A Randomised Controlled Clinical Pilot Trial to Study the Effectiveness of Neuromuscular Technique for Patients Suffering with Lateral Elbow Tendinopathy

A Research Proposal

BSc (Hons) Osteopathic Medicine

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Contents

Abstract

Objective

To evaluate the effectiveness of neuromuscular technique (NMT) for patients suffering with lateral elbow tendinosus.

Design

Prospective longitudinal pilot study: randomised double blinded design to compare the effect of NMT compared to a control group of patients suffering with lateral elbow tendinosus living in Surrey.

Subjects

80 participants, 40 entered each intervention group.

Methods

The Intervention groups were administered a treatment consisting of NMT to the affected forearm the control group was administered a sham treatment. Pain and function were evaluated by use of PRFEQ, VAS and Grip strength.

Results

To be determined on completion

Conclusion

Neuromuscular technique to the forearm extensor muscles and tendons will/ will not have any effect on the symptoms of lateral elbow tendinosus.

Introduction

I have chosen to investigate Tennis Elbow (lateral epicondylitis) for several reasons: firstly, having personally experienced this condition; secondly, having diagnosed it on several occasions as a student osteopath in clinic. Also some colleagues have had this condition due to the nature of our occupation (discussed below) resulting in pain presenting as lateral epicondylitis. It is therefore of personal and occupational interest to further investigate the reasons behind this condition and the most beneficial treatments/preventions.

Background

According to Assendelf et al (2003) Tennis Elbow has many analogous terms, including lateral elbow pain, lateral epicondylitis, Rowing Elbow, tendonitis of the common extensor origin, and peritendonitis of the elbow.

Lateral epicondylitis is a condition that affects the outside part of the elbow, the lateral epicondyle. According to Magee (2006) this is a chronic overuse injury causing damage to the tendon that joins the extensor muscles of the forearm (pulling the hand backwards) to the humerus (upper arm bone), the common extensor tendon (Figure 1)

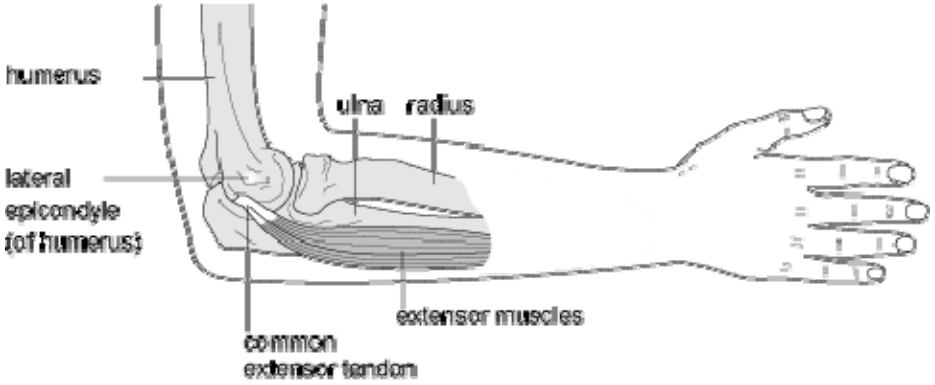


Figure 1
http://hcd2.bupa.co.uk/fact_sheets/html/tennis_elbow.html**,** viewed(Oct. 2007)

According to Roetert et al (1995) Tennis Elbow afflicts 40% to 50% of the average, recreational tennis players; however, Magee (2006) states it also occurs in persons whom use a great deal of wrist flexion and extension in their occupations or activities requiring wrist stabilisation in slight extension, usually people over 35. Stasinopoulos et al (2006) suggested that this condition tends to be more severe and lasts longer in women, perhaps explained by anatomical variations (see carrying angle appendix 12).

According to Magee (2006) most tendon damage is commonly a result of repeated overuse of the arm causing micro-trauma in the tendon leading to disruption and degeneration of the tendon's internal structures (tendinosus). Kraushaar et al (1999) state that histopathological studies have demonstrated that this is not an inflammatory condition; rather a degenerative condition that is

now more commonly known as tendinosis. The importance of distinguishing tendinosis from tendinitis is more than just a need for semantic accuracy. Appropriate treatment depends on understanding the nature of the injury and the goals of therapeutic intervention.

According to Nynke Smidt (2006) lateral epicondylitis is a self limiting condition, likely to get better without intervention, by stopping excessive or repetitive movement of the elbow and hand, 89% of patients will recover within a year, the average duration being six months-two years.

Table 1 highlights a treatment protocol recommended by the NHS.

Allopathic treatment protocol for tennis elbow
Hydrotherapy and Nonsteriodal anti- inflammatory drugs (NSAIDs)
Steroid (cortisone) Injection and Rest (2-3 weeks)
Physiotherapy.
Surgery by an orthopaedic surgeon to release the tendon

Table 1
http://nhsdirect.nhs.uk/articles/article.aspx?articleId=359&sectionId=9**, viewed (Oct. 2007).**

The literature review

According to Hart (1998) a literature review should serve the following purpose: distinguish what has been done from what needs to be done providing a context, justifying the research and avoid replication; discover the important variables, gain a new perspective; establish the context of the topic, identifying research techniques that have been used in the study; placing the research in a historical context, therefore, gaining a prospective on how the subject has developed and acquiring appropriate vocabulary,

Therefore the literature review should illustrate that the research proposal will fit the existing body of knowledge. Reviewing the current literature available on this subject can draw attention to any limitations in previous research and help refine the research proposal.

