Novel Microcurrent Treatment is More Effective than Conventional Therapy for Chronic Achilles Tendinopathy

Randomised comparative trial

Key Words
Achilles tendon, microcurrent, soft tissue, pathology.

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Summary

Background The healing processes of tendon tissue are not well understood and the difficulty in clinical management of its pathology reflects this. Previous *in vitro* studies have demonstrated that application of microcurrent can promote protein production (collagen) in fibroblasts and tenocytes. *In vivo* studies, using animal models, have demonstrated that tendon and ligament tissue responds particularly well to this application. Thus the purpose of this study was to evaluate functional outcome in patients presenting with chronic pathology in the Achilles tendon, following application of microcurrent compared with conservative management.

Method A prospective comparative study was undertaken using a blocked randomisation method. Subjects were allocated either to group A and exposed to current clinical management or to group B, the experimental microcurrent regime. Classification and subsequent evaluation of pathology were assessed employing clinical assessment tests, self-assessment and assessment by diagnostic ultrasound. Baseline characteristics were similar in both groups. Subjects were assessed at three, six and 12 months after entry into the study.

Forty-eight subjects, 24 in each group, completed the study. A statistical analysis was performed, calculating the differences between the two groups and between each interval assessment. Categorical variables were compared between the two groups using the chi-squared test. The Mann-Whitney test was performed to assess changes in ordinal variables.

Results Statistically significant differences were found in favour of group B, the experimental group, in four out of the five clinical markers used at the 0.1% level of significance.

Conclusion The application of microcurrent treatment to patients presenting with chronic Achilles tendon pathology can make a significant contribution to improvement of the condition.

Introduction

Microcurrent Therapy

The use of electricity, electrical stimulation, and electromagnetic fields is not new in medicine. Studies have shown, for example Akai *et al* (1988), Lee et al (1993) and Dunn *et al* (1988), that by externally imposing an electrical field or electrical current the electrical potentials present in and between cells, in soft tissues, may promote biological and physiological changes of these tissues. Indeed there is strong experimental evidence to suggest that tendon repair can be significantly affected by electrical stimulation with intensities at a microcurrent level. The work of Stanish *et al* (1985), Nessler and Mass (1985) and Fujita *et al* (1992) are of particular relevance.

Microcurrent is understood to be distinct from other forms of therapeutic electrical stimulation because the current intensity is significantly less than that of other forms of electrotherapy, such as transcutaneous electrical nerve stimulation or Faradic units. Microcurrent applications are believed to be effective by influencing and modifying cellular processes and activity. Employing different levels of current, frequency and polarity have been shown to have diverse effects upon different cell groups.

In respect to wound healing and the tissue repair process it is believed that not only is the intensity of current crucial to optimise its efficacy but also the polarity is vital to success (Becker and Seldon, 1985). Davis *et al* (1990) demonstrated that in skin healing, treatments using positive polarity surpassed the controls. Other combinations of negative and negative and positive were worse than untreated controls. This demonstrates that micro-current therapy has a sophisticated mechanism of action that

depends upon many different biological and physiolo-gical actions and interactions. This has also been discussed by Bourguignon and Bourguignon (1987) and Dunn *et al* (1988).

The proposed physiological effects that accelerate healing may be summarised as the following:

- A mechanism that modifies or mimics the normal processes of electro-chemical signal transduction (Chapman-Jones, 1997).
- An amplification of A.T.P synthesis (highlighted by Cheng *et al*, 1982).
- A change in the acid/base chemical balance in the cell environment (Lee *et al*, 1993).

There may be four reasons why the cell membrane is implicated in the process:

- An electric field/current is amplified within the membrane making it the most likely site of interaction.
- The cell membrane is a major site of signal transduction.
- Changes to ion flow, especially calcium, will affect cell behaviour.
- The cell membrane is involved in controlling the electrical aspects of the cell, maintaining the potential gradient through the active regulation of ion influx into and out of the cell (Chapman-Jones, 1997).

