

TENDON WORKS[®]

a Synapse micro-current technology

A CLINICALLY PROVEN METHOD FOR TREATING
DEGENERATIVE TENDON PATHOLOGY

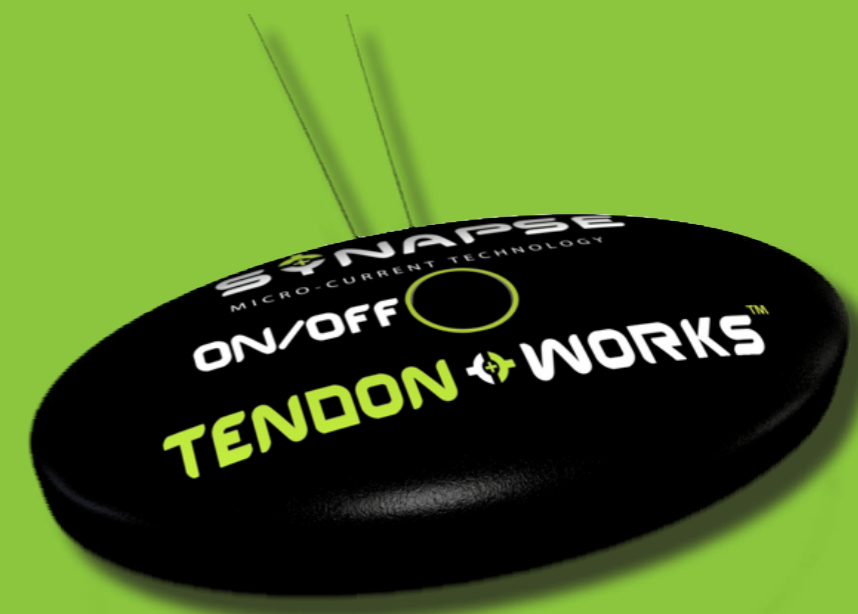
A collection of case studies and papers on Tendonworks[®]



 **SYNAPSE**
MICRO-CURRENT TECHNOLOGY

A CLINICALLY PROVEN METHOD FOR TREATING
DEGENERATIVE TENDON PATHOLOGY

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A CLINICALLY PROVEN METHOD FOR TREATING DEGENERATIVE TENDON PATHOLOGY



Degenerative Achilles Tendon

A 35 year-old rugby player with a long history of degenerative Achilles tendon pathology ruptures his Achilles tendon and returns to play Premier league rugby within five months.




CLINICAL HISTORY

Whilst playing in a Premier League rugby union game this 35-year-old prop forward player 95% ruptured his right Achilles tendon. On May 3rd he was operated on employing a technique that plaited the plantaris tendon into the Achilles tendon. There was evidence of a significant degree of degenerative pathology so the two ends of the damaged Achilles tendon were surgically separated prior to the repair.

A two-week period in a short cast was followed by two weeks in an Air Cast boot. Unfortunately, in a rush to answer his mobile phone whilst undergoing some light exercise in the gym, the player burst the stitches and was back in a cast for four weeks. This ‘accident’ occurred on the 11th June. Holes were cut in the cast for the dual purpose of being able to apply a micro-current treatment to the tendon and also to apply electrodes so that a muscle stimulator may be used. The Synapse micro-current treatment applied to this player was the same as that used for the other case studies.

When the cast was removed the use of the muscle stimulator (Compex) ensured that muscle atrophy was kept to a minimum. Rehabilitation was commenced immediately, which involved mobilising the ankle, working on the tightness of the calf muscles and proprioception exercises. By mid September the player was re-scanned using ultrasound and healing appeared to be progressing at a good rate. At this point the player started jogging. In addition, due to the nature of the pathology it was decided to carry out another two weeks treatment using the same treatment parameters as the original.

In October the player played twenty minutes of a reserve game and had no adverse reaction. A further period of training and conditioning resulted in the player successfully playing a complete eighty-minute game on October 30th four and a half months after the second injury. To date this player continues to play with no adverse effects.

 **Andy Buckley**

A 56 Year old female recreational runner experiencing a long history of bilateral mid portion Achilles pain

CLINICAL HISTORY

This patient presented complaining of an 8 month history of worsening Achilles pain, swelling, morning stiffness and pain upon rising onto her toes limiting her ability to run. She also informed of a previous on/off history of Achilles pain dating back to 1987 whereby she was treated via steroid injections from her doctor. However, this little to resolve her symptoms enforcing a long period of rest away from sport.