The journals used in this literature review were supplied by the British Medical Journal, British Library and web-based/online searches (Table 2). The benefit of these sources is that they are time effective, pooling a lot of research including many worldwide journals.

Database Searched	URL	Explanation
Cochrane Library	www.nelh.nhs.uk	free to the general public
Pub Med	www.ncbi.nlm.nih.gov/sites /entrez?db=PubMed	A medical science index which is a free version of Medline based in electronic format
British Medical Journal (BMJ)	www.bmj.com/channels/research.dtl	

Table 2

Search strategy

Key words: Tennis Elbow, lateral epicondylitis, manual therapy, osteopathic treatment, neuromuscular technique.

Inclusions and Exclusions

Table 3 demonstrates boundaries set in order to limit the search to retrieve focused, relevant and up-to-date information.

Inclusions	Exclusions	Reasons
Published in the last 10 years		research is more relevant and up-to-date
Humans		Due to anatomical variance in animals and to increase the validity of literature reviewed.
Clinical Trials and Randomized Controlled Trials, Meta-Analysis and Reviews		Measurable scientific data, clinical trial design allows evaluation of treatment choices to determine if there is a proven connection between outcome and treatment.
	Qualitative research	Does not establish if there is a casual connection between treatment and outcome.
English language		Translation would be too time consuming and expensive
Population		People of all ages from all areas, due to the already limited data available
	Cadavers	Cadavers not living tissues therefore a lack of vitality of the specimen will decrease the validity of study.
Techniques applied to the elbow, forearm and wrist joint.		To increase validity and be specific to the area of investigation.

Table 3

Table 4 shows the key word searched with corresponding hits.

Keyword	Search Engine	Hits
“osteopathic treatment, tennis elbow”	Cochrane Library	0
	Pub Med	0
	BMJ	0
“manual therapy , tennis elbow”	Cochrane Library	0
	Pub Med	17
	BMJ	1596
“tennis elbow”	Cochrane Library	8
	Pub Med	85
	BMJ	36
“lateral epicondylitis”	Cochrane Library	13
	Pub Med	207
	BMJ	49
“neuromuscular technique”	Cochrane Library	1
	Pub Med	264
	BMJ	294

Table 4

List of Literature Reviewed

Table 5 contains the research papers chosen to be reviewed due to the relevance to the research area.

Assendelft, W, Green, S, Buchbinder, R, Struijs, P Smidt, N Clinical review. (2003) Clinical review. Extracts from Concise Clinical Evidence. Tennis elbow. *BMJ*. 2003;327:329-30

Manias, P, Stasinopoulos, D (2006) A controlled clinical pilot trial to study the effectiveness of ice as a supplement to the exercise programme for the management of lateral elbow tendinopathy. *Br J Sports Med.* 2006;40:81-5.

Martinez-Silvestrini, J MD, Newcomer, K MD, Gay, R MD, Schaefer, M MD, Koretebein, P MD and Arendt, K MD (2005). Chronic lateral epicondylitis: comparative effectiveness of a home exercise program including stretching alone versus stretching supplemented with eccentric or concentric strengthening. *Journal of Hand Therapy.* 2005 Oct-Dec;18(4):411-9

Nilsson, P, PTR. Thom, E, OTR. Baigi, A, PhD. Marklund, B MD and Mansson, J MD PhD (2007). A prospective pilot study of a multidisciplinary home training programme for lateral epicondylitis. *Musculoskeletal Care.* 2007 Mar;5(1):36-50.

Paungmali, A O'Leary,S Souvlis,T and Vicezino, B (2003) Hypoalgesic and sympathoexcitatory effects of mobilization with movement for lateral epicondylagia. *Physical Therapy.* 2003 Apr;83(4):374-83.

Pienimaki, T M.D, Tarainen, T, Pertti Siira P.T, Malmivaara, A (2001) Association between pain, grip strength and manual tests in the treatment evaluation of chronic tennis elbow. *Clinical Journal of Pain.* 2002;18:164-170

Slater, H, Arendt-Nielsen, L Wright, A, Graven-Nielsen T (2006) Effects of a manual therapy technique in experimental lateral epicondylalgia. *Manual Therapy* 2006 May;11(2):107-17.
Smidt, N, Van der windt, D. (2006) Tennis elbow in primary care Trial by Bissit and colleques. BMJ 2006;333:927-8.

Table 5

Methodology

Approach

All the studies (Table 6) are quantitative in approach due to the measurable nature of the question or hypothesis, as opposed to qualitative research which deduces meaning. Slater et al (2006) was the only study to clearly state a hypothesis: that in healthy subjects with experimentally induced features of lateral epicondylagia, the lateral glide-MWM would activate mechanisms associated with analgesia and force augmentation in contrast to a placebo intervention. It can, therefore, be measured and results verified against the placebo intervention group. Measurability increases the rigor of a trial as it shows evidence of reliability (consistent measured result) and gains credibility which is especially important when considering the design of the study. A quantitative approach is therefore beneficial when trying to ascertain whether a particular treatment modality is going to be of benefit to the patient.

