NEWS : ISEPA WEB PAGES HOSTED

Some of you may recall that I have mentioned the formation of the International Society for Electro Physical Agents (at a meeting in February in Las Vegas). For the moment, the ISEPA web pages are hosts on the www.electrotherapy.org site – so you can freely access the information available and follow what is happening. At some point in the future, ISEPA will have its own website – probably linked with WCPT, but until that time, I am happy to accommodate.

NEWS : SPANISH EDITION OF ELECTROTHERAPY : EVIDENCE BASED PRACTICE

Elsevier have now done a translation of this text into Spanish – full details available on the web pages – go to the BOOKS page from the main menu. I gather that a Portuguese and possibly others are planned – will let you know as soon as I have any further updates.

NEWS : MICROCURRENT REVIEW

I have mentioned Microcurrent Therapy in several previous issues and have been looking at the literature on it since I was looking at endogenous bioelectric issues back in the late 1980’s. A new paper out by Leon Poltawski (one of my PhD students) and myself – which I will not review in detail in the normal sections of the newsletter – has just come out in Physical Therapy Reviews (Poltawski, L. and T. Watson (2009). “Bioelectricity and microcurrent therapy for tissue healing - a narrative review.” Physical Therapy Reviews 14(2): 104-114). As the title would suggest, the review looks specifically at the evidence for (and against) the use of this therapy in relation to tissue repair – it is also used clinically for pain management but this aspect is not covered in the review. This is an potentially underutilised therapy – I think because many practitioners think that current THAT small can’t be actually doing anything – or maybe it is simple a matter of awareness? Anyway, the review should prove interesting for those of you who already use microcurrent type treatments, those wanting an overview of what it does and those with an interest in endogenous bioelectrics and their relation to tissue repair.
NEWS : NHS Evidence Web Site
Sure that this will not be news to many of the you in the NHS in the UK, but for those of you overseas and for those of you not directly employed by the Health Service, you may be interested to try the following link : www.evidence.nhs.uk : which offers the facility to search for evidence using key words or phrases. I know that there are a lot of sites out there that do thin kind of thing, but you never can have too many links to source the evidence . . .

Contents :

General Electrotherapy     Electrophysical Agents and the Curriculum
                           Electrophysical Agents and the Evidence
Ultrasound                Ultrasound and Fracture Healing
Magnetic Therapy          Magnetic Wrap and OA Knee
                           Magnetic Field Therapy – Review
PEMF                     Pulsed Electromagnetic Fields and phantom limb pain
Shockwave Therapy         Shockwave therapy and plantar fascitis
Electrical Stimulation   Dose responses with TENS : A Review of Reviews
                           Electrical stimulation and OA knee
                           Muscle stimulation and bone loss
Bioelectrics              Mechanical transduction and bioelectric field strength
                           Electrical properties of acupuncture points and meridians
Vibration therapy         Whole body vibration and bone density
                           Whole body vibration and physiological effects
Tissue and Repair         Trigger point inflammation
                           Achilles tendinopathy : exercise and brace research
                           TA microcirculation and cryotherapy
                           TA microcirculation and tissue loading
                           Eccentric exercises and Achilles tendinopathy

There were several papers in a recent edition of Physical Therapy Reviews – to coincide with the ISEPA conference meeting in the USA earlier this year. I mentioned a couple in the last edition, and a couple more coming up here. The ISEPA web pages are currently hosted on my own web site (till we have a web place of our own) : follow the ISEPA link from the top menu.

Electro Physical Agents and the Curriculum
Lucy Chipchase – whose name has appeared several times in this newsletter - presents a paper in the journal looking at the increasing complexity of the electro physical agents (EPA’s) available to therapists and how this might be rationalised with a crowded curriculum, a difficult evidence base and current trends in clinical practice (Chipchase, L. S. et al. (2008). “A framework for determining curricular content of entry level physiotherapy programmes: electrophysical agents as a case study " Physical Therapy Reviews 13(6): 386-394). The authors argue that although EPA’s were historically a mainstay in physiotherapy, the increasing use of manual therapy and exercise therapy in the clinical environment has resulted in a need to rethink the EPA curriculum, primarily in terms of content. It does not specifically deal with the complex issues of the style of delivery which, I would suggest, deserves a similar evaluation at some point.
The paper provides a brief but interesting historical view of EPA use in therapy as a component of core practice, going on to look at teaching of EPA’s in entry level education programmes. Although based in Australia, a wider international perspective is taken where possible. The next two sections provide some fascinating material – looking at the relationships between current clinical practice and the curricula and then looking at the relationship between the research evidence and the curricula, ending with some suggestions regarding a way forward. This is a valuable paper for those involved not only with EPA education, but also those in clinical practice considering the relations between the evidence and practice. I have been banging on about this stuff for ages, so I found it refreshing to read that somebody else has looked at the issue, and come up with some great material.

The authors also suggest, way back at the start of the paper, that EPA’s are used as an example in the paper – the same principles **could** be applied (and probably **should** be applied) in other therapy practice areas. One of the suggestions in the ‘way forward’ section is that an international approach would be beneficial – and indeed, I would suggest that the recently formed ISEPA (International Society for Electro Physical Agents) might just be able to fulfil that role.

Nice paper, great overview and well worth a read – not just for those in education – many clinicians – and especially those involved in the education of students on practice – would gain from a read I would suggest.

**Electrophysical Agents and the Evidence**

Val Robertson – who also gets mentioned in almost every issue – provides an interesting evaluation of some key issues when considering the relationships between clinical practice with EPA’s and the published evidence for the same. The paper, *(Robertson, V. J. (2008). "Electrophysical agents and research: from instinct to evidence " Physical Therapy Reviews 13(6): 377-385)* only focuses on two modalities – ultrasound and microwave – as examples to illustrate the thesis – that clinical practice is often based on ‘not’ the evidence. If you thought (from the title) that this paper was going to review the whole topic – well, it doesn’t, and there is no way you could do that given the limits of a journal paper – one would struggle to get that done in a whole book without having to leave some stuff out!

Anyway, the summary of the content goes something like this (though Val makes a much more comprehensive and well argued case than my few lines here!) : Microwave is rarely used in clinical practice, but actually has a substantial amount of quality research to support its application in some clinical settings. Ultrasound on the other hand, is very widely used, yet is less strongly supported by clinical evidence – so the claims made by therapists that they are delivering ‘evidence based care’ is not so well founded as might be thought.

I might take issue with some of the finer details BUT in essence, I spend a LOT of time looking through the breadth and depth of the EPA literature (hence the newsletter), and I also spend a lot of time out there talking to practicing therapists about EPA’s – and I absolutely agree that current practice is not (generally) well founded on the available evidence. It is based on historical norms, words of mouth and a lot of anecdotal evidence. There is of course, nothing ‘wrong’ with anecdotal and experiential evidence – it is important in any practice – so please don’t think that I am saying that we should ONLY do what is published in RCT’s etc etc – BUT there are some areas of EPA usage which ARE evidenced but RARELY practiced. I would suggest that microwave therapy is infrequently available (in the UK at least) based on modality availability surveys. Robertson notes exactly the same issue. Most therapists assume that the modality has been largely abandoned in the physiotherapy world due to either (a) a lack of evidence to support it or (b) no evidence is available – neither of which are in fact true.
Do read this paper. It makes a good argument and uses Ultrasound and Microwave therapies as a means of illustrating the points made. I find, in a similar way, that many therapists are shocked to hear of the supportive evidence for some other interventions (like NMES for example) which has some VERY supportive research evidence and yet many therapists consider it to be ‘old fashioned’ – like the old application of Faradism – and rarely used in some practice areas. There is a disparity between the published evidence and clinical practice. I would suggest (Val refrains from doing so) that this is true in other practice areas – not just EPA’s, but the argument and well presented, coherent, and deserves consideration.