INTERVENTION

Consisted of five physical therapy sessions over a six week period combining soft tissue techniques of the calf muscles, calf/Achilles stretching, subtalar joint mobilisations with a progressive eccentric strengthening exercise program and the use of the synapse micro-current tendon works unit. This regime resulted in a marked reduction in pain, swelling, and no morning stiffness. A walk/run program was then initiated slowing increasing distance, speed and time. On most recent presentation, the client informing she is comfortably able to combine walking/running up to 30 minutes.

To date, the client has reported no re-occurrence of symptoms and is regularly running and attending the gym.

TESTIMONIAL

A client of Andy Buckley - Pamela Medlock

'I have been visiting Andy Buckley on and off for a number of years concerning various sporting injuries.

My current visits concern my Achilles tendons. I missed the Julie Rose 10k for the first time in many years (October 2009) and eventually conceded that I needed help. In March I attended physiotherapy.

At the second session of physio Andy made mention of Tendonworks and suggested I looked on the website to make my own mind up. Knowing that there is no quick fix to Achilles tendons I was anxious to try anything that might speed things up and the research looked promising. Considering the cost I was somewhat disappointed that when using Tendonworks I couldn't actually feel anything happening.

The machine was used in conjunction with daily exercises suggested by Andy and regular physiotherapy. However on 14 May I ran, it was only for 20 minutes in chunks of 1 minute jogging and 2 minutes walking. I am delighted to say that I feel fine. This is after less than 2 months of treatment.

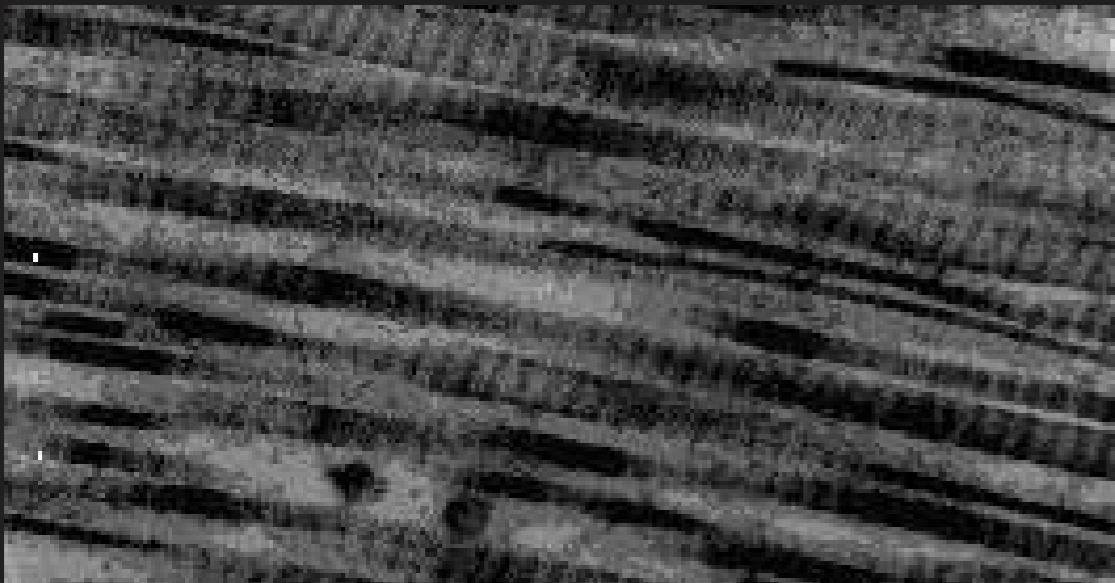
So even if I couldn't feel anything during the Tendonworks® [treatment], obviously something was going on and I am absolutely delighted with the outcome. I would advise that I have been diligent both in the use of the Tendonworks® machine and also with the exercises suggested. I have also attended physiotherapy under the guidance of Andy.

It has worked for me. However, I followed the regime to the letter – there is no quick fix for this injury”.

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Ruptured Achilles Tendon

A 23-year-old, Premier League, International Rugby Union player with ruptured Achilles tendon plays Premier level rugby within five months following the injury.




CLINICAL HISTORY

This player had no previous recorded incidence of Achilles tendon problems. In February 2004 he was charging a ball down in a competitive Premier League rugby union game and upon landing spontaneously ruptured his right Achilles tendon. This was repaired surgically using a fibre wire and Vicryl. He was put in a short cast for eight weeks in 45 degrees of plantar flexion. Following this period he was given a brace and at this point he commenced his treatment. The treatment consisted of introducing into the tendon a uniform, cell calibrated micro-current with the dual purpose of mimicking the normal processes of electro-chemical signal transduction and amplifying mitochondria A.T.P synthesis, which has the reported effect to significantly increase tenocyte activity and hence the capacity and level of the regenerative process.