Design

The reviewed studies are clinical trails. According to Lewith et al (2002) this is a valid form of evidence measuring intervention over a period of time, taking the mean results, measuring the rate of change (determining any improvement resulting from the intervention over a period of time). This is known as a longitudinal study. Clinical trials are the only study design for evaluating and establishing a causal connection between outcome and treatment. Randomised clinical trials (RCT) are similar to clinical trails but involve randomisation, further validating the study and are the highest hierarchy of evidence. Randomisation is usually achieved by assigning participants to either a treatment or sham treatment group to ensure that groups are comparable on all factors that influence outcomes except for the treatment. Various methods randomly assign subjects to different groups. The treatment may or may not be delivered or evaluated blind. Both the studies by Slater et al (2006) and Martinez-Silvestrini et al (2005) are RCT's. The former study was double blind. According to Lewith et al (2002) blinding is used to control for expectations effects.

Single blinding occurs when either the investigator or participants are blinded, double blinding occurs when both investigators and participants are unaware to which group they have been allocated, the most desirable form of blinding because it reduces bias and increases the rigor of the study. However, the other studies, (excluding meta-analysis, the most rigourous review method, performed by Assendelft et al (2003) and Smidt et al (2006)) were of a non-randomised design.

According to Lewith et al (2002) pilot studies have scope to develop and expand as part of the research proposal and can be used as justification for the benefits of further research.

Propective studies identify participants at the start of all the studies and follow them up at a specified time, rather than retrospectively. “Prospective studies are more costly than retrospective studies but are considerably stronger” (Polit, Denise F et al. (2001) p179), however, meta-analysis might be considered retrospective as analysis occurs once studies are complete.

Sample

Sample size

According to Polit, Denise F et al. (2001) sample size is a major issue in conducting and evaluating quantitative research, reflecting the reasoning for only selecting papers with quantitative data as qualitative methodology does not lend itself to a large sample size.

There is no simple equation to determine how large a sample is needed, but quantitative researchers are generally advised to use the largest sample possible since it is more reliable and representative. Validity increases with sample size. However, according to Lewith et al (2002) power analysis (see Appendix 13) can help determine the optimum sample size to achieve adequate statistical data. However, there are other considerations such as economic constraints to the ideal sample size.

Table 6 shows the samples sizes used in the reviewed lit.

	Assendelft et al (2002)	Martinez-Silvestrini et al (2005)	Nilsson et al (2007)	Paungmali et al (2003)	Pienimaki et al (2001)	Smidt et al (2006)	Slater et al (2006)	Stasinopoulos et al (2006)
Design	Meta-anylisis	RCT	Pilot study	Clinical trial	Clinical trial	Meta-anylysis	RCT	Pilot study
Sample size	?	94	78	24	45	194	24	40

Table 6

The table above shows the largest sample was used in the meta-analysis. According to Lewith et al (2002) pilot studies do not need to be definitive; it is enough that they indicate the possibility of a beneficial effect, therefore, do not require large numbers and are less resource intensive, and designed to be expanded on. Slater et al (2006) Paungmali et al (2003) used the smallest sample, however, neither were pilot studies. The pilot studies used relatively large samples by comparison, making them more representative. Stasinopoulos et al (2006) commented that small sample size makes the study susceptible to internal validity.

In summary trial sizes were small, where specified only three studies included a sample of more than fifty participants hampering the size of the intervention groups.

Sampling Methods

According to Polit, Denise F et al. (2001) convenience sampling entails the use of the most readily available people as study participants, however this may be problematic as subjects might be atypical of the population; therefore the price of convenience is the risk of bias and erroneous findings. Another type of convenience sampling is snowball sampling, where early sample members are asked to refer others who meet the study's eligibility criteria. This method of sampling is most often used when the population consists of people with specific traits who might ordinarily be difficult to identify. With the exception of the study by Slater et al (2006), all the participants recruited had to have lateral epicondylitis. Paungmali et al (2003) used media releases and referral from heath care providers. Convenience sampling was used in the trials, allowing for resources and costs to be kept to a minimum whilst maximizing the sample size obtained from a specific target population. However, Polit, Denise F et al. (2001) state that convenience sampling

is the weakest form of sampling for quantitative studies, due to immeasurable risk of bias which can be limited by randomization.

Inclusion and Exclusion Criteria

Inclusion criteria are important in order for a study to be replicated and to ensure for ethical reasons subjects are over eighteen years. In all the studies inclusion criteria was that of lateral epicondylitis (with the exception of Slater et al (2006): healthy subjects without lateral epicondylitis). Most studies included similar definitions of lateral epicondylitis, and diagnostic means. Table 7 below shows the most common manual tests used for clinical diagnosis in the literature reviewed.

Manual tests used in clinical Diagnosis
1. Local palpation
2. Eliciting pain over the region of lateral epicondyle with use of manual provocation test.
3. Resisted wrist extension
4. Resisted middle finger extension test
5. Mills test
6. Chair lifting test

Table 7

Exclusion criteria are also important as some conditions may mimic lateral epicondylitis (see Appendix 4). There are also conditions which are relative contra-indications to physical therapy, including osteoporosis, malignancies, haemophilia, and diabetes, stated as part of the exclusion criteria by Pienimaki et al (2001), Stasinopoulos et al (2006), Martinez-Silvestrini et al (2005) and Paungmali et al (2003). Other studies did not clearly state their exclusion criteria.