**Ultrasound and Fracture Healing**

Again, I get to mention this in most issues of the newsletter, and when I put up a set of recent references on the web page looking at the published evidence, most people were surprised just how much of it there is out there – so lets add another one! The lead author on this particular paper (Rutten – based in Holland) has published in this area previously, as have some of the others on the authorship list. The paper in a recent issue of the journal Bone (Rutten, S. et al. (2008). "Low-intensity pulsed ultrasound increases bone volume, osteoid thickness and mineral apposition rate in the area of fracture healing in patients with a delayed union of the osteotomized fibula." Bone 43(2): 348-54) looks at data obtained from a clinical RCT comparing the progress of delayed union of the osteotomised fibula. Thirteen patients were recruited, all of whom had a delay in the fibular union following a high tibial osteotomy. The aim of the study was to try and further identify the mechanism through which the LIPUS is effective (something which remains poorly understood). The introduction, although necessarily brief, actually provides a succinct summary of the current state of the art and makes for a very useful 5 minute read for anybody wanting to catch up with where we are in the knowledge, and would rather read something from a group of experts in the field rather than just the stuff on my web pages (where the is a LOT about LIPUS for enhanced fracture healing).

The 13 patients were divided into n = 7 in the LIPUS group and n = 6 in the control group. All patients had a high tibial osteotomy (for OA) and at the 6 month follow up, were recruited to the trial if the fibula osteotomy (which is renown for delayed union) if radiological healing was not evident. The control group in this case received a sham LIPUS intervention (as opposed to ‘nothing’). The LIPUS was delivered in the standard way (described in the paper and on the web pages if you want it) but essentially was 20 minutes daily at 30mW cm-2 @ 1.5 MHz using the Exogen device. Group allocation was blinded and the intervention was of 5 months duration. Full details are provided in the paper.

There were several outcomes employed, via a biopsy taken 2 – 4 months following the start of the treatment. A 2.5mm drilled biopsy was taken and subjected to histological analysis. (detailed provided). There were several areas of interest – namely, the new bone formation zone, an area of cancellous and an area of cortical bone. The bone density and metabolic activity was noted at each and in addition, the angiogenic activity was noted by assessing the number of blood vessels in the area.

There are a lot of results, but they summarise thus : There was a 47% greater osteoid thickness in the treated samples compared with the placebos and there was also an increased bone volume (by 33%) and greater mineralised volume (34%) in the treated samples. There were no more osteocytes in the treated samples. The rate of bone formation was 27% greater in the treated group (statistically significant), and the blood vessel numbers were marginally greater in the treated samples, but this was not statistically significant (8%). The cancellous areas of the sample showed greater bone volume and mineralisation than the controls whilst other values were not significantly different. In the cortical bone sample, there were no major differences between treated and controls, and those differences that were identified are detailed.

The discussion provides some interesting analysis and comment. The results suggest that the mechanism of LIPUS in this clinical arena includes increasing bone formation through increased osteoblast activity. The
new bone formation was significantly greater in the treated group, though the number of blood vessels was not (the angiogenic response) which would suggest (according to the authors) that any increase in local blood flow is not directly related to new vessel formation (this is a brief summary of an extensive discussion – go read the original – it is worth it). The authors conclude that the demonstrated advantage in the treatment group is achieved by increasing osteoid thickness, the rate of mineral deposition and greater bone volume. Increased stability and blood flow was apparent, but probably not a marked difference in angiogenesis.

The laboratory and clinical evidence to support the use of LIPUS in various types of fracture healing has been established over the last 10 – 15 years. This paper adds to the knowledge in this area by clarifying the mechanism(s) through which the modality may be operating.

**Magnetic Therapy : Magnetic Wrap and OA Knee**

There is a growing interest in the field of magnetic therapy, though many remain sceptical that it is anything other than a placebo or gimmick treatment method. I am not trying to either support or trash this line of treatment, but report a couple of trials that might be of interest. One of the biggest problems that I can see with magnetic as a treatment, other than the lack of some decent trials, is the issue of dose – i.e. the amount of applied energy and under what conditions. The first paper by a group from Taiwan (Chen, C. Y. et al. (2008). "Effect of magnetic knee wrap on quadriceps strength in patients with symptomatic knee osteoarthritis." Arch Phys Med Rehabil 89(12): 2258-64) considers the effect of a magnetic knee wrap for patients with symptomatic OA knee (but I guess you could have spotted that from the title!!). This was a clinical trial, and it was an RCT design (which should tick a couple of ‘good’ boxes for those of you out there who worry about some quality control issues in electrotherapy research). There were 50 patients recruited to the trial, who presented with mild or moderate OA knee (mean age of 66) though only 37 completed. The intervention period was for 12 weeks and patients were allocated to either a treatment (n=24) or a sham (n=26) group. Although the main outcome measure was isometric strength of the quads, secondary measures were taken using the Health Assessment Questionnaire Disability Index (HAQ-DI) and the Health Assessment Questionnaire Pain Scale. The authors argue that although various electromagnetic field treatments have been shown to be effective with this patient group, there are cost and access implications. The alternative method is to use permanent magnets and thereby a static magnetic field, and this is the area where I think that there is most scepticism.

The inclusion and exclusion criteria are identified and rationalised. The knee wrap (real or placebo) was worn over the affected knee for 12 weeks (using the worse knee if bilateral problem). The wrap was worn while awake (except for bathing) and some basic compliance was also recorded. Interestingly, exercise and other physical activity was ‘prohibited’ during the treatment phase – I can appreciate why from an experimental control perspective – though it may seem irrational from a clinical perspective. Physical activity and drug intake were kept as constant as possible. The randomisation and blinding procedures are detailed in the paper. The knee wrap used was a commercial device and there is not a lot of detail provided with regards its technical specification other than the magnetic field strength (measured rather than manufacturers claim) which was at 35mT on the knee wrap surface. This is a short distance field in that by 17mm from the wrap, the field was no stronger than the ambient field. The application of the outcome measures is described, with the isokinetic quadriceps strength being tested with a Biodex device at both 30 and 60 degrees a second angular motion. The group sizes were informed by an a priori power calculation, and analysis was based on an intention to treat analysis (detailed).
Although 13 patients withdrew from the trial (i.e. did not complete), only 2 of these reported that it was because they thought the treatment ineffective. The profile of those who withdrew was not significantly different from those that remained. A consort type diagram is included so that the reader can follow all subjects through the process.

There was no significant difference between the groups at baseline measure. There was a significant increase in the quadriceps strength at both 30 and 60 degrees a second. The strength changes are detailed in the results section, but the key issue is that there were no significant strength changes in the control group, whilst in the treatment group, the changes were already apparent by 1 week into the trial. The changes in HAQ-DI scores decreased in both groups (i.e. got better) but the changes were significantly greater in the treatment compared with the control group at week 12. There was a trend for the pain scores to be better in the treatment group at week 12, though this did not reach statistical significance (\(p=0.063\)). The basic compliance measures did not identify any significant differences in use between the groups, though looking at the median and ranges for the two suggest (to me) that the treatment group appear to have used the wrap for less hours a day on average than the control group – but this was a very basic compliance outcome measure, and I would not personally hold a lot of store by the results). There are some additional and interesting results for which you will need to go find the original paper.

There is a useful discussion with several interesting and valid points raised. My own expectation was (before getting to the full results) that the knee wrap would bring about a differential pain relief between the treatment and sham groups, and this was likely if anything, to explain the differences in quadriceps strength changes measures. The fact that the quads changes appear to be of a greater magnitude than the pain relief does not actually help to clarify the mechanism for the clinically significant changes in patient status observed in this trial. It certainly adds to the slowly growing body of evidence that static magnetic therapy may have a real effect beyond the placebo. Whether it is ‘better’ than using electromagnetic fields as a method to deliver the energy remain to be seen, but in circumstances where resources are limited, this treatment option might enable patients to take away a device which has a useful effect in mild and moderate OA knee. There is plenty to be followed up on in this work, and the authors acknowledge some of the trial limitations. The work does however provide useful additional data to extend our existing knowledge in this field.