When microcurrent is applied to a patient via small electrodes the treatments generally produce no noticeable sensory or neuromuscular effect on the patient or practitioner.

Regeneration

Science and scientists have yet to reach agreement upon the aetiology of chronic tendon pathology. The pathophysiology of the tendon with chronic pathology and the healing processes involved are debated in the literature, particularly with reference to the Achilles tendon (Leadbetter *et al*, 1992; Clement *et al*, 1984; Blackman *et al*, 1990). Conservative management regimes have proved to be unreliable, with inconsistent results and a generally low level of success, as highlighted by Williams (1986) and Niesen-Vertommen *et al* (1992).

Despite the fact that studies have reported augmentation of healing processes following microcurrent stimulation in connective tissue, for example skin (Alvarez *et al*, 1983), and in a collagen matrix (Dunn *et al*, 1988) a literature search revealed that there have been no clinical studies which demonstrated the efficacy of the tech-nique for the treatment of tendon pathology in human subjects using non-invasive skin surface application. Only animal models, *in vitro* cell cultures, and invasive *in vivo* techniques have been used to demonstrate the effectiveness of microcurrent electrical stimulation (Owoeye *et al*, 1987; Spielholz, 1986).

It was against this background of cell behaviour modification that the clinical potential of microcurrent stimulation to augment healing in tendons was to be evaluated. It was reasoned that microcurrent electrical stimulation would induce a modification in cell behaviour which would augment healing processes in Achilles tendons with chronic pathology.

The following question was addressed: Do patients exposed to microcurrent return to a normal functional outcome more quickly than those receiving conservative treatment? (Functional outcome was measured as the subject being able to perform activities undertaken prior to the onset of symptoms, evaluated by pain, stiffness and flexibility levels.)

Methodology

The experimental hypothesis was tested employing a prospective comparison study of two groups, A and B, with block randomisation. Those in group A would continue their prescribed treatment. Group B, the experimental group, would receive the microcurrent treatment regime.

Subject Selection

Ethical approval for the study was obtained from the local ethics committees at the hospitals involved in the study. All the subjects involved provided written consent before their participation in the study.

Subjects were included if they were 18 years or older, and had a minimum three-month history of one or more of the following: Achilles tendon pain, stiffness or function impairment.

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Patients with acute rupture were excluded. Using the method of Pocock (1983) group sizes were calculated. We estimated a 70% recovery rate for the new treatment compared with 30% for the standard treatment. This resulted in a minimum of 21 subjects per treatment group. Thus to allow for dropouts and leeway in response rates we recruited 24 subjects for each group. To ensure that equal numbers were allocated to each group a balanced, or restricted randomisation method was employed. The standard treatment group (A) and the experimental group (B) were randomised after baseline clinical assessment and eligibility for the study were determined.

Apparatus and Procedure

The subjects allocated to group A underwent the current clinical management prescribed by their clinician for the treatment of an Achilles tendon presenting with chronic pathology. These treatment methods varied from clinician to clinician.

Group A subjects were also given eccentric, progressive gastrocnemius and soleus stretches. This was done for two reasons: The same stretching programme was used with the microcurrent treatment to aid the re-modelling phase of the immature collagen fibrils; therefore giving the programme to both groups would allow discrimination between the treatment with and without the microcurrent. Secondly, this method had previously been demonstrated to provide positive results in subjects with Achilles tendinosis (Neisen-Vertommen *et al*, 1992).

All subjects were required to stop any treatment they were currently undergoing for a period of one month so that they all started from a similar point. A three-month cessation was suggested in order to 'bleed out' previous treatments that might have interfered with the current study but the ethics committee rejected this request.