Subjects who had previous treatment for their condition in close proximity to the start of the studies may bias results. In order to decrease this bias, Nilsson et al (2007), Stasinopoulos et al (2006) and Paungmali et al (2003) listed recent previous treatment as part of the exclusion criteria. The other studies may have been subject to bias by not doing so. However, according to Lewith et al (2002) by applying strict inclusion and exclusion criteria, (ensuring a rigidly controlled a study), the more error variance is reduced and the less likely it is to be widely generalizable. To

ensure a reliable and replicable study both inclusion and exclusion criteria should be clearly defined.

Ethics

Ethical considerations are important when developing a trial Lewith et al (2002) state that it is necessary to consider whether the intervention to be studied has the potential to cause harm, especially as it may be necessary for current treatments to be withdrawn. This was overcome in the study by Paungmali et al by having exclusion criteria (mentioned above); therefore participants did not have to be withdrawn from any medication since participants on prescription medications were excluded from the study. All studies were presented to an ethics committee.

Rigor

According to Lewith et al (2002) rigor refers to the methods of research applied, determining the internal validity, external validity and reliability. In clinical trials, every effort must be made to minimize bias. This is a huge obstacle when conducting a successful clinical trial. In order to minimize bias ideally there should be a large sample size and subjects should be randomly allocated to groups. This should be blinded as bias becomes apparent when the study is unblinded and the practitioner is informed of the treatment assigned. Double blinding, is the most effective way of reducing the likelihood of bias from both the participants and the investigator. Double-blind studies are often placebo controlled.

Bias and implementation by practitioner researchers, can easily affect the outcomes seen in clinical trials in the literature reviewed as the majority of the trials were flawed by the lack of blinding and control groups. However difficult it is to overcome bias, it is important as it concerns the main outcome. Lewith et al (2002) state it is important to ensure that the researchers apply the same number of measures to each group over the designated time period and clinic visit should be held at the same time of each day for every visit. Bias can also be reduced by using rigorously

trained and certified personnel. The study by Slater et al (2006) used an experienced physiotherapist to perform both the interventions in the placebo and experimental groups.

Internal and External Validity

"Internal validity refers to the question whether conclusions are drawn from intervention studies are likely to be unbiased, external validity refers to the question whether results are applicable in real life and generalizable to persons or situations likely to use or represent the intervention in real life" (Lewith et al (2002 p101).

In the study by Stasinopoulos et al (2006) all patients were instructed to use their arm but avoid activities that irritated the elbow such as shaking hands, grasping, lifting, knitting, handwriting, driving a car, or using a screwdriver during the period of the study. They were also told to refrain from taking anti-inflammatory drugs throughout the course of the study. By implementing these conditions this increases the internal validity of the trial as it establishes the cause-effect relationships and therefore the results are due to the manipulated independent variable. However, according to Lewith et al (2002) studies may be highly internally valid and conclusions unbiased but their external validity may be decreased and therefore unable to generalize to people outside the context of the experiment.

The patient's occupation and activities where not cited in the literature reviewed with the exception of Stasinopoulos et al (2006), where all participants were manual workers. However, the bias that this may have caused can be reduced by the randomisation and a control group.

Replication of the trails

"The procedures used, including definitions of main concepts along with data, should be open for other scientists to scrutinize, thereby enabling others to replicate the work." (Hart (1998) p83).

In the study by Martinez-Silvestrini et al (2005) the methods were possibly easier to replicate as they included pictures of the concentric and eccentric contractions.

Data collection and Analysis

Table 8 illustrates standardization of the tests used in the literature reviewed. The studies by Assendelft et al (2003) and Smidt et al (2006) were not included in the table as the tests used were not mentioned in the meta-analyses of RCTs.

Tests:	Martinez-Silvestrini et al (2005)	Nilsson et al (2007)	Paungmali et al (2003)	Pienimaki et al (2001)	Slater et al (2006)	Stasinopoulos et al (2006)
Pain questionnaire (PQ)				•		
Visual analog scale (VAS)	•		•	•	•	•
Pain drawings				•		
Grip strength		•	•	•	•	
Pressure pain thresholds (PPT)				•	•	
Patient- Related Forearm evaluation Questionnaire (PRFEQ)	•	•				
Sick leave		•				
Recorded Drop out						•
Wrist extension	•				•	
Thermal pain threshold			•			
Sympathetic Nervous system (SNS) indicators			•			
Resisted Middle Finger	•					
Chair Lift Test	•					

Table 8

According to Polit, Denise F et al. (2001) the visual analog scale (VAS) is a type of psychosocial measure which can be used to measure subjective experiences such as pain. Pain scales using the VAS and grip strength tests were used in the majority of the studies (see table above); this is a good way of assessing pre and post assessment. VAS scales permit researchers to efficiently quantify subtle graduations in the strength or intensity of individual characteristics. The grip strength test can be measured electronically thus increasing the reliability of the study due to computerization producing a more accurate result. Patient- Related Forearm Evaluation Questionnaire (PRFEQ) was used in the study by Martinez-Silvestrini et al (2005) and Nilsson et al (2005). According to MacDermid J (2005) this is a reliable, reproducible, and sensitive

assessment of lateral epicondylitis and recommended that it should be a ‘standard primary outcome measure’ in research involving this condition.

The PRFEQ is also beneficial as it lends itself to descriptive statistics; “descriptive statistics enable the researcher to synthesize and summarise quantitative data” (Polit, Denise F et al. (2001) p375). Martinez-Silvestrini et al (2005) performed a t-test in order to test for statistical significance between intervention groups.