**Magnetic Field Therapy – Review**

Review papers are always welcomed in that somebody has the glorious task of trawling through the literature and pulling together an objective consideration of what is out there (this is something that I actually quite enjoy doing, but I do appreciate that for many it is simply too time consuming to be doing for topic after topic). Anyway, Colbert et al (based in the USA) have had a review just published which looks at static magnetic fields as a therapy and offers a critical review of that old chestnut – treatment parameters (Colbert, A. P. et al. (2009). "Static magnetic field therapy: a critical review of treatment parameters." Evid Based Complement Alternat Med 6(2): 133-9). As I mentioned in the previous section, static magnetic fields get a critical and sceptical audience all hot under the collar in that it is argued that they are not capable of having sufficient therapeutic effect (unless dynamic, pulsed or in some other way made to vary). The review (it is only 5 pages plus references – and is freely available so far as I can see – no subscription needed) concentrates on summarising research conducted on human subjects (leaves out the animal, cellular and lab work) and includes both patient oriented and normal subject related trials. Having searched a lot of databas-
es etc, the authors come up with 56 studies that they reviewed (42 patient related and 14 healthy subjects). They describe their search and review method, and their key information: the reported treatment parameters. Here is another old favourite of this newsletter – it is the treatment parameters, machine output and various settings that are so often incompletely reported – certainly not adequate for replication of the trial, but neither are the reports adequate to enable further meta-analysis. This is a great shame – if somebody goes to the effort of conducting some research in an area, and then goes to the trouble of getting it published, it would be SO much more useful if sufficient data/parameters were included in the report to enable the work to be taken further. In this case, almost two thirds of the reviewed papers carry insufficient critical information.

Given the lack of sufficient detail, the authors work through an analysis of 10 key treatment issues relating to magnetic field therapy rather than working through the results of the trials – which would be all but impossible given the lack of detail. The paper was actually written in 2007, so although it is a 2009 publication, the last couple of years worth of data will be necessarily ‘missing’.

Papers were scored using a quality grading system (described) giving a maximum score of 20. There were three reviewers (a clinician/researcher a biophysicist and a product developer). Thirty nine different clinical pathologies were identified from the 42 clinical papers, with OA knee being the most ‘popular’. The majority of the clinical trials were of an RCT type design. Only 2 studies of the 56 described all the parameters (10) in sufficient detail and therefore achieved the max 20/20 score. It would seem that the worst reported elements were associated with the magnetic device itself (field strength etc) whilst the more clinically biased parameters (how many sessions, duration etc) were more commonly reported.

The discussion provides some useful information and will be particularly relevant to those doing research relating to static magnetic therapy (gives a checklist of parameters that should be recorded and reported) and also to those consulting the magnetic field therapy literature – it gives you some points to look for and to note if they are not there.

I am sorry if this paper does not actually do what you were hoping for – a full evaluation of treatment parameters in this emerging therapeutic field – but I guess the reason for it not delivering is, as the authors illustrate, in the main because there is insufficient information available in the publications to make that a realistic possibility. Read, enjoy and make the most of a lot of work done.

**Pulsed Electromagnetic Fields and Phantom Limb Pain**

This is a paper that was from last year, but I did not report it then, so have taken the liberty of including it in this issue even though we are half way through the year. Wilkes et al (from the USA) provide a case study, and while it involves the application of radiofrequency energy, this is not the type of application that most of you are likely to be involved with – this is a high dose application, and in fact something that I have reported on a couple of times over the last few years (Wilkes, D. et al. (2008). "Pulsed radiofrequency treatment of lower extremity phantom limb pain." Clin J Pain 24(8): 736-9).

Phantom limb pain is widely reported post amputation and there are a lot of pain management approaches employed (briefly outlined). TENS is one that I do have some experience of, but the majority of treatment approaches involve drug therapy or nerve blocks. There was one fascinating piece of info in the introduction to this paper – the results from a survey of American veterans with phantom limb pain, showing that only 1% reported sustained benefit from any treatment. Maybe I was just unaware of the apparent lack of efficacy of treatment for this problem.
Anyway, this ‘case’ was from a 63 year old woman who ended up with an above knee amputation (a revision following an earlier below knee). The last surgery was 4 years prior to the currently described intervention. She presented with a complex and ongoing pain history (described), but essentially had both stump and phantom pain, stump neuroma and significant disruption to her daily living activities.

Radiofrequency treatment was of the non destructive type which uses short bursts of RF energy, resulting in a heat build up in the target tissue which dissipates between pulses (very similar in that sense to a pulsed shortwave application – but at higher energy). The patients ongoing management is summarised and discussed. Following a temporary improvement with local nerve block, the pulsed radiofrequency treatment was applied to her sciatic nerve (using 120 second duration, temperature of 42 C using pulses of 20ms delivered at 2Hz. She reported complete pain relief post procedure, and at 1 month follow up remained free of the phantom limb pain and weaned herself off medication. By 4 months there was some return and the procedure was repeated.

Although this particular intervention is not one that is in the repertoire of most therapists (it is effective classed as a ‘medical/surgical’ type intervention, it is (a) interesting to see how effective it was compared with the normal treatment and (b) presents an interesting opportunity to carry out some research with therapy type pulsed shortwave devices to see if they can have a significant clinical effect at even lower doses?

The discussion includes some review of current thinking on phantom limb phenomena and also discusses the possible mechanism whereby the pulsed radiofrequency treatment might be effective (the exact mechanisms are certainly not yet known).

**Shockwave therapy and plantar fasciitis**

Another popular topic in terms of the newsletter – and given the increasing volume of evidence out there in relation to Shockwave as a therapy, you may have found some of the summary info and pages that I have now put up onto the web site (go the MODALITIES from the main menu and scroll down from there). This paper from a research group based in Germany describes a multicentered RCT looking at shockwave therapy for chronic plantar fasciitis (Gerdesmeyer, L. et al. (2008). "Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study." Am J Sports Med 36(11): 2100-9).

The trial involved substantial patient numbers (n=245) and essentially compared a treatment group with a placebo group. The initial proposition is that although shockwave is considered to be effective, there was a need for a large scale RCT style trial to provide better quality evidence. Further more, it is argued that a high proportion of this patient group ‘recover’ either spontaneously or with conventional therapy (cited at around 90%). It is the recalcitrant lesions that are problematic, and they are the target of this research – the most problematic cases. There are several different types of shockwave application, and this one (radial shockwave) has a smaller penetration into the tissues than the focal shockwave treatments (summary on the web pages if you want them).

The way to get these high patient numbers is to employ a multicentre design (in this case 3 centres in the USA and 5 in Europe. The patient allocation, randomisation and blinding (patient and researcher doing the
assessments) are described. All patients had at least a 6 month history and a condition that had not responded to conventional treatment. There is a comprehensive flowchart of all recruits and participants (page 2102) which is a quick and easy way to follow the trial from recruitment to final follow up. Group allocations were 129 in the treatment group and 122 in the placebo group. There were 3 treatment sessions (real or placebo) 2 weeks apart, and patients were followed up at 12 weeks post final treatment and then again at a year post final treatment – so we have decent numbers and a useful follow up period.

The details of the applied shockwave are included in the paper, but essentially, this involved 2000 shocks per session delivered at 8 shocks per second. The placebo unit was designed to look identical, and importantly, make the same ‘noise’ as the real thing. Some shockwave treatments (the high powered ones) need a local anaesthetic, but this intervention was an outpatient treatment without anaesthetic delivered either by an orthopaedic surgeon or podiatrist.

The outcome measures are fully detailed in the paper, and I will briefly summarise them here: The primary outcome was based on a composite VAS pain score (3 elements – heel pain on first steps in the morning, heel pain on daily activity, heel pain in response to a standard local pressure) which is described in detail together with missing data management. These measures were taken at the 12 week and the 12 month follow ups. Treatment success was also recorded, and the patients that were followed through to the 12 month period were those who were deemed to have achieved a successful outcome at 12 weeks (allowing those who did not get a ‘good’ result to pursue other treatments). There were a raft of secondary outcomes which included the Roles and Maudsley score, SF-36, the investigators judgement of effectiveness, patient view of treatment satisfaction and whether they would recommend the treatment to a friend (which I thought was an interesting one). There is a useful section on statistical analysis, power (90% on primary outcome) and data management processes.

The results showed that the two groups were no different in terms of demographics or clinical condition at baseline. The VAS scores showed a significant reduction in pain for the treatment group over the placebo group at 12 weeks and at 12 months. For example, at 12 weeks, the treatment group had a 72% reduction in pain score compared with a 45% reduction in the placebo group. At the 12 month stage these were scored at 85% reduction in the treatment group and 43% reduction in the placebo group. All primary and all secondary outcomes were significantly better in the treatment group compared with the placebo group. Over 90% of the treatment group patients would recommend the intervention to a friend (I do like that outcome – think I might use it in future for something . . . .). The reported adverse effects seem to concentrate on pain and/or discomfort during the treatment and for a limited period thereafter (minutes rather than anything worse than that).

