the other used two devices delivered different forms of microcurrent and different current intensities.

In the first study, participants were assigned to treatment group according to a predetermined computer-generated block randomisation sequence to ensure approximately equal group sizes. The assessor was not blinded to the sequence but assigned each participant as they entered the trial after initial assessment. Participants continued to be assigned up to a maximum of 15 in each group, allowing for attrition down to 12, which has been recommended as a minimum group size for pilot studies[11]. Once this sample size was reached, induction to this study closed and the second study began. Random assignment was also planned for this study, but the late arrival of a set of microcurrent devices meant that randomisation could only be applied after eight participants had already begun treatment using the other device. Hence there was only partial randomisation of assignment in the second study. Since there was no placebo group, and the microcurrent device look physically very different, neither participants nor assessor were blinded to the form of treatment received. However, sonographic ratings used in the data analysis were made with the assessor using recorded images and blind to clinical findings.

The parameters of microcurrent used in the studies are summarised in Table 1. Devices A and C were current regulated, so that the output voltage was automatically adjusted to maintain the nominal current if circuit impedance changed during treatment. Device B did not have this feature, so the actual current is likely to have differed from the nominal. The waveforms of the devices differed significantly, with two being biphasic and one monophasic. All were programmed to switch off after a predetermined time, but treatment times were maximised where possible. Treatment was once daily for three weeks except for

Device C, whose supplier requested a specific pattern of application that varied from week to week.

Table 1: parameters of microcurrent used in studies

	Study 1		Study 2	
Device	**A1**	**A2**	**B**	**C**
current amplitude	50µA current regulated	500µA current regulated	Nominal 25µA current not regulated	50-500µA current regulated
Waveform	Monophasic square-wave. Trains of 8 pulses of duration 1-3 ms, inter-pulse interval 5-10 ms, equivalent to frequency range 75-160 Hz.	Monophasic square-wave. Trains of 8 pulses of duration 1-3 ms, inter-pulse interval 5-10 ms, equivalent to frequency range 75-160 Hz.	Biphasic square-wave Frequency modulated 4000-12000Hz. No pulsing.	Biphasic square-wave Amplitude stepped up and down in 50µA increments every 0.1s Frequency stepped up and down 10-900Hz range in 50Hz increments every 0.1s
Treatment duration	99 minutes	99 minutes	6 hours	30 minutes
Protocol	Once daily for 3 weeks	Once daily for 3 weeks	Once daily for 3 weeks	Week 1: 3 treatments /day for 5 days; week 2: 2 treatments /day for 5 days; week 3: 1 treatment /day for 5 days;
Total treatment time	34.65 hours	34.65 hours	189 hours	15 hours

The devices varied in size. The smaller ones (groups C and D) were taped to the arm and held in place with tubigrip; the larger one (groups A1 and 2) was either carried in the pocket or left on a surface when the patient was stationary. The current reached the tissue via two adhesive electrodes approximately 16cm^2 in surface area (provided by the supplier varying between devices). One was applied directly over the common extensor tendon, the other affixed to the posterior elbow, just proximal to the olecranon. With Device A, the "active" electrode was placed over the tendon; with the other devices, the electrodes were interchangeable. The skin was pre-cleaned with an alcohol swab in all cases, and in the second study participants were also asked to abrade the skin lightly with sandpaper to remove the top layer of epidermis and so aid electrical contact.

Participants were individually shown where and how to apply the electrodes and how to operate the microcurrent device assigned. Devices B and C only required a button to be depressed to commence treatment, by Device A required a sequence of button pressing. This was rehearsed with each person, and written instructions were provided to all participants. Treatments did not have to be applied at the same time each day, but where more than one treatment occurred in a day (with device C) participants were instructed to leave a gap of "several hours" between each treatment. A printed diary was provided for participants to record whether and when treatment was applied, and any adverse or notable events they noticed.