The aim of the treatment was to boost the production of type I collagen and accelerate the process of spatial fibrillar remodelling to reduce healing time and influence the normal and expected prognosis of Achilles tendon rupture in this type of subject.

Intensive physiotherapy was commenced which had as a priority to increase the range of movement in the tibio-talar joint which had been significantly reduced due to the shortening of the tendon and the length of time the ankle had been fixed in plantar flexion. This was affected to such a degree that a normal walking gait presented a significant problem. Regular musculo-skeletal ultrasound scans demonstrated that the tendon was healing exceptionally well and as a result a more robust rehabilitation programme was adopted concentrating upon building the wasted medial gastrocnemius (using MBT boots), proprioception and mobility exercises.

By pre-season in June 2004 the player was gently running again and by mid-August played twenty minutes of a competitive game with no adverse effect. Two weeks and two games later the subject played a full game and has continued to play all scheduled games to this date (November 2004) with no recurrence of any symptoms. In November the player gained his first full international cap eight months following this severe injury.



Novel Micro-current Treatment

is more effective than conventional therapy for chronic achilles tendonopathy: A randomised controlled trial.
Authors: Dr. David Chapman-Jones & Professor D Hill

Background

The healing processes of tendon tissue are not well understood and are reflected in the difficulty of clinical management of this pathology. Previous in-vitro studies have demonstrated that the application of micro-current has the ability to 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 the study was to evaluate, following the application of micro-current for therapeutic purposes, the functional outcome in patients presenting with chronic pathology in the Achilles tendon in comparison with the current conservative management.

METHOD

A prospective comparison study was undertaken utilising a blocked randomisation method. Subjects were allocated to either group A and were exposed to current clinical management or group B the experimental micro-current regime. Classification and subsequent evaluation of pathology was assessed employing clinical assessment tests, self-assessment and assessment by diagnostic ultrasound. Subjects were assessed at three; six and twelve month intervals post entry into the study.

Forty-eight subjects (48), twenty-four (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. Baseline characteristics were similar in both groups.

CONCLUSION

The application of micro-current treatment to the patient presenting with chronic Achilles tendon pathology may make a significant contribution to the clinical management of the condition. Therefore, because from a biological perspective tendons tend to behave in a similar manner, these findings may reasonably be extended to treat other tendons presenting with similar pathology.

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Outline program of research

with Tendon Research Unit, Manchester University

Led by Karl Kadler.

The aims of the project are:

1. To determine the effects of Synapse micro-current on the alignment, proliferation, gene profile, and migration of tendon cells.
2. To determine the effects of Synapse micro-current on the biomechanics, assembly and turnover of the tendon extracellular matrix.
3. To use the knowledge obtained from Aims 1 and 2, in combination with micro-current and pharmaceuticals, to improve tendon healing beyond what is currently achievable.

Chronic degenerative tendon pathology is one of the hidden problems in medicine affecting a wide range of the population including elite sports competitors, racehorses and the 'everyday' ageing population. Synapse is an ISO 9001 (2008) registered company producing a small range of medical devices (ISO 13485) focusing on regenerative medicine. Two key areas of medicine are targeted: tendon pathology and complicated non-healing venous leg ulcers. Synapse produce a product that uses their patented microcurrent technology to improve tendon healing. However, the molecular and cellular basis for the beneficial effects of microcurrent on tendon biology are unknown. Prof. Karl Kadler is an expert in tendon development and structure, and has developed ex vivo and in vivo models of tendon development and healing. The motivation for this PhD CASE project is to make best use of the cell and animal tendon models in Kadler's laboratory to obtain a mechanistic insight into the beneficial effects of Synapse microcurrent. The hypothesis to be tested by the successful student is, 'Synapse microcurrent improves tendon healing by improving cell alignment and extracellular matrix organisation, thereby improving tendon biomechanics'. The necessary expertise and experimental systems are available at the University of Manchester and within Synapse to provide a strong foundation for a PhD student to test this hypothesis.