The microcurrent treatment was delivered by a computer controlled solid-state unit, with a touch screen control panel (Face and Body Perfector Ltd, Bucks). The device has a constant current generator, with a negative feedback mechanism that works on the principle of Ohm's law. It monitors the resistance to the flow of current and changes the voltage accordingly, thus ensuring that the average pre-set current will be delivered in a homogeneous manner regardless of differences in the sub-cutaneous fat levels or resistance in the skin and surrounding soft tissues.

In summary, group B subjects received daily electrical stimulation to the Achilles tendon, applied via two skin surface carbon fibre electrodes containing an integral coupling gel, which ensured a good contact between electrodes and skin. One electrode was placed on the medial side of the tendon and the other on the lateral side corresponding to the area of the pathology (fig 1). This was determined by the clinical and ultrasound investigation.

The following treatment parameters were used: A positive current of 40 mA modified to a square waveform, 10 hertz. Subjects were treated for 30 minutes per day for 14 days. Following the treatment period the subjects were put on a progressive pain-free eccentric stretching regime, for the gastrocnemius and soleus complex. This was designed to promote the re-modelling phase of the immature collagen fibrils in the healing Achilles tendon.

Fig 1: Electrode placement on the Achilles tendon

Clinical Assessment

Assessment of the subjects' tendon(s) was undertaken at the following intervals:

1. Baseline assessment as subjects entered the study.
2. At three-monthly intervals for one year. The first assessment was three months after the end of the course of treatment.

Each assessment interval included the following:

- Clinical examination.
- Diagnostic musculoskeletal ultrasound imaging (this was undertaken blind to the clinical findings).
- Dorsiflexion and plantarflexion range of movement.
- Self-assessment using indicators such as levels of discomfort/pain, noticeable functional disability, and duration of the problem. Subjects kept a weekly progress diary which although not appropriate for any statistical analysis provided useful supplementary information.

- A general assessment, rated as follows:

  Excellent Full range of movement through the Achilles tendon comparable with the contralateral side. Athletes can run at full competitive speed and distance and undertake their cumulative weekly training regime with no significant symptoms.

  Good Can train at pre-injury levels with only intermittent or mild discomfort, and dorsiflexion of the affected Achilles tendon is within 5° of the contralateral side. For bilateral cases, dorsiflexion of at least 20°.

  Fair Patients are asymptomatic or mildly symptomatic in relation to activities of daily living. Discomfort prevents athletes from returning to pre-injury activity in terms of speed and distance, precluding any competition.

  Poor Patients are symptomatic during activities of daily living, for example driving or walking upstairs, and unable to perform them without discomfort.

In order to undertake statistical analysis of the general assessment each classification was allocated a numerical score: poor = 1, fair = 3, good = 5, excellent = 7. This ordinal scoring system, although not validated by previous studies, did provide a useful tool to assess individual progress.

Diagnostic Ultrasound Assessment

The value of sonography as an aid to clinical diagnosis of tendon pathology is supported in the literature (Bertolotto *et al*, 1995; O'Reilly and Massouh, 1993; Khan 1991; Cook *et al*, 1998), although its use for monitoring treatment is debated (Gibbon *et al*, 1999; Chapman-Jones, 1997). Lian *et al* (1996) showed a strong relationship between symptoms of jumper's knee and the ultrasound characteristics of the patella tendon among high-level male volleyball players. We concluded that ultrasound would provide some additional useful information and it was used both for establishing initial diagnosis and also for monitoring progress.

Data Analysis

Categorical variables were compared between the two treatment groups using the chi-squared test. The unpaired t-test was used to compare the ages in the two treatment groups.

After calculating the difference between each interval the Mann-Whitney U test was performed to assess changes in the ordinal marker variables such as Achilles tendon pain and stiffness and the results of the general assessment.

It was necessary to allocate a rating scale to the signs and symptoms that occur with a positive diagnosis of Achilles tendon pathology because there are several dimensions, such as pain, stiffness and loss of range of movement, involved in assessing an individual's progress.