All the literature reviewed utilized tables. Tables are useful because the reader has the actual numbers available if required, for example, in order to perform power analysis. A disadvantage of using tables is that results are generally less easily and quickly interpreted compared to a graph.

Rigor increased as all the studies presented to governing bodies. This was further increased when intervention was performed by professionals from recognized units and published in reputable journals, such as the BMJ. This is a recognized journal, read by the general public as well as medical professionals, therefore enabling readers to keep up to date with the expanding and constantly progressing body of knowledge that is available.

Dissemination, utility and recommendations

Results

In the review by Simon Mellor (2003), the only treatment shown to be beneficial was to take NSAIDs and avoid provoking activities. These are often the first line therapy in the early stage of the disease at a point when many cases would show spontaneous resolution. Corticosteroid injection may be helpful in breaking the pain cycle but patients should be warned against inflicting further injury by reintroducing activity during the subsequent pain-free ‘honeymoon period’. There is also a trend for symptoms to re-occur some months after steroid injection. In 2003, at the time of this study, there was no evidence to support the use of physical therapies. In the study by Bissit and colleagues (2006) which compared the effectiveness of physiotherapy, corticosteroid injections, and ‘a wait and see policy’, Corticosteroids were the most beneficial for

short term relief, however, had poor long term results, possibly due to the rapid decrease in pain in the above-mentioned ‘honeymoon period' which could have lead to excessive activity, causing a detrimental effect in the long term. Physiotherapy showed superior short term effects compared ‘to wait and see’. Physiotherapy was the most positive treatment modality in the long term. ‘Wait and see’ also had beneficial long term effects compared to corticosteroids.

Recommendations

The study by Paungmali et al (2003) showed that mobilisation with movement showed pain relieving effects and improved pain free grip strength whereas the study by Slater et al (2006) using experimentally induced conditions did not show any improvements.. This highlighted the need to use patients diagnosed with lateral epicondylitis and not those who had been clinically induced. This will be address as part of the proposed study.

The review by Slater et al (2006) recommended further research in order to improve understanding of the mechanisms associated with lateral epicondylitis and that of physical therapy. The need for further research of the mechanism behind the condition was also highlighted by Paungmali et al (2003) which described the physiological effects of MWM treatment technique and showed that there were some functional changes that cannot be fully explained by the local mechanical effects of physical therapy.

According to Assendelft et al (2003) the symptoms of tennis elbow account for many consultations in primary health care and days lost from work, showing more research into this condition would benefit the tax payer as well as the general public. The review by Bissit et al (2006) suggested that economic analysis would be useful to determine whether the small difference in the long term effectiveness between physiotherapy and wait and see policy would be cost effective.

From the review of relevant literature it is clear that there is a lack of research by the osteopathic profession into lateral epicondylitis and currently no clinical research behind neuromuscular technique. Therefore, further research, with the intention to improve knowledge into this

condition and to help advance the osteopathic practitioner and patient knowledge, would be beneficial. The research reviewed supports further investigation into lateral epicondylitis and manual therapy as there is currently little research available and there has not been any research to date into the effectiveness of neuromuscular technique for this condition. The common tests that have been used are the VAS and grip strength and the PRFEQ has proved to be effective. This will therefore also be used in the proposed research.

Conclusion

Themes gap and summary

Themes that commonly appeared were that lateral epicondylitis is also considered to be a tendinopathy. The common denominator is that this condition is a result of repetitive overuse, as cited in the literature reviewed.

There is evidence that manual therapy is effective in the treatment of lateral epicondylitis. However, due to small trial sizes and unsatisfactory methods, evidence for the effectiveness in the treatment of this condition, is inconclusive.

With regards to osteopathic considerations, there was insufficient evidence or research into the treatment of lateral epicondylitis. This needs to be addressed, if the general public is to accept osteopathic treatment and in order for osteopathy to move forward. Therefore, the current research question has been refined and formulated, which can be seen in the research proposal that follows this literature review.

The Research Proposal

Summary of the literature review

The literature reviewed illustrated the need for further research into this condition especially as it affects so many people and not just athletes.

A recurring theme was that lateral epicondylitis is a tendinopathy and will, therefore, be referred to for the purpose of this research proposal as lateral elbow tendinosus. This is a degenerative condition as a result of repeated overuse, causing micro trauma to the tendon on the lateral epicondyle of the elbow. There are gaps which need to be addressed in order to improve the effectiveness of manual therapy in the treatment of this condition.

Aims and objectives

The aim of this proposal is to see if osteopathic treatment will decrease symptoms and increase forearm function and strength. The osteopathic treatment applied will be neuromuscular technique (see Appendix 1) to the affected forearm and is intended to inform healthcare professionals in ways that will improve the outcome for patients suffering with this condition.

Research hypothesis

Experimental Hypothesis

Neuromuscular technique to the forearm extensor muscles and tendons will decrease the symptoms of lateral tendinosus.

Null Hypothesis

Neuromuscular technique to the forearm extensor muscles and tendons will not have any effect on the symptoms of lateral tendinosus.

Methodology

Design

Phase 1	Longitudinal study (find out the rate of change, does it get better over a period of time) Before and after (1 intervention, change?) Cross-sectional (one off study/ explanative)
Phase 2	Prospective/ Retrospective
Phase 3	Pilot study (justification for your proposal, scope to expand develop.