Participants were asked not to use any other form of treatment for their tennis elbow during the trial, apart from pain killers and a tennis elbow brace. If participants already had

a brace, its continued use was encouraged during activities likely to stress the tendon. All were asked to avoid use of painkillers and heavy upper limb activity on assessment days, so as not to interfere with pain-free grip strength measurements. At subsequent assessments, questions were asked to ascertain compliance with these rules. Participants were not forbidden from engaging in heavy upper limb activities, at work or in recreation, although education and advice on activity modification was provided.

Outcome measures

Several measures were used to track changes in the condition. These were:

- Pain free grip strength (PFGS - expressed as a ratio of maximum grip strength on the unaffected side);
- Pain and functional limitation as indicated by the Patient-rated Tennis Elbow Evaluation (PRTEE), a questionnaire developed specifically for use with this disorder;
- A patient-rated Global Change Score (GCS) by which the participant rated change in the overall status of the condition over time; a successful outcome was defined as a global change score ≥ 2
- Sonographic evaluation of the common extensor tendon and lateral epicondyle, using a numerical rating scale to estimate the extent of abnormality in the tendon and the degree of hyperaemia.

In addition, the occurrence of any adverse events was recorded, along with participant impression of the treatment in terms of ease of use, convenience and acceptability.

All assessments were carried out by the same person, a registered physiotherapist who had received additional sonography training specifically for tennis elbow assessment. The reliability of sonography was evaluated by comparing ratings provided by the physiotherapist with those obtained from a musculoskeletal radiologist using recorded movie clips from 20 bilateral examinations. Intra-rater reliability for diagnosis of tendinopathy was very good (ICC>0.80), and for rating of hypoechoic areas, calcification, overall greyscale abnormality and hyperaemia was good to excellent (ICC 0.72-0.97), but was poor for tendon thickening and fibrillar disruption (0.46 and 0.35 respectively). Intra-rater reliability (important for longitudinal studies where all assessments are conducted by the same person) was higher for all measures, but still only moderate for tendon thickening and fibrillar disruption. The validity of the grip strength and questionnaire for assessment of tennis elbow has been established by a variety of studies, as has their reliability. Additional reliability testing of the dynamometer and protocol used for grip strength measurement in this study was carried out, and test-retest reliability of the grip strength ratio was found to be excellent (ICC>0.90).

Assessments were carried out at baseline, after the course of treatment and at 3 weeks and 3 months post-treatment. A longer follow-up would be desirable, but was not feasible within this investigation.

Data analysis

Raw data was entered on a spreadsheet programme to enable initial collation of quantitative and qualitative findings, calculation of ratios and normalised values where appropriate. Descriptive statistics were calculated for each group, enabling outliers and possible data-entry errors to be identified, and to check whether parametric tests could be applied. Where appropriate, non-parametric tests were selected for subsequent analysis. Significance was set to $p<0.05$ for all inferential tests, which were conducted using SPSS 17.

Independent samples t-tests or Kruskall-Wallis tests were used to check for significant differences between groups on several variables that might have an influence on outcomes: age, sex, duration of symptoms, previous episodes, whether the dominant arm was affected, and baseline severity. A repeated measures analysis of variance was then conducted to test for differences over time within and between treatment groups in each study. Where appropriate, pot-hoc tests were applied to identify significant changes.

Any missing data in the PRTEE questionnaire was imputed using the rules provided by questionnaire originators. Missing scores on any other measure were imputed for individuals by substitution of their previous score, making a conservative assumption of no change in dependent variables.

RESULTS

After screening by emailed or postal questionnaire, a total of 73 people were invited to initial assessment. Twelve were excluded due to not meeting eligibility criteria, 31 began treatment in the first study and 30 in the second. A flow chart for the studies is presented in Figure 1,

Inspection of diaries suggested that all participants completed the allotted number of treatments, apart from two who missed one treatment and one who added a treatment by mistake. There were 15 instances of treatments being missed for a day or more during the three weeks. In these situations more treatments were added to the end of the course to bring the total up to the required 21.

One-way ANOVAs for all parametric data, and Kruskall-Wallis tests for categorical, ordinal and non-parametric data, showed that there were no significant differences between any of the groups at baseline for age, sex, symptom duration and baseline severity (as indicated by the PRTEE score). Since these latter variables are the ones most commonly identified as potentially influencing response to treatment, there is some justification for making statistical comparisons between all four groups. Such tests were therefore conducted and are reported below.