There is a well constructed discussion with some useful comparison with previous work and results. The big differences between this work and some previous trials appears to be (a) the application of the therapy at the point of maximum tenderness – as opposed to application at a ‘fixed’ point for everybody and (b) the application of the radial shockwave therapy requiring no anaesthesia – which appears to be more effective than the stronger shockwave needing local anaesthetic. Finally, the study WAS ‘sponsored’ but a company that make the shockwave device and some of the authors were supported by that company BUT there are clear declarations of these associations and a categorical statement that the company did not influence data collection, analysis or publication.

This is a quality trial in my view. It is strongly supportive of the therapy over a placebo intervention. The authors have been careful in their design and have also been careful in their reporting of the process and their research method including the bits that people often miss out – like how they handled missing data etc. There are criticisms that one could make, but this is good evidence coming from a well constructed piece of
research and a ‘must read’ for those with an interest in plantar fasciitis, shockwave or recalcitrant lesions – or for those who want to read how a well done RCT can be presented.

**Dose responses with TENS : A Review of Reviews**

There seem to be an increasing number of systematic reviews in the field of TENS, and somebody comment-ed in a recent discussion that we will soon have more reviews that we have original RCT papers! This is a re-view of systematic reviews presented by Claydon (from NZ) and Chesterton (from the UK). It raises some interesting points and also highlights some issues that I am very pleased to see in print at last – namely that some systematic review methodology could be flawed in that it does not take any account of the applied dose of the intervention – in other words an RCT could score VERY highly on an RCT score system (because they describe all the right things) BUT if they delivered an ineffective dose, there is no account taken in the review method – so you could end up with a highly ranked paper which delivered what is in effect a totally ineffective treatment dose. The result is (in my view) that the systematic review can come to the conclusion that TENS is ineffective but that might not be the right conclusion. I know I am not alone in these concerns, and it would appear that Claydon and Chesterton are expressing something similar (Claydon, L. S. and L. S. Chesterton (2008). "Does transcutaneous electrical nerve stimulation (TENS) produce 'dose-responses'? A review of systematic reviews on chronic pain " Physical Therapy Reviews 13(6): 450-463).

OK, so back to the paper which sets out to review the existing systematic reviews which look at the efficacy of TENS for chronic pain relief with a particular emphasis on dose related effects.

The results (in short) were that they identified 6 reviews, two of which identified that high intensity TENS was more effective than low intensity TENS when compared with placebo application, though the authors raise some points about existing trial quality and review methodology which need to be taken into account when designing future RCT’s or systematic reviews.

This review of reviews type activity has been carried out previously (the often cited paper by Sloka and Walsh in 2003 for example) but have been largely inconclusive due the methodological issues with the reviewed trials. Given that more evidence has been published in the period since the 2003 paper, Claydon and Chesterton set out to include the more recent materials.

The inclusion and exclusion rationale is identified together with the applied methodology for the review. 6 review papers were identified though as previously, it was noted that the wide range of outcome measures employed makes meta-analysis problematic. The VAS and NRS pain scales are the preferred method of assessing pain as a clinical phenomenon in chronic pain studies, and if researchers want/need to use other recording methods, one might be so bold as to suggest that they should be done in addition to the VAS/NRS systems. The ‘score’ of the trials included in the reviews was not that impressive (ranging from 1.9 to 3.5 out of 5) though none of the trials appear to have been excluded on the basis of low methodological quality. It appears the the reviews were equally split between positive and negative findings. The papers reviewing TENS for chronic pain, chronic low back pain and rheumatoid arthritis were inconclusive (this may have something to do with the recent NICE decision not to support TENS in the management of low back pain). The other three reviews (looking at chronic musculoskeletal pain and OA knee) concluded that there was a positive effect of the therapy.

This (Claydon and Chesterton) paper goes on to look at specific clinical problems and TENS (RA hand, chronic low back pain, OA knee and Chronic pain). They also go on to look in some considerable detail at the breakdown between positive and negative trial outcomes against the high and low quality trial methodology.
The discussion is useful and is a MUST read for anybody involved in TENS (or similar) research and for those looking at RCT methodology issues (even if you do not agree with all the ideas and conclusions). For example, only 5 of the 24 RCT’s reported in all the reviews had a sample size which gave adequate statistical power to detect a large treatment effect – this is critical. It is great to do research in the clinical arena, but to go to the effort of setting up an RCT and then not to recruit adequate patient numbers is a great shame. The results are under powered and the conclusions may not be entirely correct. The fact that these underpowered trials are then included in the subsequent systematic reviews further compounds the error. It is pointed out (in case you think that I am trying to hide it) that of the high quality trials that had sufficient power (n=5) showed negative results. The smaller (underpowered) trials had a greater tendency to provide positive findings.

This review paper then goes on to look at outcome measure issues and dose responses, again looking at the differences in outcomes between low and high quality trials and between underpowered and sufficiently powered papers. In the dose response section, the authors suggest that when looking at sufficiently powered trials (RCT’s), both high intensity, high frequency TENS applied locally and low frequency, high intensity TENS applied at a remote location produce a large hypoalgesic effect.

There are SO many problems with the research methodology (of the original trials and the subsequent systematic reviews) that the only (obvious) conclusion is that more work is needed BUT the additional work needs to be of sufficient quality and power to enable ‘safe’ conclusions to be reached. The authors of this paper have made considerable effort to analyse not only the original trials but also the quality of the systematic reviews carried out to date. The point that they make is that a systematic review can come to an ‘unsafe’ conclusion (my words, not theirs) but not taking into account all the relevant factors, and hence one should remain cautious when reading such a review. There are serious implications for researchers and methodologists which are worthy of consideration.

**Electrical stimulation and OA knee**

SO, lets move away from reviews of reviews, and even RCT’s, and have a look at a series of case reports looking at the effectiveness of electrical stimulation for OA knee (Fary, R. E. et al. (2009). "Effectiveness of pulsed electrical stimulation in the management of osteoarthritis of the knee: Three case reports." *Physiotherapy Theory and Practice* 25(1): 21-29). The research group (based in Australia) look at the effect of sub sensory pulsed electrical stimulation (which they term ‘PES’) taking into consideration symptoms and functional change.

The authors argue that although one can use electrical stimulation effectively with OA knee, the majority of the work done so far has been primarily concerned with pain relief. There is a suggestion from the growing
body of experimental literature that it may be possible to have an effect on the disease process (i.e. not just the pain) but that this would involve long term stimulation, and therefore these case studies were undertaken in order to establish whether there were short term symptomatic results and to also consider compliance and comfort issues – as a means of trying to establish whether longer term stimulation (months) would be a viable option.

The treatment in these cases was delivered over a 16 week period for n=3 patients (2 x F; 1 x M) all aged over 60 with confirmed OA knee. Two of the patients had a bilateral presentation, and they were asked to select their ‘worse’ joint. Some background data on each of the three patients is provided in the paper.

The stimulation was delivered using a commercially available, portable (battery powered) device which has been used in previous studies. The machine output (described by the manufacturers – not sure whether these authors actually tested the output) is: a pulsed monophasic stimulation with an exponentially decaying pulse of 2ms duration. The stimulation is delivered at 100Hz using skin surface electrodes and conductive gel. The electrodes are held in place with a Neoprene wrap, with one electrode (cathode) placed over the anterior patella and one (anode) over the anterior thigh. The intensity was determined by turning up to a sensory level and then reducing until the sensation was no longer felt. Patients were advised to use the device for at least 8 hours a day, and it was advised to do this at night (for convenience). A compliance meter built into the device recorded actual usage.

Outcome measures were numerous, recorded at baseline, 4 and 16 weeks (pain, function, global assessment and quality of life) whilst others were recorded less frequently (ambulatory activity levels (0 and 16 weeks) and global perceived effects (16 weeks only). Pain was recorded using a VAS scale. Function with a questionnaire, though there was no comment regarding its derivation or established validity/reliability with this population. Patient global assessment used an established scale as did quality of life (QoL) – the SF36 and the perceived global effect scale. A small accelerometer was used to measure physical activity, and this has also been previously employed in such trials.