The literature reviewed demonstrates the importance of design in producing accurate research. A clinical trial establishes a causal connection between outcome and treatment. Randomisation further validates the study ensuring that groups are comparable in all factors that may influence outcomes except treatment. Double blinding ensures both investigators and participants are unaware to which group they have been assigned, further reducing bias. The design therefore affects the rigour of the study.

The design employed in the proposed research is a prospective longitudinal pilot study.

Sample

Ideal sample

Repetitiveness	Patients with diagnosed lateral tendinosus
Randomness	Randomised control group
Large (money, time and restraint due to inclusion criteria)	80 patients living in Surrey

A randomised pilot study will be carried out on participants living in Surrey. This is a large area, chosen in order to obtain a sufficient sample size (eighty subjects) for the purpose of this quantitative study. The area was chosen because of the accessibility of the location of the osteopathic clinic (SIOM) because participants would need to attend on numerous occasions. This has the advantage of reducing journey time and transportation costs, therefore, ensuring an

achievable large sample. Recruitment of participants will be done via advertisements (see Appendix 2). In order to recruit participants more randomly, advertisements will be placed in public places. For example in doctors' surgeries, building merchants, public facilities and sports clubs. Advertising will also be featured in the local press and on the SIOM clinic website.

Successful applicants, who meet the inclusion criteria (Table 1), will be assessed by means of a health questionnaire (Appendix 3) in order to see if they are able to participate in the study. The health questionnaire will screen for exclusion criteria (Table 1). Any subjects who answer 'yes' to any of the questions will be excluded from the study. Note: by having exclusion criteria this increases bias and decreases external validity as results become less generalizable. However, not having exclusion criteria may be unethical as participants might have a condition that is contra-indicated for osteopathic treatment (Appendix 4).

Targeting lateral tendinosus does increase bias but it is justified because subjects need to have this condition in order to establish whether the treatment is effective, as demonstrated by Slater et al (2006). This condition is targeted by use of the inclusion criteria. Diagnosis can be established using commonly accepted methods of testing used in the majority of the literature reviewed. Listing the specific tests ensure that the study can be replicated (Appendix 5). The validity and replicability of the testing therefore, increases the rigour of the study.

Inclusion and Exclusion criteria illustrated in Table 1

Inclusion	• Adults aged 18-55 • Elbow pain > 3 months localized on the lateral epicondyle • Pain in 2 or more tests of the following tests: including: resisted middle finger test, Resisted wrist extension and Mills test (Appendix 5),
Exclusion	• Any other pain in affected arm in last three months • Csp/Tsp dysfunction/ pain • Diagnosed by GP with OA or RA • Neurological deficit (radial nerve symptoms, carpel tunnel) • Surgery to elbow previous treatment to elbow including steroid injections within 4 weeks of entering study. • Inflammatory conditions affecting elbow or wrist • connective tissue disorders • generalised myalgia, neuromuscular diseases • cardiovascular diseases • health conditions that would have precluded ttt (e.g. osteoporosis,

	malignancies, haemophilia, diabetes) • prescription medications such as beta-adrenoceptor blocking agents or anti-inflammatory or analgesic drugs • Aversion to manual contact and previous therapy to elbow joint (to minimise expectation bias) • History of fracture to humerus, radius or ulna. • Pending litigation • Unable to perform tests due to excessive pain

Table 1

Following the inclusion/exclusion criteria, the remaining participants will be asked to give their informed consent in order to be included in the study (Appendix 6).

Subjects will be randomly allocated by computer in one of two groups.

1. NMT (Appendix 7)

2. Sham group (Appendix 7)

Independent variable will be lateral elbow tendinosus

Dependant variable will be the treatment administered.

A longitudinal study will enable the researcher to determine if the treatment for lateral elbow tendinosus will have an effect on the short and long term prognosis. Participants will attend for intervention (treatment or sham) on three occasions at intervals of a week apart, and then again for assessment three months later.

An osteopath will be used in the study to apply the intervention (1: NMT and 2: Sham). administered to the affected forearm. Delivery of the treatment (1) and placebo treatment (2) to the affected elbow will be performed by the same osteopath in order to increase internal validity.

Table 2 shows the tests that will be used

Pain Scale: VAS system (see Appendix 8)

Pain free grip strength (see appendix 9) mean of three grip strengths: recorded using a computerized dynamometer.

Patient- Related Forearm evaluation Questionnaire (PRFEQ) by Newcomer et al (2005) (Appendix 10). This questionnaire is involves the patient describing symptoms experienced over the past week and is divided into two sections. The first part consists of five questions where the participant rates pain experienced on activity in the affected elbow over the past week. The second part includes ten questions to assess functional disability, including rating difficulty on specific activities for example turning a door knob and usual activities (work, hobbies). For each question in section 1 a score of zero to ten is awarded (0=least pain, 10= worst pain). In section 2 rated from zero to ten according to difficulty performing tasks (0=not difficult, 10=unable to do. The scores are totalled at the end producing the 'Total score' (highest score=100 this is the worst score possible, therefore highest amount of pain and disability). Example of how to use this questionnaire (Appendix 9).

Table 2

Data Collection

Computerized testing will be performed to assess grip strength. The researcher will be unaware to which group the patient has been allocated when testing (Blinded). The VAS system this will be carried out by subjects pre and post each intervention. The PRFEQ will be carried out by subjects on arrival at the clinic before each intervention and then again at the three month follow up appointment. Results will compiled in data collection sheets (Appendix 11)

Analysis

Analysis will be performed by the researcher using computer analysis software, which is more rigorous as it reduces bias (minimising error) and increases the credibility of the study.