Figure 1: passage of participants in the study.

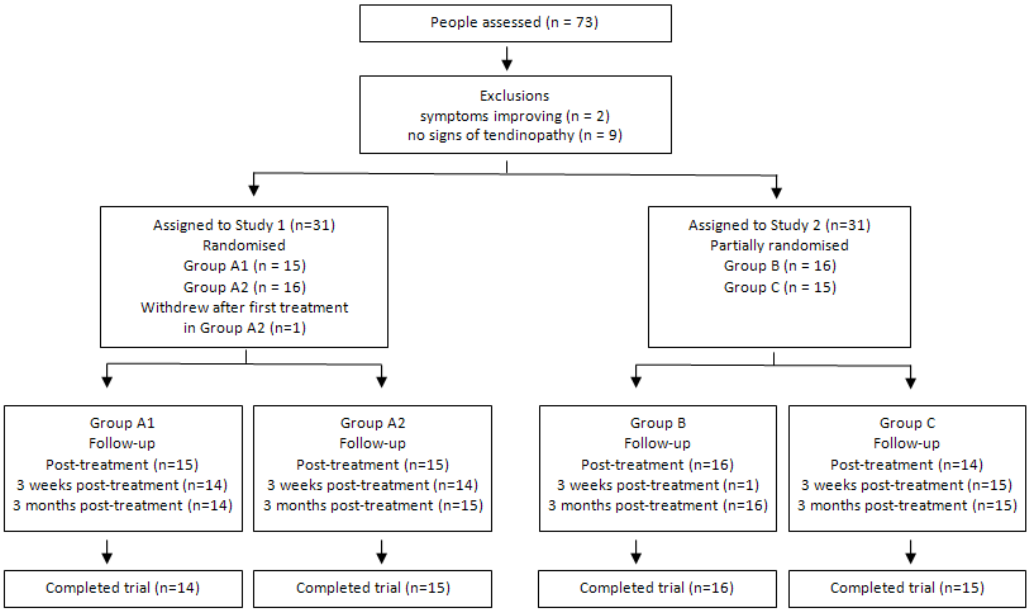


Table 2: Baseline characteristics of participants included in analysis (A=ambidextrous)

	overall	Study A		Study B	
Group		**1**	**2**	**3**	**4**
n	61	15	15	16	15
females	29	9	7	7	6
Age mean (range)	53 (40-69)	55 (48-63)	52 (40-69)	50 (42-61)	54 (43-69)
Arm dominance	10L; 49R; 2A	11R; 2L; 2A	14R; 1L	13R; 3L	11R; 4L
Dominant arm affected	48/61 (79%)	11/15 (73%)	14/15 (93%)	13/16 (81%)	10/15 (67%)
Duration this episode median (range) months	7 (3-240)	5 (3-18)	10 (3-30)	12 (3-48)	8 (3-240)
Previous episodes	23 (38%)	4 (27%)	6 (40%)	5 (31%)	8 (53%)
Baseline PRTEE score mean (range)	38 (6-81)	36 (6-81)	39 (8-76)	40 (15-78)	40 (14-67)