Even though this was a small study (with n=3) there are a lot of results (detailed in the paper). In summary, two of the three patients reported being considerably better after the 16 weeks of therapy, whilst one patient reported no overall change in condition. Clearly much more detail is available in the results section.

The usage (compliance) is recorded at between 562 and 915 hours over the 16 week period (8 hours a day for 16 weeks gives just under 900 hours use). No problems were reported with machine use and tolerance appears to be good.

The trial did not set out to establish whether this was an effective therapy or whether it achieved disease modification. It did set out to see whether there was any benefit (on multiple scales) and whether there was patient compliance and tolerance. The intervention did appear to be effective in 2 of the three patients. It was well tolerated and therefore there appears to be a justification for running a well controlled RCT – something which one looks forward to reading all about.

Muscle stimulation and bone loss

I get frequently asked about the potential value of various electrotherapy modalities in terms of osteoporosis and associated bone loss problems – and at the moment, there is a raft of evidence, but nothing conclusive that I have seen in the clinical research literature (though, as ever, I may have missed it). Anyway here we have a fascinating report concerned with the potential benefit of electrical muscle stimulation as a means of limiting bone loss – though it is a lab study on rats – so don’t get THAT excited about treating your
osteoporotic patients – it may well work, but this is not a clinical trial in humans – but never the less, this is interesting and potentially valuable stuff.

The researchers (based in New York) have published in Bone (Lam, H. and Y. X. Qin (2008). "The effects of frequency-dependent dynamic muscle stimulation on inhibition of trabecular bone loss in a disuse model." Bone 43(6): 1093-100) and I will provide a brief summary of their work. Their stated objective was to evaluate the effect of dynamic muscle stimulation on disuse atrophy of trabecular bone and furthermore to look at the effect (if any) of different stimulation parameters (frequency). The work was completed using rats, and an established ‘model’ for bringing on a disuse atrophy (using hindlimb suspension). 56 rats were divided into 7 groups. One (the control) got only the hindlimb suspension. The others received muscle stimulation at varying frequencies (1, 20, 50 or 100Hz) for 10 minutes a day, 5 days a week for 4 weeks. Analysis was performed of both metaphysis and epiphysial regions of the distal femur using tomography and histomorphology.

The authors pain a succinct but useful background picture rationalising why this approach might be useful and a summary of some of the key previous work in this field (worth a reads in its own right).

The method for the hindlimb suspension method is described. The groups (4 of them) which received the stimulation were anaesthetised during the 10 min stim period, and electrodes were applied to upper and lower lateral quads. The stim (at the appropriate frequency) was applied in a 2 sec on : 8 sec off protocol to minimise fatigue. The stimulation itself was very simple (1ms square wave pulse) at 1 or 20 or 50 or 100Hz. The animals were sacrificed at 4 weeks and the lower femur was subjected to both tomographic and histomorphologic testing (full details provided – I will not replicate them here) though there were 3 different metaphyseal test zones and one epiphysial test area. There was a significant body weight loss in all the test groups, but it was no different in the suspension without stimulation vs the suspension with stimulation groups.

In the metaphyseal regions of the distal femur, there was significant trabecular bone loss (quality and quantity) in the control groups. The animals in the stimulation groups showed highly significant improvement in bone state, though this was much less apparent with the 1Hz stimulation, and although the 100Hz stim group were better off than the controls, this was not significant. Looking at all the bone regions tested, the 50Hz stimulation appears to have produced the ‘best’ results of the 4 stimulation options. The data showed therefore that what the authors call ‘mid range’ stimulation (the 20 and the 50Hz) was capable of preserving bone mass, trabecular number and connectivity. There is a useful consideration of the mechanism in the discussion. It is strongly possible (from this and other studies that I have read) that the induced muscle contraction produces a physical force on the bone and this is the likely mediator of the observed effect. There are some limitations of this particular work – mainly that they looked at bone formation and did not look at bone reabsorption (authors acknowledged) but at the end of the day, this provides some very useful lab based data looking at the potential benefit of muscle stimulation as a means of tackling osteopenia. I can think of a dozen clinical trials as a follow up to this one – and I am sure that we will see some coming through in the reasonably near future.

**Mechanical transduction and bioelectric field strength**

For those of you who have heard me talk on the tissue repair study days or who have read some of the stuff that I have published on tissue bioelectrics, will know of my ongoing interest in this field. This paper (which you may have missed unless you were going hunting for it) from Hart in the USA (Hart, F. X. (2008). "The mechanical transduction of physiological strength electric fields." Bioelectromagnetics 29(6): 447-55) looks at endogenous bioelectric signals, mechanics and glycoproteins. This may not instantly grab you, but if you are delivering electric fields to the tissues, it is argued that they have effects on cells, and that these effects
have a mechanical intracellular component. One has to consider how the applied field can result in mechanical changes – a transduction process – and this paper takes a comprehensive look at just such a thing. There may be another element in that if you are applying mechanical stress in the first place (manual therapy, exercise, manipulation, mobilisations etc etc) there might be an important bioelectric consequence of your therapy and the bioelectric intervention model (something that I am currently working on) might just be partly responsible for how your therapeutic effects are achieved – so don’t jump over this one even if you do not like the maths and the modelling!

Hart argues that the mechanical transduction of electric fields is a plausible mechanism for electric field effects – i.e. that the applied electric field can bring about intracellular mechanical effects via a glycoprotein structure. Hart argues that this effect is most likely to be important at low frequencies (below 10Hz) and at higher frequencies, it should be less apparent. Hart does not suggest that this mechanotransduction effect replaces voltage gated models already written about – indeed, he proposes quite clearly that this is likely to be an additional component rather than as a replacement for existing explanations. I do appreciate that most of you will not find this stuff that exciting, but if you are into trying to identify how applied electric fields might be able to have their physiological and hence, therapeutic effects, then this paper might just be for you. It needs further development, and has some limitations (which are acknowledged), but there are a range of possibilities that open up IF this effects is substantiated in further experimental work.

**Electrical properties of acupuncture points and meridians**

Another paper from Bioelectromagnetics (a great journal in my books) and another topic that comes around every now and again – acupuncture points, meridians and bioelectric properties. This one is a systematic review from a group predominantly based in the States (Ahn, A. C., A. P. Colbert, et al. (2008). “Electrical properties of acupuncture points and meridians: a systematic review.” Bioelectromagnetics 29(4): 245-56).

Both acupuncture points and meridians are widely held to be points of low electrical resistance on the skin surface (though of course, this is a very Western approach to the TCM philosophy) and many devices claim to identify the location of these points and meridians by finding the points of low resistance. This is the first systematic review I have seen in this field – though I think I have seen most if not all the papers to which it refers. This review aimed to review and summarise the studies which have looked at acupuncture points and meridians to see if there is any substantive evidence that they are electrically ‘different’ or ‘distinct’.

A search strategy was employed (identified in the text) and limits were placed (such as English language papers – which is a bit of a limiter in this field, no animal studies, clinical significance papers, no controls etc). A review methodology was developed (by a team of people covering a wide range of research, clinical and academic skills) and the employed method is described. The original number of papers (over 1600) was swiftly reduced to 320 of primary interest and after further evaluation, 16 papers (representing 18 studies) were fully evaluated.

There are several pages describing the reviewers findings and it would be both impossible and inappropriate to fully replicate their work here – this is intended to provide a straightforward overview. Each section

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**Seen any interesting papers?**

**Is there a paper that you have written and ought to be reviewed here?**

**E mail and let me know** electronews@electrotherapyonline.co.uk

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(acupuncture points and meridians) is dealt with firstly by looking at the data obtained and secondly offering an interpretation of that data.