The outcome measures of the two groups will be statically analysed. The mean value and standard deviation at the time of each intervention and follow up will be recorded in Table 3.

Intervention		1			2			3			Follow up		
Tests	**Groups**	**M**	**SD**	**n**	**M**	**SD**	**n**	**m**	**SD**	**n**	**m**	**SD**	**n**
Mean grip strength (kg)	1			40			40			40			40
	2			40			40			40			40
PRFEQ	1			40			40			40			40
	2			40			40			40			40
Mean VAS pain scale	1			40			40			40			40
	2			40			40			40			40

Table 3
Group 1 = NMT treatment intervention
Group 2 = sham intervention
m = mean
SD = standard deviation
n = number of participants tested

Statistical Testing will include standard deviation and the t-test. “A common research situation is the comparison of two groups of people on a dependant variable. The appropriate procedure for testing the statistical significance of a difference between the means of the two groups is the parametric test known as the t-test.” (Polit, Denise F et al. (2001) p352).

The critical value for statistical significance will be set at $p < 0.05$. The t-test will enable the appropriate hypothesis to be accepted as true or rejected as false.

Disseminating the results

Any patient who withdraws from the study will be contacted in order to establish the reason.

Outcome measures will be evaluated.

Potential Limitations

Potential limitations for this study are that patients may drop out due to frustration of suffering caused by the condition. The effectiveness of this treatment has not been previously studied, therefore the amount of symptomatic relief that may be achieved is unknown. Patients in the control group will not receive any treatment and may become despondent.

The study aims to assess the long and short term effects of this treatment. However, the daily activity of the participants between each intervention will not be controlled so as not to decrease the external validity. This may alter the progression of the condition and therefore the internal

validity. Many of the patients may have manual jobs or participate in sporting activities. Due to the nature of the condition, the bias this may cause will be reduced by random allocation of participants. Participants who drop out, miss appointments or fail to comply with guidelines will be excluded.

Presentation and Utility

Once the research is completed and results analysed, the experimental or null hypothesis will be validated including the long term effect of NMT in the treatment of lateral tendinosus. This will be achieved using statistical evidence in order to objectively establish whether the technique was responsible for causing a change in pain and function and decreasing the symptoms.

The analysis, findings and the implications of this research will be presented to the national council for osteopathic research with the aim of improving osteopathic practice. It is important that the results can be accessed by healthcare professionals as well as patients for personal and educational use.

The participants will be made aware to which intervention they were allocated and the results of the study explained, demonstrating the findings.

A timetable of the proposed study can be seen in Table 4

October 2008	Submit the study protocol to the ethics committee (National Council for Osteopathic Research). Promote forthcoming trail in sport centres.
	Once approval is gained Advertisement will commence.
November 2008	Begin pilot study
February 2009	Study ends
March 2009	Analysis of data
May 2009	Final outcome and write up

Table 4

Resources Required

Table 5 outlines the possible costs incurred in carrying out this research:

Researcher Assistant (Osteopath, 5 years experience)	80 participants require NMT technique 3 treatments lasting 10 min.(1hr20min overall for both interventions for 80 participants) £200
Researcher	Data Collection Post intervention on 3 occasions then again for the last follow up. An afternoon clinic session on each occasion. Analysis and conclusion Results and Analysis
Password protected database and computer technology for analysis	Free will be purchased by SIOM
Computerized dynamometer	Free will be purchased by SIOM
Paper and stationary	£100.00
Advertisements in local press.	£200.00
Total	£500.00

Table 5

Observation of the costs outlined in the table above show the majority of funding required will be allocated to employing a research assistant and advertising as this is essential in order to obtain sufficient participants. Employing an experienced, qualified Osteopath to administer the interventions ensures that the treatment is applied effectively, increasing the reliability and validity of the study.

If there is an excess of potential participants then, with their consent, contact information will be stored so they may be asked to take part in a future study (possibly expanding on this pilot study).

Personal reflection

I have gained new knowledge and vocabulary about the condition. Establishing the chronic nature of lateral elbow tendinosus will affect my treatment of this condition.

It has also been of great significance in increasing my understanding of the research process as I now question the credibility and rigor of studies in order to establish whether the claims are justified.

Conclusion

By reviewing the relevant literature and previous studies, it enables the researcher to have an understanding of the research process which is important when critically evaluating a study and relevant in order to obtain reliable and high quality research.

This study will advance clinical osteopathic research into lateral elbow tendinosus. Should research support the experimental hypothesis, this would validate the use of NMT in the treatment of this condition, benefiting the osteopathic profession as there is currently no evidence to support the use of this form of osteopathic technique.

As this is a pilot study, any recommendations highlighted could then justifiably expand on this study.

Neuromuscular technique could also be applied in the treatment of other forms of tendinopathy such as that affecting the medial elbow (otherwise known as Golfers Elbow) or the Achilles' tendon. Further research into the effectiveness of NMT in treating these conditions would be beneficial.