The experimental system will be to apply a microcurrent across a living tendon construct, which has been developed by Kadler's group as a cell-based model for studying tendon development and healing (Kapacee et al., Matrix Biology, 2008; Kapacee et al. Matrix Biology 2010; Kalson et al., Matrix Biology 2010; Bayer et al., Biomaterials 2010). The tendon constructs comprise cells (e.g. human mesenchymal stem cells (hMSCs) or adult tendon cells) grown in fixed-length fibrin gels that are anchored to metal posts. The cells replace the fibrin with ordered arrays of collagen fibrils during 7 days in culture and have cellular, ultrastructural, and biomechanical properties similar to tendon. The availability of metal posts at each end of the construct is ideal for making electrical connections. Using available Instron microtensiometer, electron microscopes, spinning disc confocal light microscopes for live-cell imaging, microarray, molecular biology and biochemistry approaches, the PhD student will be able to investigate the effects of microcurrent on cell migration, cell proliferation, ultrastructure, gene profiling and biomechanical properties of the constructs. A variety of microcurrent loading regimes (voltage, current, and power variations) will be correlated with mechanical properties, gene expression, signalling pathways and cell behaviour.

The proposed PhD study will use stem cells and adult tendon cells. The stem cells are hMSCs, which are already available in Kadler's laboratory. hMSCs will be used in year 1. Cells isolated from human patellar tendon and Achilles tendon will be used in Year 2, after we have identified volunteers and obtained ethical permission to isolate the cells. It might be interesting, but not essential, to compare the cellular responses of human and equine cells to microcurrent, as these are the two species in which tendon pathology is clinically relevant. This aspect of the work will be investigated if we are able to obtain equine tendon cells via our veterinary colleagues.

The expected outcomes are to identify the mechanism of how Synapse microcurrent works and to provide new insights into how to improve functional outcomes in affected patients. The final target outcome aims to devise a new and improved method of using Synapse microcurrent in combination with pharmaceuticals to accelerate and improve tendon tissue repair and evaluate if the application has resonance with other similar conditions.

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Micro-current Treatment

of Chronic Tennis Elbow - an exploratory Study

September 2010

Leon Poltawski & Tim Watson

School of Health & Emergency Professions, University of Hertfordshire, UK

Micro-current therapy (MCT) involves the application of usually sub-sensory electric current to the body for therapeutic effect. In some disorders it can both relieve symptoms and promote repair of tissue damage. Two exploratory trials were conducted to compare the effectiveness of four different forms of MCT in the treatment of chronic tennis elbow.

METHODS

Each trial compared two different forms of MCT. All included participants had clinical and sonographic signs of tennis elbow, and had symptoms for at least three months, which had not improved significantly in the previous month. Treatment was daily in most cases (5 days a week for one group) for 3 weeks, and was applied by the participant at home after instruction by the investigator. No other treatment was allowed, apart from ad lib use of analgesic medication and a tennis elbow brace. Outcome measures were pain-free grip strength, pain and functional limitation as measured by the patient-rated tennis elbow evaluation (PRTEE), patient-rated global change, sonographic rating of tendon structural abnormalities and excess blood flow, adverse events and patient acceptability. Assessments were made at baseline and at 3, 6 and 15 weeks later.

RESULTS

61 people completed the treatment. Groups did not differ significantly on baseline characteristics. By final assessment 53 participants had improved, although 8 reported no change. Group A performed best, with 93% reported much better or fully recovered by final assessment, compared to 75% in group C, 73% in group D and 47% in group B. Mean pain-free grip strength and PRTEE scores improved significantly in all groups, with group A performing best on all measures. Differences between it and groups C and D were statistically insignificant, although this may reflect the small sample sizes. There were limited signs of structural normalisation and blood flow changes in all groups. MCT was more successful for those with high baseline blood flow levels, which tended to fall with treatment. Tendon blood flow tended to increase or remain stable in those with lower baseline blood-flow. Signs of healing did not necessarily correlate with symptom changes. Side-effects were rare and minor, usually tingling sensations or reddening of the skin. The treatment was well-regarded by patients and compliance with the protocol was very good.

CONCLUSIONS

Although tennis elbow resolves spontaneously in most people, comparisons with other studies suggests that some of these forms of MCT can accelerate recovery. A monophasic current of amplitude 50 μ A applied for 35 hours over 21 days was the most effective form assessed. A higher current is significantly less effective, and similar size currents with biphasic or mixed waveforms also appear less effective, although the differences are smaller and may also reflect different treatment durations. There is limited evidence that MCT affects tendon blood flow, the effect depending on baseline flow levels. These levels appear prognostic of treatment outcome, and may reflect the stage of healing of the tendon. Longer treatment times and combination with an exercise programme may enhance treatment effects, and a full-scale controlled clinical trial using such a protocol is justified.



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