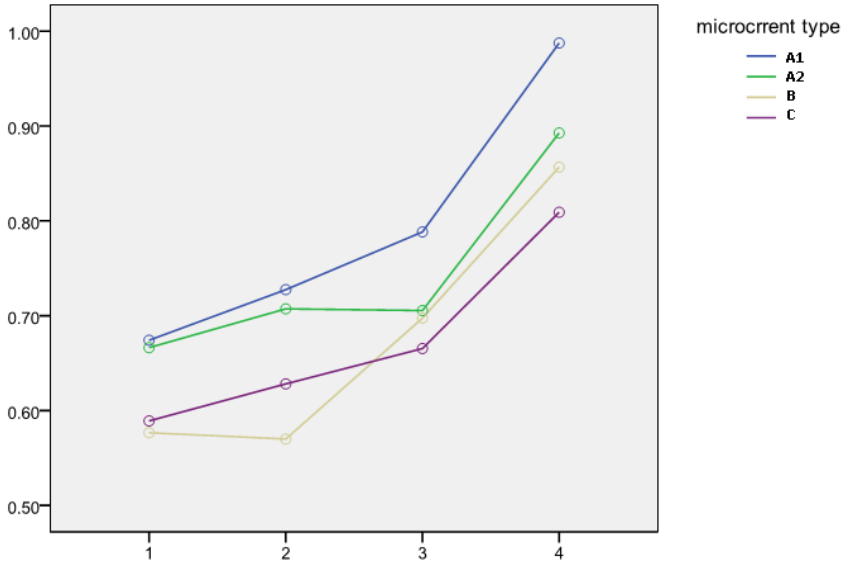
Pain-free grip strength

The ratio of PFGS on the affected side to maximum grip strength on the unaffected side was compared between groups over time. There were improvements with time in all groups, but no significant differences between groups at any time point.

Table 3: Grip strength ratio mean (95%CI) values for groups at each assessment (Data for participants with bilateral symptoms excluded)

	1 (n=12)	2 (n=11)	3 (n=12)	4 (n=11)
Baseline	67 (46-89)	67 (42-91)	58 (40-75)	59 (37-81)
3 weeks	73 (49-96)	71 (50-92)	57 (39-75)	63 (43-83)
6 weeks	79 (56-101)	71 (47-94)	70 (54-86)	67 (44-89)
16 weeks	99 (83-115)	89 (68-110)	86 (69-103)	81 (62-99)

Figure 3: PFGS ratio at each assessment for each group



Patient-rated tennis elbow evaluation questionnaire

The total scores and pain and function sub-scores of the questionnaire were compared between groups and over time. The charts show how mean values for pain and total score varied with time for each group. Decreases in scores represent improvements, hence all four groups improved with time. Separate repeated measures ANOVAs were conducted for studies A and B. These showed that there was a trend to better pain score improvements in group A1 than A2 (p=0.077), with a statistically significant difference at third assessment. Function and total scores showed a trend to difference between groups A1 and A2 (p=0.087 and p=0.072 respectively), with A1 significantly better than A2 at assessments 2 and 3, but no significant difference by final assessment. There were no significant differences between groups B and C in pain, function or total scores at any assessment.

Figure 4: PRTEE pain score at each assessment for each group

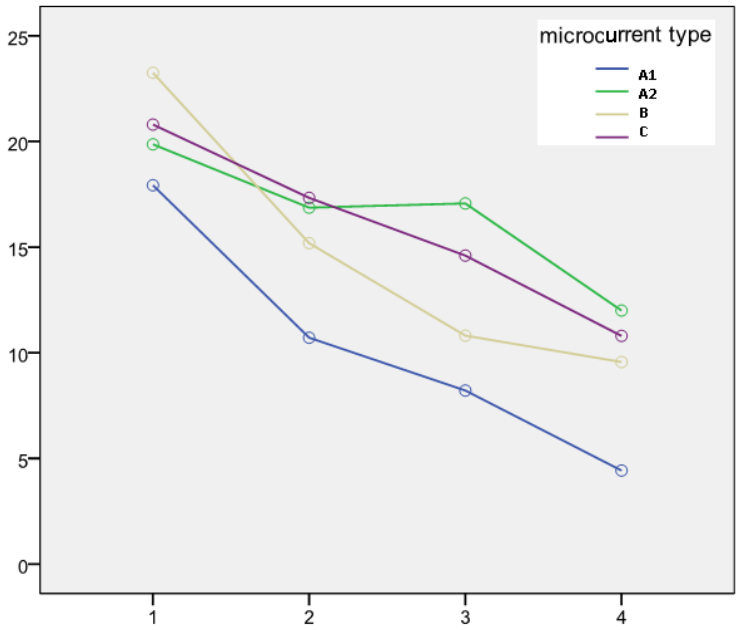
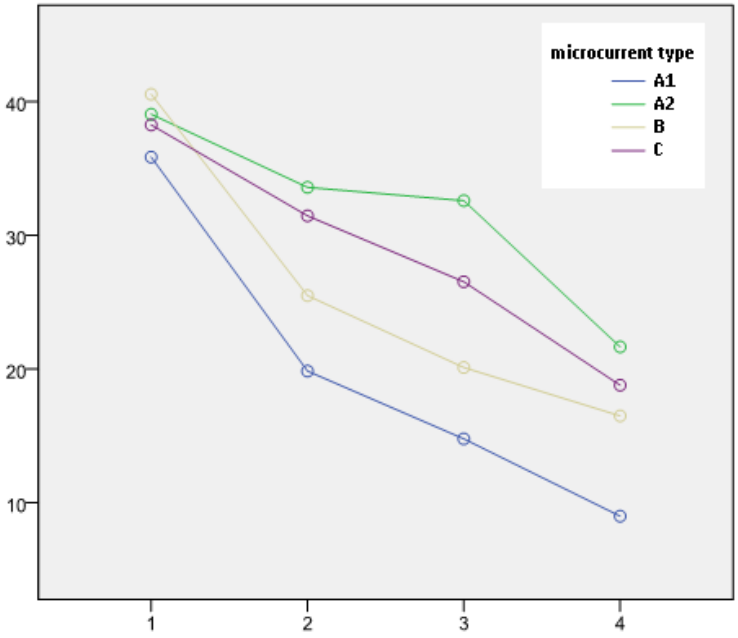