In terms of the acupuncture points, most of the trials were of low quality with small sample sizes (the mean was n=13). Most of the study participants were non injured (healthy) volunteers, and the actual measurements taken using DC or low frequency currents (hence the resistance or impedance/conductance was what was measured). Five of the 9 studies in this group showed an association between acupuncture points and lowered electrical resistance or impedance BUT the higher quality studies (as judged by the review specific criteria) failed to demonstrate such an association. There were differences in methodology (there are two basic ways of doing this – (a) find the points and then measure the electrical characteristics at that point or (b) to scan for points of low resistance/impedance and then look to see if they correlate with an acupuncture point. There are problems with both approaches (discussed). In view of the diversity of test methods employed, it is difficult, if not impossible to carry out any real meta-analysis. There is considerable debate, even within the acupuncture community about the size, location and relative distribution of these points, and there is just as much debate between researchers in this field. The authors of this review take some trouble to look at these differences and try to rationalise why different experimental protocols may have come up with very different and even conflicting results. They do not proffer definitive answers (in my view) but they do make a valuable contribution to the debate.

In terms of the acupuncture meridians, the studies appear to be of generally higher quality with more subjects recruited and in terms of the methodology appear to be more sophisticated. Severn of the 9 studies showed a positive association (one was mixed and one showed no relationship). Once again the studies involved ‘normal’ healthy subjects. The results are more complex than that, and those of you with an interest in acupuncture or tissue bioelectrics will undoubtedly want to look at them in a whole lot more detail. Generally though, lower impedance measures seem to be the order of the day far more consistently with the meridian studies than for the point studies. Even with the ‘better’ studies for the meridians, the authors of this paper suggest that the evidence is inadequate to conclusively state that the meridians are sites of lower impedance and higher capacitance compared with non meridian skin.

As with almost all systematic review (that I get to see anyway), the main conclusions were that there was no definitive evidence one way or the other, and in part this may be due to small sample size, weak methodology and of limited scope (mainly upper limb in normal subjects). The evidence supporting the concept that the meridians are ‘different’ is stronger than the evidence to support the same claim for the acupuncture points. Better studies are needed and if nothing else, this review highlights the points that need to be addressed in order to raise the quality of future work. This is a good review paper. You may not find yourself in agreement with the reviewers, and you may feel that the limitations of this systematic review limit the strength of the conclusions, but it does make for an interesting read (but I almost always say that!) and provides a platform from which further work can be planned and undertaken.

**Whole body vibration and bone density**

Another recurrent and emerging theme in the newsletter is concerned with vibration as a therapy – so here is a paper from Sweden (Rehn, B., P. Nilsson, et al. (2008). "Effects of whole-body vibration exercise on human bone density - systematic review " Physical Therapy Reviews 13(6): 427-433) which looks at vibration exercise and bone density and it is another systematic review (such joined up planning in this edition!). There is a LOT of talk around out there about the beneficial effects of the combination of exercise and whole body vibration, but many practitioners are unsure of the validity of this approach – they are sceptical – and to a large extent, this might relate to the public awareness and PR work in this developing area.
The reviewers review both the lay and the scientific rationale for combining exercise and vibration – normally involving light exercise on a vibrating plate or platform. The effectiveness of this ‘therapy’ on muscle strength, especially in the lower limb has been previously identified. This review looks at it from the perspective of bone health and particularly, bone density. The review only looks at work in humans and is only concerned with studies where bone density was a primary issue. Literature was identified through standard searching in various databases, but also looking through the grey literature – to be commended. Each paper was reviewed and analysed by two reviewers and scored against a Pedro scale (widely used and cited – though it has been criticised as a ‘method’). In addition to the Pedro score, a whole body vibration exercise (WBVE) scale was employed which specifically considered the intervention parameters. 169 papers were initially identified, 26 of which were of interest and 9 of these were eventually selected for review.

The results (in brief) showed that 8 out of the 9 studies demonstrated a positive effect for WBVE on bone density compared with either a control condition or a weight bearing system. Five of the positive studies produced significant results whilst the other three showed improvement, but that it was not statistically significant. The increases in bone density were shown in differing locations in different studies. Bone density increases in the back, hip and proximal tibia were shown as were cortical changes in the tibia (most used DEXA as the primary outcome measure). The vibration parameters fell into a relatively confined range with vibration frequency typically being between 12 and 45Hz and vibration amplitude in the 0.7 – 4.2mm range, and the majority of the selected studies using primarily a vertical displacement. Five of the selected studies considered the effect in post menopausal women whilst the others looked at various combinations of young people (often girls) with and without concomitant health problems.

The evidence summarises into a ‘moderate’ category, and furthermore, the authors conclude that the improvement in bone density for post menopausal women is not superior with WBVE compared with weight bearing and resistance training methods (though some would argue with this stance I have no doubt). There are further areas where more detailed work is needed (as you might expect) and amongst these are the ‘best’ parameters for the vibration platform. The authors do conclude that there is moderate evidence for the use of WBVE as a training modality to increase bone density in post menopausal women. There are many further options for investigation (possibly as a preventative intervention, maybe as a treatment for those with generalised osteoporosis – the sedentary elderly for example), and hence further work is needed. For those of you who have not delved into this literature thus far, the review would be a very useful introduction and summary of the current (2008) evidence. For those who already have an interest in this field, it will provide a reasonably comprehensive consideration of the literature.

**Whole body vibration and physiological effects**

Following on from the previous review paper, here is another one concerned with whole body vibration exercise – but considering both young and older people, and from what I can see, it was not included in the Rehn review – most probably because it explicitly did not look at bone density changes (Cochrane, D. J. et al. (2008). "A comparison of the physiologic effects of acute whole-body vibration exercise in young and older people." Arch Phys Med Rehabil 89(5): 815-21). The research team are based in NZ and the UK. 12 healthy young people (mean age 21) and 12 healthy older people (mean age 69) were recruited for this work which was conducted in a lab (university) setting in the UK. This study was not looking at bone density per se – though the background arguments are to a great extent the same as those provided in the preceding review. One of the key differences between this study and others is that each subject undertook a series of 9 difference test conditions in a static ½ squat position with varying loads applied (described in the methods section). The order of exposure was randomised as one might expect. Each intervention was of 4 min-
utes duration followed by a 30 second rest. The tests were conducted over 2 visits with at least 24 hours between sessions and a maximum of 5 test conditions on a visit.

Given the 9 different test combinations, the method would take too much space to detail here but at least Archives Phys Med Rehabil should not be too difficult for most of you to access if you want the detail.

The outcome measures were related to various physiological parameters and several peripheral measures (such as normal activity during a week. Various anthropometric measures (height, weight, skinfold thickness, limb length) were taken plus VO2, heart rate, blood pressure and a rating of perceived exertion during the activities.

At the end of the day, both vibration and load increased the VO2 scores in older and younger groups with the vibration increasing VO2 by almost 20%. The WBV also increased heart rate (as did load). There are a lot more results than this – go grab the original for the detail.

The authors summarise the findings thus: It is suggested that in both young and older people, VO2 was significantly enhanced with vibration and an additional load. The WBV was found to affect VO2 in older and younger people in a very similar way but that the metabolic response to vibration appeared to be slightly lower in the older subjects than in the younger subjects.

There are some issues and limitations with this paper – the authors identifying some of them. The older people being tested were certainly not a classic sedentary group – they appear to have been somewhat more active than average – and that may have influenced the results. I was also surprised by the ½ squat position for the testing – though I can certainly appreciate why, from a methodological viewpoint it was advantageous – most similar studies use a variety of standing positions – though with the knees bent – so there are some similarities. Anyway, this adds useful data to the evidence pot.

**The last papers in the edition are concerned with various aspects of tissue injury and repair**

**Trigger point inflammation**

Here is the first one which strictly is neither tissue injury or repair – but it does look at inflammatory markers at myofascial trigger points in a complex study on ‘normal’ subjects and is certainly of interest in this regard. The research team (from the USA) undertook the study in an attempt to determine the presence and concentrations of numerous biochemical markers in samples taken from active, latent and non trigger points (trapezius and gastrocs) and have come up with some interesting results (Shah, J. P. et al. (2008). "Biochemicals associated with pain and inflammation are elevated in sites near to and remote from active myofascial trigger points." Arch Phys Med Rehabil 89(1): 16-23).