Although no satisfactory scoring system came to light a method was devised drawing on three similar assessment criteria: a 35-point shoulder rating scale (Ellman *et al*, 1995), a method used in the assessment of elbow trauma (Harrie and Verhaar, 1995), and a patella tendinopathy rating scale (Visentini *et al*, 1998).

Pain and Stiffness

We believed that the level and frequency of pain or discomfort a subject reports is a good indicator of the severity of their pathology. The pain scale was defined as in table 1.

Table 1: Pain scoring system

Subjects' level and duration of pain/discomfort	*Score*
Totally non-symptomatic	0
Pain with exercise, ceases when activity stops	25
Pain with exercise, gives prolonged symptoms	50
Pain with daily living activities, eg driving	75
Constant pain	100

In addition subjects were asked to indicate, on a 1-10 scale, the severity of their pain/discomfort, where 1 is a very mild discomfort and 10 is likened to having red hot burning tongs put on their tendon.

0----1----2----3----4----5----6----7----8----9----10

No pain Red hot tongs

We linked this rating to the scores in table 1 to enable a greater degree of discrimination. For example, a patient who reported pain with exercise which ceased soon afterwards would score 25 on the pain table. If the pain was quite severe during exercise and the subject reported a score of 7 on the pain scale, he would score a total of 32 (25 + 7).

Flexibility/stiffness was classified and scored as in table 2. The scores used in order to attribute a numerical value for flexibility or stiffness are less than the pain scales because the symptoms of stiffness were considered to be less severe. If subjects have two or more of the flexibility categories, which is likely for more severe cases, then the scores are added together.

Table 2: Flexibility scoring system

Tendon flexibility/stiffness	*Score*
No stiffness	0
Stiffness after exercise	5
Morning stiffness	5
Loss of dorsi/plantarflexion more than 5°	5

Table 3: Ultrasound scoring system

Ultrasound findings	*Score*
Normal	0
Paratenonitis	1
Tendon enlargement up to 4 mm	2
Enlargement 4-6 mm	3
Enlargement 6-8 mm	4
Enlargement 8-10 mm	5
Enlargement 10 mm+	6
Degenerative changes	7
Tendinosis including partial ruptures	8
Tendinosis with paratenonitis	9

The pain and stiffness scores were designed to provide a degree of discrimination for the clinical condition under consideration and to differentiate between subjects presenting with different clinical scenarios. An example can best illustrate the reason for the numerical gap, 0, 25, 50, 75 and 100 chosen between each marker. Assume subject X presents with an initial score of 57. He has pain with exercise, which gives prolonged symptoms (50) at a subjective pain score of 7. If following his treatment he still reports pain but at a reduced level of 4 and it ceases when activity stops he will have a score of 29 (25 + 4).

However, if the existing values for each marker are changed to contiguous numbers 0, 1, 2, 3, 4 the following could occur. The patient would have scored 9 at the initial assessment (2 + 7), which would have improved to 5 (1 + 4). It would then not be able to discriminate between this and a condition in another patient Y who also scored 5 (total daily pain at level 1) whose condition from a clinical perspective could be considered more severe because the tendon is giving symptoms with little or no aggravation. In addition subject X would originally present with a condition that the assessment scheme would tell us was worse than that of Y.

The stiffness score and general assessment scores were based on the same rationale.

Results

In order to summarise the results of the study only period 1, the initial assessment, and period 4, the final assessment, will be presented. Forty-eight subjects with chronic Achilles tendon pathology were examined in this study. Half received treatment A, current conservative management, and half received treatment B, the new microcurrent regime.