Figure 5: PRTEE total score at each assessment for each group



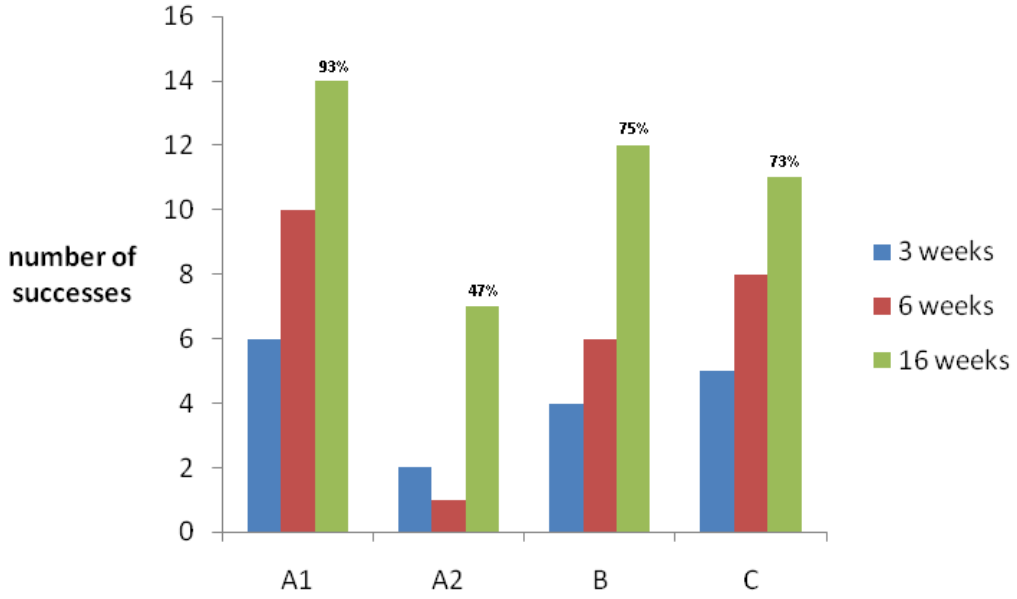
Global change and success rates

A Mann-Whitney test of differences between global changes scores of groups confirms that the median improvement in group A1 was significantly better than that in Group A2 at all time points, but that improvements in Groups B and C were not significantly different at any assessment. A Kruskal-Wallis test of differences between all groups with significance set at

p=0.01 to compensate for multiple testing established that there was a significant difference between all groups at final assessment, with A1 performing better than all other groups at this assessment.

The number of people in each group with a successful outcome, defined as much improved or completely better, is presented in the chart.

Figure 6: number of successful outcomes in each group over time (final assessment number also expressed as %)



The chart illustrates that all groups showed continued improvement with time, apart from group A2, where there was a deterioration between post-treatment and 6-week assessments.