It is suggested that MTP’s (myofascial trigger points) are very frequently present in patients who experience chronic pain disorders. They are tender, sensitive and not only present as a ‘sign’ on assessment but also used by many therapists as a part of their treatment programme (not what this paper is about - I am just making an observation). The research team have previously developed a needle based sampling system which enables the collection of tissue fluid whilst being minimally invasive. The aim of this study was to look at the biochemical ‘milieu’ of substances associated with pain and inflammation in an active MTP in upper fibres of trapezius and further to compare the data with samples from latent (non active) UFT trigger points, samples from the UFT where trigger points are absent, and also from samples obtained from a remote (uninvolved) site in the upper medial gastrocnemius. Interesting proposition . . . . so read on.
Nine subjects were recruited from a ‘normal’ population. The recruitment and exclusion (both important issues) are detailed in the paper. Subjects were divided into 3 groups based on assessment findings: ACTIVE (MPT present, idiopathic cervical pain <3 months, n=3 subjects): LATENT (MTP present, no cervical pain, n=3 subjects): NORMAL (MTP absent, no cervical pain, n=3 subjects). The procedure involved the use of this novel instrument using a variation on a theme of a 30 gauge needle (detailed in this and previous publications).VAS pain scales and pressure algometry (pressure pain threshold – PPT) were taken at set points. The penetration of the ‘needle’ into the point is detailed in the paper (too much information for most readers here). 22 samples were taken from the trapezius and a further 10 from the gastrocnemius and were then subjected to several biochemical assays looking for 9 different chemicals [bradykinin, substance P, calcitonin gene related peptide, tumour necrosis factor alpha, interleukin 1B, interleukin 6 and 8, serotonin and norepinephrine and also the pH of the fluid (sorry for those who want to see all the abbreviations and symbols for these chemicals – I can do it on my computer but GUARANTEE by the time I e mail the newsletter to you, it will end up as a garbles mess).

There are some predictable and some surprising results. The active group had higher pain scores on the VAS (that is predictable) and they also had lower pressure pain thresholds (as you might expect) BUT they were also lower when taken over the gastrocnemius point – not just the UFT area though the PPT differences were not significant (all leg pathology and pain had been ruled out at baseline screening – so it was not a local event).

In terms of the biochemical screening, there were lots of tests from lots of samples, so the results are long with lots of plots in the original paper (though they are easy to read) Some of the active group data was combined with data from a previous experimental study as there were no statistical differences in the separate results. The concentration of all markers were significantly higher in the active than in the latent or normal subjects with the exception of pH which was lower. There was no overall difference between the latent and the normal group data. There were also differences in the gastrocnemius data between the three groups. Similar to the trapezius results, the concentrations were higher in the active than the latent and the control groups and once again, the pH was significantly lower in the active group. Further statistical testing showed that the gastrocnemius concentrations were lower in the gastrocnemius than in the trapezius samples. There were some minor variations, but this is a reasonable summary of the data. For the full set, as ever, head for the original paper and see the tables and plots for yourself.

In conclusion that authors have demonstrated that chemicals associated with pain and inflammation are significantly raised in the vicinity of active MTP’s, confirming previous results. The inclusion of interleukins 6 and 8 (not tested previously) is a new result. The data also suggest that the raised levels of these chemicals is not confined to the local area – given that they were also raised in the gastrocnemius of the active group compared with the normal and latent groups – though these levels were not elevated to the same extent as in the trapezius test data. There are some interesting links drawn between this test data and the more clinical models put forward (by Simons for example) and if you use trigger points in either assessment or therapy, you would be well served to consider the discussions points made. Links are (potentially) made between the raised gastrocnemius concentrates and central sensitisation, though given that central sensitisation was not assessed, this remains a hypothetical (though interesting) proposal. The study has limitations, and the most obvious one, which the authors acknowledge, is the very small sample sizes – though they do defend this on the basis of having achieved a significant result even under these circumstances.

Although one might be able to criticize the experimental approach on several levels, this remains, in my view, a fascinating paper and one that will be looked at over and over (I suspect) by those working more inti-
mately with trigger points. My own interest, in the biochemistry of the inflammatory events, was certainly fired up by this data and I look forward to further studies along these lines.

**Achilles tendinopathy: exercise and brace research**

A brief summary of the last few papers – I am running out of time and space here – though it is certainly not because they are uninteresting research publications! Petersen et al (mentioned previously in this publication) have published the results of an RCT comparing the effect of eccentric training and an Air Heel brace on patients with Chronic Achilles Tendinopathy (*Petersen, W. et al. (2007). *Chronic Achilles tendinopathy: a prospective randomized study comparing the therapeutic effect of eccentric training, the AirHeel brace, and a combination of both.* Am J Sports Med 35(10): 1659-67*). This is a 2007 paper, but it is included here as I have not mentioned it before, though I should have done so, and because it fits with the Achilles tendinopathy papers put together in this final section.

The basic structure of this RCT was to take a group of patients with chronic Achilles tendinopathy (n=100) and divide them into three groups. One group were managed with an eccentric exercise programme, one group with the AirHeel Brace and one group with both interventions. Measurements were taken at baseline and then at 6 weeks, 12 weeks and 54 weeks – so we have an RCT with decent numbers and with a long enough follow up to provide useful data.

The outcomes included the VAS pain score, and ankle score based on the AOFAS hindfoot scale and an SF-36 for quality of life issues plus an ultrasound scan. The short version of the results indicates that there was significant improvement in all three groups, and after analysis, there was actually no significant differences between the improvement obtained. The fact that the AirHeel Brace is as effective as the eccentric exercise programme might be a surprise to some – but that is what these results would suggest. It is also shown that combining the brace with the eccentric programme does not seem to add anything of significance to the outcome. The AirHeel brace is a specifically designed brace for this patient group and it provides a ‘pulsing’ compression via two interconnecting air sacs which, it is proposed, heals to reduce both swelling and discomfort – though to date this has not be unequivocally established through any reported trial. All the patients in this study were recruited through local paper adverts and all had a problem with a minimum duration of 3 months.

The eccentric training programme is described. Patients were instructed in these exercises, were provided a written instruction and they were checked at 6 weeks to make sure they were doing them correctly. Exercises were to be done 3 times daily, 7 days a week for the 12 week period. Those using the brace were instructed to wear it ‘during the daytime’

There are more results than I have intimated here. In addition to those mentioned, it was noted that there was no change in tendon diameter (based on the ultrasound scans) from the baseline measurement in any of the three groups. Although the ‘official’ results indicate no gross difference between the three groups, there were some outcomes and some time points where the combined group had an apparent advantage – even though it may not have been statistically significant. There are two key issues in my mind here. One is that the eccentric group did not demonstrate as good an outcome as has been reported in some previous trials – something noted by the authors, but not really explained. Secondly, that the AirHeel brace used alone, appears to have had just as good an effect on the outcome. Both issues need further work, but for those with an interest in this field of therapy, the results should be of interest. Chronic Achilles tendinopathy has certainly been shown to be one of the most problematic and most recalcitrant lesions which therapists are asked to manage, (*Poltawski, Watson and Byrne 2008*) and anything which contributes to our knowledge of effective treatment programmes is to be welcomed.
Knobloch et al have been cited in previous Electrotherapy Newsletters (Vol 2 Issue 2 and Vol 2 Issue 4), so they are certainly not newcomers in this research field. They have a paper from last year which, as the title suggests, presents the results of a lab study which evaluates microcirculation changes in the mid portion of the Achilles with ice/compression combined against the effect of cryotherapy alone (Knobloch, K. et al. (2008). "Midportion achilles tendon microcirculation after intermittent combined cryotherapy and compression compared with cryotherapy alone: a randomized trial." Am J Sports Med 36(11): 2128-38).

This study involved n=60 subjects who were uninjured volunteers, divided at random into two groups: one receiving cold therapy alone (using the KoldBlue system, previously reported in this publication) and one receiving cold therapy combined with compression (using a CryoCuff system — which will be familiar to most of you even if you have not used it). The introduction to the paper briefly discusses the salient issues including the microcirculatory issues associated with Achilles midportion and insertional tendinopathy, cold therapy and previous research evidence. It also introduces the key outcome measure (O2C) which evaluates capillary blood flow, tendon oxygen saturation and postcapillary venous filling pressures (again, all of which I have commented on in this newsletter on previous occasions).