The distribution of age, sex and individual pathology was similar between groups, demonstrating the success of the randomisation procedure. There were 17 men (70.8%) in treatment group A and 18 men (75.0%) in treatment group B. The difference was not significant. The

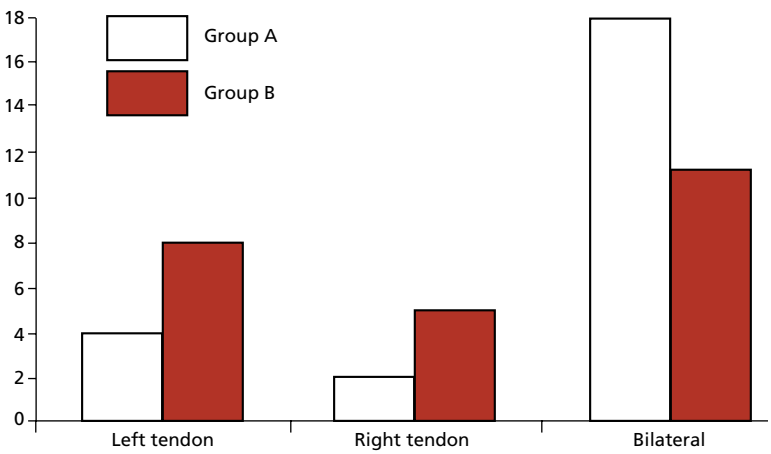

Fig 2: Number of subjects and the Achilles tendon affected

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This study was conducted at Chase Farm NHS Trust Hospital, The Middlesex Hospital, and St Bartholomew's Hospital, London, in conjunction with the Centre for Measurement and Information in Medicine, City University.

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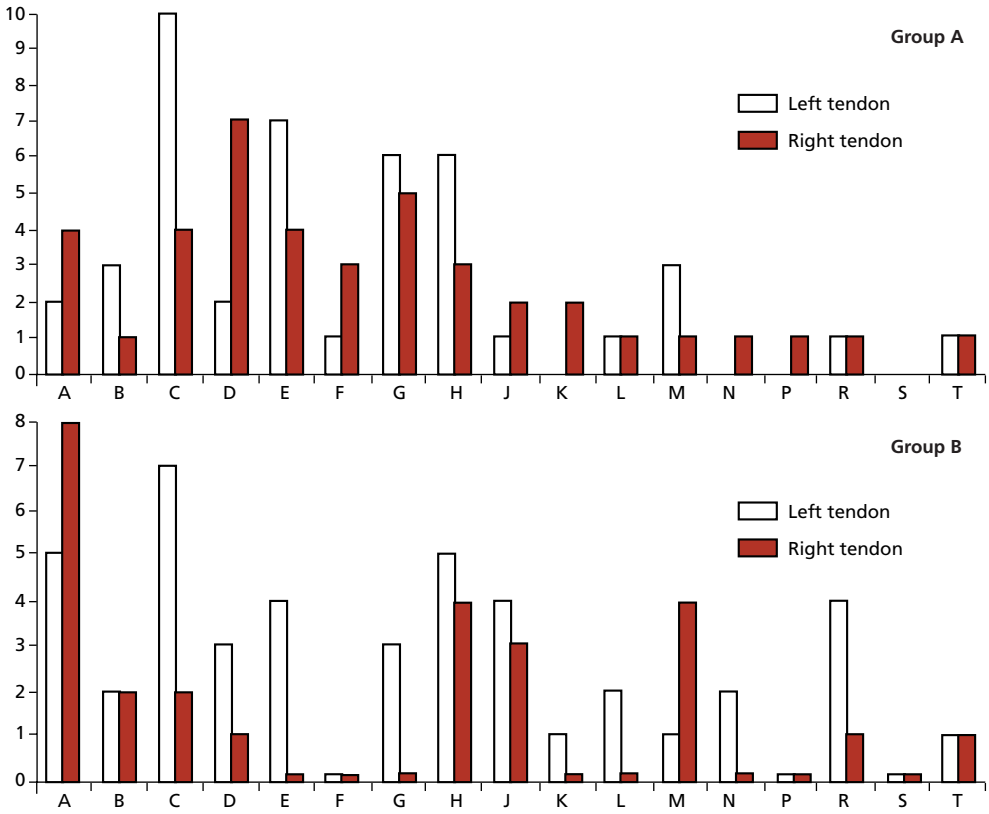