Adverse events and side effects

Group A1
Two people reported occasional tingling either in the forearm or little and ring fingers; one reported initial discomfort during the first few treatments, and another felt forearm muscle tightness and discomfort during and for a few minutes after treatment. One person handled the device with wet hands and reported receiving an electric shock, with arm ache for a few subsequent days. Another person reported receiving a mild pulsing shock when touching the USB cable socket.

Group 2
Seven people reported tingling usually for a the initial few minutes; one of these said the feeling was stronger some days and that symptoms were stirred up on those days. Another reported three episodes of arm ache the morning after treatment. One person reported strong unpleasant bilateral leg tingling during the night after the first treatment and

withdrew from the trial. Another person reported mild erythema under the cathode after treatment, which quickly disappeared.

Group 3
One person reported tingling during the first few treatments. Three people experienced mild erythema under both electrodes. In one case this quickly resolved; in the others it was attributed to overzealous use of the sandpaper.

Group 4
Nine people reported tingling, two of these saying it felt strong at times. One person experienced numbness in little and ring fingers during one treatment, one felt post-treatment arm heaviness, and another reported fasciculation of the deltoid muscle for 30 minutes after one treatment. There were three reports of erythema that seemed likely due to over-vigorous skin abrasion.

Other comments

Generally, participants found all the devices easy to use. Being able to choose a convenient treatment time was appreciated, although several people did not like the rather complicated protocol (varying numbers of treatments each week) required for Device C. The portability of Devices B and C was found helpful, as was the fact that they did not require any programming. However nobody said they found the programming necessary for Device A difficult.

The main practical problems reported were associated with the length of the electrode leads with Device A. The leads were found to catch on furniture if the person moved around, even when the device sleeve was used. The sleeve design means that it is necessary to unplug and replug the leads after treatment is started, which might lead to inadvertent pushing of buttons. All devices have indicators to show whether current was flowing, but the LED on Device C was reported as difficult to see and the audio alarm on Device A does not work at 50µA. Its sleeve also obscures the viewing screen.

Device A used rechargeable batteries and participants using it were supplied with a recharger and a spare pair of batteries to avoid missed treatments. Despite the provision of new batteries, several participants reported having to recharge them several times. This was not an issue with the other devices, whose batteries were single use and lasted a full course of treatment.

Device B has a treatment time of 6 hours, and most participants used it at night, keeping the device in place with micropore tape and tubigrip. One participant said that movement during sleep had resulted in the electrodes moving or detaching on two occasions, and this may have happened in other cases without being apparent. All participants said they used the alcohol wipes per protocol, but unused materials returned after treatment suggested that this was not always the case. Use of the sandpaper for skin abrasion (required in Study 2) was inconsistent, with some using it per protocol, some abrading the skin too vigorously and others not using it at all.

Because all participants received oral and written instructions on location of the electrodes, their correct placement was not initially checked. However, it later became apparent that some participants were placing the electrode that should have been directly over the

tendon, 2 or 3 cm distal to it. The current density and configuration at the tendon may have changed because of this misplacement.

DISCUSSION

The main aim of this study was to discover whether a particular set of microcurrent parameters appears to be more effective than others in the treatment of chronic tennis elbow, so as to inform planning of a full clinical trial of the modality. The sample sizes of each group are small, so that there is a significant risk of type II error (concluding that there are no differences between groups when there actually are). Hence, it is important to consider the trends revealed by the data as well as the results of statistical tests. As the graphical data demonstrates, all groups improved over time, with trends suggesting that group A1 has the best outcomes, group A2 the worst. Groups B and C appear to perform equally well, with outcomes between those of the other two groups. Statistically significant differences in improvements are seen mostly between groups A1 and A2. The former group performed better on pain, function and total scores in the Patient Rated Tennis Elbow Evaluation, and for global change scores and success rates, all of which are subjectively rated by the patient. Pain-free grip strength values are semi-objective (they rely on the patient identifying their own pain threshold), and showed no statistically significant differences between any of the groups, although there was a trend to Group A1 performing better than the others.