The paper includes a clear CONSORT diagram which enables the reader to follow all recruits through the trial process. These subjects were recruited from sports clubs and from the university of the lead author, and were effective healthy normals (i.e. not chronic tendinopathy patients). The profile for participants including baseline and demographic data are reported, and they seem to be consistent with equivalent data obtained from previous studies.

The outcome measures were centered around the use of the O2C system which combines laser Doppler and flowmetry to measure microcirculation changes in both the deep (8mm) and superficial (2mm) tissues and the reliability of this system has been previously evaluated, giving no more than 5% variability within subjects. There is (in my view) a lack of some methodological detail in this paper regarding the actual application of the therapy. Certainly, whichever group the participants were in, they got 3 x 10 minutes application of ‘the therapy’ each followed by a 10 minute rest period. The treatment were delivered with cold water/ice mix at 15 degrees C – one delivering just the cold and one the cold combined with a pressure (the CryoCuff). The treatments were applied to the ankle such that the midportion of the TA was included in the treatment zone. The total test time was for 60 minutes and the participants were supine throughout. The O2C probe was applied at a fixed (measured) point on all subjects (which one might argue with in that if you are 2.5m or 1.8m tall, then a point 4cm proximal to the distal attachment of the TA is not the same equivalent position). In addition to the O2C system, participants were also asked to report their cold perception score (scale 0 – 10) as a subjective outcome.

The results in the main paper are detailed, and (as ever) I will summarise for the sake of brevity — and of copyright! Subjectively, the participants felt the maximal cold sensations at slightly different times during the three interventions and with the different applications, but typically between the first and second minute of application, and the ‘amount’ of cold felt looks pretty similar with both applications. The recovery appears to be slightly faster with the CryoCuff applications. In terms of the capillary flow, there was no significant difference between the two applications (deep or superficial) during the interventions. There was however a significant difference during the recovery period, with the CryoCuff participants recovering faster (deep and superficial).

The oxygen saturation results are a bit more complex (though fully detailed), but in summary the saturation levels decreased during each application period (more so for the CryoCuff) and there was a recovery (greater than baseline) during the recovery phases — this too was significantly greater in the CryoCuff group.
The postcapillary filling pressures decreased during the cold application (deep and superficial, both applications), with a recovery during the rest intervals, which appears to be a stronger response in the CryoCuff group.

Overall then the responses for the CryoCuff group appear to be stronger both during the applications and in the recovery phases and therefore the authors argue that the CryoCuff gave the ‘better’ response to treatment, and therefore conclude that 3 x 10 minute intermittent applications of cold therapy using the CryoCuff system is superior to applying cold alone (i.e. no compression). There are limitations with the study (discussed) and it needs to be noted that this particular RCT was carried out on healthy volunteers – not patients, and none of the participants had either an injury or any kind of TA problem – so it would be interesting to see how the results transfer to a patient population. In the meantime however, the knowledge base has been added to and more is known about the differential effects of different methods of cold application.

**TA microcirculation and tissue loading**


The recent considerations that TA blood flow may in fact be a contributor to pain and discomfort in some patients is still under discussion (beyond the scope of this newsletter) but the basic idea in this care goes like this: it has been suggested from previous work that flow changes have been demonstrated in the region of abnormal imaging for between 50 and 100% (depends on the trial) of patients with TA pain, leading to the use of sclerosing injections to try and deal with the problem. In athletes some with painful TA’s have shown circulation problem and it is suggested by the authors that this might be a load related phenomenon. The primary aim of this work was therefore to look at tendon blood flow, using a ultrasound Doppler technique and to look at the association between presenting pain and the flow in a group of active athletes. The second aim was to look at the association between flow and activity levels (my paraphrase).

The participants in this study were Badminton players (mixed ability – some at national level and some at club level), who played at least 1 x weekly. They were assessed using both ultrasound imaging including colour Doppler and pain measures together with an index of their activity levels. Pain levels and function were assessed using the VISA-A (8 item questionnaire – previously reported in the newsletter) which has previously been shown to be reliable. The ultrasound scanning technique that was employed is detailed in the methods section. The participants were scanned following a badminton activity (of varying duration, depending on their level). Tendons were categorised as to their ‘normality’ and any abnormality was recorded. Colour Doppler was used to assess tendon vascularity, counting the number of vessels. Full details are described.

Sixty one players were recruited (24 elite and 37 recreational). 13 of the 61 self reported TA pain and 2 of these had bilateral issues (giving 15 tendon problems in the total group).

The results (abbreviated) showed that there was no significant association between blood flow changes and pain and this was not influenced by the players level. There seems to be a relationship between the lower scores on the VISA-A questionnaire and the presence of Doppler flow changes. The number and length of the visualised blood vessels did not vary with reported pain. The US scans showed abnormal findings in 12 of the 13 tendons with midportion Doppler changes, and there was a significantly greater AP dimension of the tendon in those with Doppler changes.
In terms of reported badminton activity and Doppler changes, those who had been playing for longer were significantly more likely to have the Doppler changes. Age, gender, level of play or hours of badminton a week did not demonstrate significant association with the Doppler changes.

There are more results – plenty of table data and more statistical data than I have reported here, but this will give you the main thrust of what was found. The strongest findings were that the longer a player had been playing, the more likely they were to have the Doppler flow changes, and there was a (non significant) trend for there to be a link between hours a week played. Only just over 20% of the tendons evaluated in this study showed a Doppler flow and only 20% of these were associated with TA pain. The authors suggest that the presence of Doppler flow may be a sign of adaptation to increased mechanical loading rather than being linked to the pain findings. Given the complexity of the vascularity / pain / tendinopathy etc discussions which are ongoing, this study adds to the debate, but from my point of view, does not actually provide sufficient information to resolve the issue – not that it was a bad piece of work in any way – just that the results do not allow the issue to be resolved – yet . . . . . . .

**Eccentric exercises and Achilles tendinopathy**

The final paper for this issue (the next 30 are already lined up!) looks at eccentric training for patients with chronic insertional Achilles tendinopathy – though it reports the outcome of a pilot study rather than a full blown trial (Jonsson, P. et al. (2008). "New regimen for eccentric calf-muscle training in patients with chronic insertional Achilles tendinopathy: results of a pilot study." Br J Sports Med 42(9): 746-9). The group (mainly from Sweden with Australian overtones) argues that although eccentric training programmes have been shown to be effective for patients with midportion TA problems, it appears to be less effective for those with insertional TA presentations. They aimed to evaluate the effectiveness of a new type of eccentric training for this latter group.

27 patients with a total of 34 painful insertional TA problems were recruited. All had a long standing problem (mean of just over 2 years) and undertook a new programme of eccentric exercise that did not load into dorsiflexion (the current normal). The exercises were performed 3 x 15 repetitions, twice a day, 7 days a week for 12 weeks. Pain and return to activity were the primary outcomes. The results suggest that some two thirds of the patients were satisfied with the outcome and were back to their previous activity, with a mean pain reduction from almost 7/10 to just over 2/10. Nine patients (11 tendons) were not satisfied (pain from 7.7 down to 5.8. The new exercises appear to be more effective, but clearly need to be followed up with a larger scale trial. The exercise (my brief description) involved a heel raise (using the non painful side), followed by an eccentric phase with a return to plantargrade standing (i.e. NOT into a dorsiflexion range). If no pain was experienced, then a load was applied using a backpack and ‘dead’ weights. There is a bit more to the programme than that, but it covers the essentials – as ever, see the full paper for the full details – as indeed you are encouraged to do when it comes to the results – which I have severely abbreviated in my comments above. Given that just under a third of patients in previous studies have shown a good response to eccentric training with the exercise taken into a dorsiflexed position, the two thirds improvement in this pilot is a good outcome, and would be worth following up (not sure whether this is planned or not). For those of you treating patients with an insertional Achilles tendinopathy in the meantime, it might be worth a try – if (as ever) you can get the patients to actually comply with the regime!
That will do for now folks. I hope that something in here has been of some value to somebody . . . . . .

If there are papers that you are aware of (or indeed, have written) please do let me know and I will do my best to get them included if I can. The next Issue is scheduled for September 2009 and I already have a great line up of papers to bring to you.

Regards

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