Key

A	Normal	G	Enlargement 1	N	Rupture 3
B	Paratenonitis	H	Enlargement 2	P	Rupture 4
C	Tendinosis	J	Enlargement 3	R	Calcification
D	Peritendonitis	K	Enlargement 4	S	Non-surgical
E	Degenerative	L	Rupture 1	T	Cystic
F	Post-surgical	M	Rupture 2		

Fig 3: Achilles tendon pathology distribution

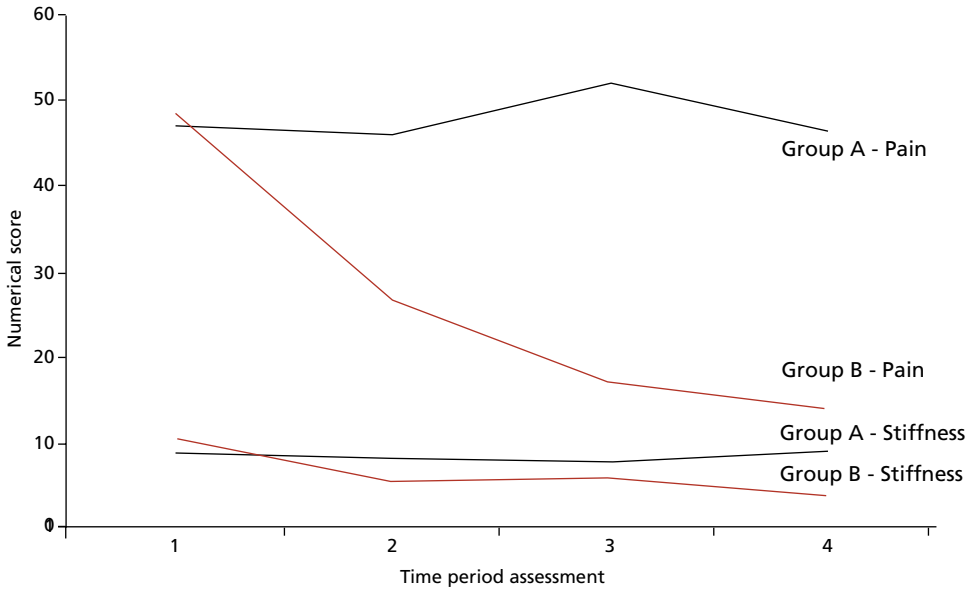

Fig 4: Difference in pain and stiffness between groups A and B using mean score over the four assessment intervals

mean age of treatment group A was 36.0 years (SD 7.8 years) and group B 39.3 years (SD 10.4 years). The difference was not significant.

This study was not specifically targeted at athletes, although a number of the subjects fell into this category. The number of athletes and non-athletes was as might be expected of patients attending an orthopaedic/rheumatology clinic.

Baseline Assessment

From a a possible total of 48 tendons affected in each group, group A subjects presented with four left, two right and 18 bilateral tendon problems, resulting in a total of 42 tendons with pathology. Group B subjects presented with eight left, five right and 11 bilateral problems, a total of 35 tendons with pathology. These differences between the groups were not significant.

Each tendon was treated as a separate entity rather than aggregate the results of both tendons in a single subject. We do concede that the case could be argued with equal validity each way and it is perhaps one of the most controversial aspects of the study method and requires some explanation.

A tendon was included only if it was symptomatic at the time of the initial assessment. A majority of subjects, 29 out of 48, presented with bilateral Achilles tendon problems, which were not always equal in severity. As each tendon was treated separately, there were considered as separate for data analysis. Thus the 24 subjects in each group had 42 (group A) and 37 (group B) tendons for analysis. These numbers were not significantly different.