Since all groups in this study received some form of MCT, it is not possible to test whether outcomes would have been different had participants received placebo microcurrent, another form of treatment, or no treatment at all. Some improvement over time would be expected in all groups, since tennis elbow is a self-limiting condition in most cases. Although statistical tests are not appropriate, it is useful to make a comparison with data obtained from other studies in which there was a group that received minimal intervention. Two studies comparing several forms of management of tennis elbow measured the pain-free grip strength ratio in a "wait and see" group, whose members received advice and used analgesia and – in some cases - a tennis elbow brace[12, 13]. Absolute and percentage changes from baseline in the PFGS ratio in these groups were similar to or exceeded those seen in the four MCT groups, suggesting that the MCT was no better than minimal intervention on this outcome measure. In the best performing MCT Group (A1), the PFGS ratio reached 0.99 within 15 weeks, whereas in a minimal intervention group[13] it only reached 0.87 by 26 weeks and 0.97 by 52 weeks. This might mean that recovery happened more quickly in this group than in the minimal intervention group. However, baseline PFGS ratios in the minimal intervention groups were considerably lower than those in all MCT groups, and so comparisons must be made with caution.

In two studies involving observation of no-intervention groups, PFGS was also used as an outcome measure, but it was expressed as an absolute value rather than in ratio to maximum grip strength on the unaffected side. In one[14], PFGS increased by 6% over 6 weeks, compared to 4-28% in the MCT groups; in the other, it increased by about 35% in 12 weeks (data taken from a chart), compared to 23-67% in the MCT groups. Baseline PFGS values in the first study were similar to those of the MCT groups, but those in the second were significantly lower (worse) than in the MCT groups.

These two studies also used the PRTEE as an outcome measure with groups receiving no intervention. In one[14], the mean total score decreased by 2.4 points in seven weeks, compared to changes of 9-21 in the MCT groups. Changes in pain subscale scores were also much better among the MCT groups than in the no intervention group. In another study[15], the PRTEE total fell by 4 points in 12 weeks, compared to falls of 18-27 points over 15 weeks in the MCT groups. Although the baseline PRTEE values in these studies were higher (worse) than in the MCT groups, comparisons using the data they provide suggests that the differences were not significant.

Two studies employed a patient-rated criterion of success identical to that used in the present study, i.e. the proportion of patients regarding themselves as much better or fully recovered[12, 13]. Success rates in those groups were 27-32% at six weeks and 55-60% at 12 weeks. These compared to rates of 7-67% and 47-93% in the MCT groups. Hence, on this measure, several forms of MCT appeared to result in considerably higher levels of success than minimal intervention at comparable time points. However, the baseline severity of the other groups appears to be lower than in the present study (the measures of severity used are not identical) so, once again, this interpretation is tentative.

The diverse outcomes observed in these studies are likely to be partly a consequence of the different baseline characteristics of the groups. Eligibility criteria may also have been a factor. For instance, participants with concomitant neck and upper limb disorders or peripheral nerve involvement were excluded from the minimal intervention groups but not the MCT groups, so long as tennis elbow was diagnosed. Their presence may have influenced outcomes in some cases. The "wait and see" groups described in two of the comparative studies[12, 13] actually involved education and advice from a clinician, activity modification, various forms of analgesia and, in some cases, use of a brace. These forms of management (which were also used in the current study) may have made a contribution to outcomes. The only additional input to the comparator groups in the other studies[14, 15] appears to have been pain medication, and additional consultation with a clinician in a very small number of cases. The baseline characteristics of these groups appear more similar to those of the MCT groups and so they may be the more valid no-treatment comparators.

All comparisons with other studies must be used cautiously because of the differences in the populations and protocols that have been described, and the potential for other uncontrolled factors that have not been identified. With this caveat in place, the following interpretation may be made: Some forms of MCT appear capable of improving signs and symptoms of chronic tennis elbow, but effectiveness is diminished in more severe presentations of the disorder.