We also undertook the following further statistical analysis:

- Aggregated the data from both tendons in bilateral cases.
- Selected the best responding tendon from each bilateral case in both groups.
- Selected the worst responding tendon from each bilateral case in both groups.

There was no statistical difference in the overall outcome. Group B subjects still performed statistically better than group A subjects.

At the baseline assessment a comparison between the groups showed there was no statistically significant difference in respect of the severity of their condition. However, one of the markers, the general assessment score for the left side, was found to be significantly higher in treatment group A than B (Mann-Whitney $P = 0.035$). Group A had a median general assessment score of 3 (range 1-7), whereas group B had a median general assessment score of 1 (range 1-7).

One-year Assessment

The final assessment was undertaken one year after the initial assessment. All the tests and the diagnostic ultrasound examination undertaken at the initial assessment were recorded at one year. This enabled a direct comparison of the condition of each subject's Achilles tendon to be made between the two assessment periods one year apart. Forty-two Achilles tendons were evaluated for response to treatment in group A at one year, the same as the initial entry assessment. This comprised 18 subjects with bilateral pathology, resulting in 36 tendons, and six with unilateral pathology.

Thirty-five Achilles tendons were evaluated for response to the new treatment, group B. This was made up of 11 subjects with bilateral Achilles tendon pathology, 22 tendons, and 13 subjects with unilateral pathology (eight left and five right).

Evaluating the parameters of pain and stiffness, the general assessment score showed statistically significant differences in favour of treatment B in all three of the markers reported to < 0.001. Tables 4 and 5 demonstrate this.

Table 4: Summary of pain, stiffness and general assessment at baseline and after one year

	Group A		*Group B*	
	Range	*Median*	*Range*	*Median*
Baseline				
Pain	31-82	56	28-99	56
Stiffness	5-15	10	5-15	10
General assessment	1-3	3	1-3	1
One year				
Pain	0-98	55	0-83	10
Stiffness	0-15	10	0-15	5
General assessment	1-7	3	1-7	7

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Table 5: Summary of statistics, at baseline and after one year, range and (median) score

	Group A		*Group B*		*Difference*
	Period 1	*Period 4*	*Period 1*	*Period 4*	*M-W P level*
Pain	31 to 82 (47)	0 to 98 (47)	28 to 99 (48)	0 to 82 (14)	≤ 0.00005
Stiffness	5 to 15 (9)	0 to 15 (10)	5 to15 (10)	0 to 15 (4)	≤ 0.00005
General assessment	1 to 3 (2.68)	1 to 7 (3.5)	1 to 3 (1.59)	1 to 7 (5.6)	≤ 0.00005

The key figures are the median pain scores. They are the same at baseline assessment but after one year group B showed a significant improvement while group A dropped minimally to 55. The general assessment score shows a similar picture.

Discussion

The subjects exposed to the experimental microcurrent treatment (group B) clearly responded better than group A, demonstrating an improved functional outcome. (Normal outcome was summarised as being able to play sport and carry out everyday tasks without any significant degree of pain, stiffness or swelling of the Achilles tendon.)

Another aspect that was covered in the overall study, but not presented here, was the time taken to return to normal function. At the time of agreeing the study design we considered that all subjects might get better, but the rate at which they did so might be important. We now know this is not the case. When the data of group B subjects are compared between three months and one year there is no significant difference. Most progresss was made during the first three months; thereafter it was maintained, or improved or deteriorated only minimally.

However, three subjects in group B did not follow the pattern of the rest of the group. The reason for these outliers is important as it has implications for the clinical management of such tendon problems. One subject, a female physical education teacher, sustained a severe inversion injury of her ankle in a running race three months into the study. Her work commitments resulted in her continuing to exercise at the same intensity for the remainder of the study. The other two subjects had previously undergone multiple debridement operations on their Achilles tendons that had resulted in function deficits in the muscle/tendon unit. These subjects account for the high pain range at the one-year assessment

A limitation to this study was the lack of a definitive standardisation of conservative treatment. Therefore it is not possible to evaluate whether the range of present conservative treatment regimes used are of value to the pathologies occurring in the Achilles tendon.

Perhaps the only conclusion that may be drawn and may have been a contributing factor to the group A subjects' poor progress was the lack of consistency in the treatment regimes to which the subjects were exposed. This lack of consensus about the efficacy of current treatment regimes and the controversy surrounding some of them made it evident that a study design that involved mixing the standard and new treatment regimes would be inappropriate. For this reason, it was concluded that the only suitable method by which the proposed new treatment regime could be properly evaluated and that would yield significant results, would be one that separated the two groups.

For these reasons the prospective randomised parallel method selected was the most appropriate study design.

A further limitation was the lack of validity data on the scoring system developed for this study. However, it was based on three scales in current use and appeared relatively robust when used in this study.

Mechanism of Microcurrent Action

This study supports previous publications cited that microcurrent therapy has a role to play in the clinical management of chronic tendon pathology. Previous studies, for example, Chapman-Jones (1997) and Lee *et al* (1993) have demonstrated that microcurrent has the ability to augment soft-tissue healing and promote fibroblast and tenocyte proliferation in a controlled environment. However, this is the first non-invasive study that has demonstrated that microcurrent-based treatments have the potential to augment the healing processes in chronic tendon pathology in human subjects.

The precise mechanism of action of

microcurrent is unclear. If, as is suspected, a significant cause of chronic tendon pathology is a diminution of tenocyte activity, resulting in a failure to adapt to overload, then the promotion of tenocyte activity and subsequent increase in collagen production to promote healing by modifying cell behaviour is feasible.

Whether the optimal treatment parameters were used is open to debate. However, we felt that the evidence from previous studies, particularly Illingworth and Barker (1980), that highlighted that lower levels of microcurrent, below 100 mA, occurring naturally in the body would demonstrate the greatest efficacy.

Ultrasound

In relation to diagnostic musculoskeletal ultrasound it was felt to be a helpful examination to assess the progress of the pathological state of the Achilles tendon. There did appear to be general agreement in the ultrasound findings with Achilles tendon pain, stiffness and the general assessment. This supports other studies evaluating this modality (Gibbon *et al*, 1999; Chapman-Jones, 2000).

We feel this imaging modality should be adopted more commonly for this use.

Conclusion

This study has demonstrated that the appropriate application of microcurrent treatment to an Achilles tendon presenting with chronic pathology may make a significant contribution to its clinical management. This supports the findings of other studies employing animal and *in vitro* models. Therefore because from a biological perspective tendons tend to behave in a similar manner, it does not seem unreasonable to suggest that these findings may be extended to other tendons presenting with similar pathology.

Author's note

Since this research was conducted we have continued to witness some remarkable results using this method of treatment for tendon, ligament and skin injuries/conditions. Research is continuing in order to investigate the biological mechanisms that underpin the clinical results.

We are now beginning to believe that microcurrent has the effect of promoting the release of particular growth factors such as fibroblast and epidermal growth factors and transforming growth factor alpha.

Key Messages

- Biological regeneration in tendons is very slow, taking six to eight weeks to heal. It is necessary to be patient and give treatments time to work.
- Tendons have an embryonic form of regeneration; Damaged tendon tissue is not replaced with connective scar type tissue but with new tendon tissue. In the early stages of healing this is very delicate and is easily broken down by techniques such as friction massage. Imaging, particularly by musculoskeletal ultrasound, is important to establish the exact nature of the problem.
- Different problems require different management approaches and yet clinically they can present with similar symptoms.
- Microcurrent therapy in conjunction with appropriately staged eccentric stretching exercises (at the re-modelling phase of healing) is the most reliable method we have found for treating such conditions.

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