The comparisons between the different forms of microcurrent suggest that the treatment provided to Group A1 may be the most effective and A2 the least effective, with the effectiveness of MCT in groups B and C lying somewhere between the others. The only difference between treatments used with groups A1 and A2 was the amplitude of the microcurrent, so the lower amplitude of 50μA appears to be more effective than the higher value of 500μA. This conclusion is supported by the tow other comparisons: types B and C, whose data trends suggest are superior to A2, also have time-averaged amplitudes considerably less than 500μA; also, although the differences in outcomes between Groups B and C were insignificant, the trend was to a better improvement in Group B, which had the

lower current amplitude of the two. In fact, current density may be a more significant parameter than amplitude, but the results of this study are in accord with those using microcurrent to treat damage in other forms of tissue, the majority of which support amplitudes less than 100μA[1].

Other treatment parameters varied in several respects between groups, so it is difficult to isolate particular parameters and judge their relative contribution to the whole effect. However, a number of observations may be made.

Although the nominal current delivered to groups B and A1 were comparable, their outcomes were different. This suggest that another parameter influences effectiveness. The treatment time was much shorter in A1 than B, but this is unlikely to have been the cause of better outcomes as other studies suggest that longer treatment times are more effective. The other substantial parameter differences were the high frequency and biphasic waveform of the microcurrent in group B. One or both of these may have been important to the relative poorer performance of this device. However, the uncontrolled current delivered to group B means that departures from the nominal 40μA current may also have influenced the outcome.

There was a non-significant but consistent trend to better outcomes in group B than group C. Both devices used with these groups delivered biphasic current, so this parameter does not explain the difference. The current delivered to group B was lower, and this may be the main factor, but the much longer expose to microcurrent may also have contributed to the better performance in that group. This would be in accord with evidence from other studies where successful treatments tend to involve longer treatment times.

The majority (10/15) of participants in Group C, who received a highly modulated microcurrent waveform with peak amplitudes of 500μA and peak frequencies of 900Hz, reported tingling during treatment. Fewer (6/16) reported sensory effects in Group A2, whose microcurrent was of 500μA but was less modulated. Very few in groups A1 and B (1/15 in 2/15 respectively), both of which had low current amplitudes, reported tingling. Hence it is possible that a neurostimulatory mechanism plays a role in the action of some forms of MCT, but unlikely that it is the main driver in all forms, since its most significant impact in this study was in Group A, where it was sub-sensory for the majority of participant. Indeed, unless the lower current accounts for all the difference in responses between groups, the pattern suggests that a lower frequency, less modulated waveform may be more effective.

Apart from these parameter variations, several other factors may have influenced outcomes. Because the main focus of the investigation was on comparing different forms of MCT, no other treatments were provided to participants. Normally, electrotherapy is provided as part of a broader package of treatment. With tendinopathies, exercises are usually prescribed and it seems likely that these could act synergistically with other forms of treatment that promote healing, to enhance the quality of the tissue repair and remodelling process. Hence, the effectiveness of MCT might be improved by the incorporation of a controlled exercise programme into the treatment protocol. Also, upper limb comorbidities did not exclude participants from thus study, but were not specifically treated as part of the protocol. This may also have reduced the apparent effectiveness of treatment. Secondary analyses to investigate these possibilities, and the impact of other potential confounders,

are planned. Sonographic data is also being analysed both as an outcome measure and to see whether some forms of tendinopathy are more responsive to MCT than others.

Conclusion

It must be emphasised that these deductions are based on trends of data, many of which are not statistically significant. Hence, the conclusions are tentative and require testing in studies of greater sample size. The main focus of the study has been to establish whether a study of the effectiveness of MCT with chronic tennis elbow is warranted and, if so, with what treatment parameters. This investigation suggests that MCT may indeed have value in the treatment of this disorder, but is most likely to be effective in its less severe presentations. Of the forms of microcurrent tested in this investigation, a monophasic, low frequency current of amplitude 50µA applied for a total of 35 hours over 21 days produced the best outcomes. Other forms of microcurrent may also produce symptomatic relief, and different mechanisms of action may be involved according to the form used. Further data analysis is planned to compare structural changes in the treated tendons and to investigate the impact of various baseline characteristics on prognosis.

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