Appendix 1

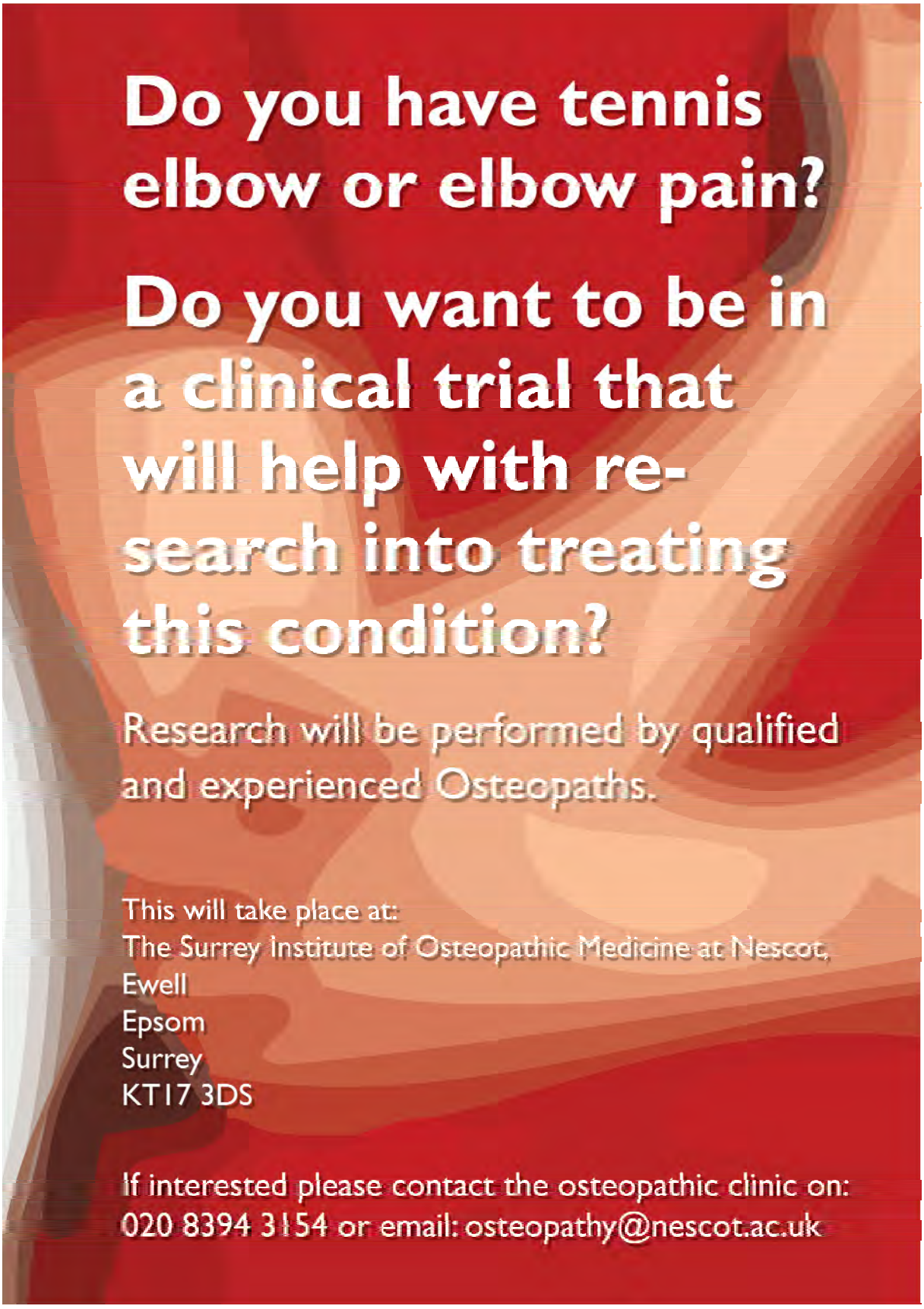
Neuromuscular technique

Roberts B (1997) State that neuromuscular technique (NMT) can be used to reduce muscle tension and spasms, reduce pain and enhance the range of motion of joints whose function depends on the involved muscles. Soft tissue manipulation may also improve movement during specific tasks. Although the muscle relaxation achieved with manipulation techniques is primarily short-term, long-term effects occur.

According to Chaitow, Leon (2003) NMT, as a modality, may be incorporated into any system of physical medicine. It may (and indeed often should) be used as treatment on its own, or it may accompany (proceeding for preference) manipulative and other physical modalities. Its main use up to the present has been in the hands (literally) of the osteopathic profession. However, those physiotherapists, chiropractors and doctors of physical medicine who have studied and used NMT have found it complementary to their own methods of practice.

Appendix 2

Advertisement



Appendix 3

Health Questionnaire

Please Tick the appropriate box when answering the following questions

Are you under the age of eighteen?

- Yes
- No

Are you currently pending litigation regarding arm pain?

- Yes
- No

Have you experienced any other pain in affected arm in last three months?

- Yes
- No

Have you experienced and pain in your neck or upper back in the last three months?

- Yes
- No

Have you been diagnosed by GP with Osteoarthritis (OA)or Osteoporosis affecting your arms, wrist or hands?

- Yes
- No

Have you ever noticed any numbness to your arms or hands?

- Yes
- No

Have you ever noticed any sensation changes or pins and needles affecting to your arms or hands?

- Yes
- No

Have you ever noticed any weakness affecting your arms, wrist or hands?

- Yes
- No

Have you ever noticed any swelling or redness affecting your arms, wrist or hands?

- Yes
- No

Have you had previous surgery to elbow hands or wrists?

- Yes
- No

Have you ever broken your arm?

- Yes
- No

Have you had previous treatment to elbow including steroid injections within the last four weeks?

- Yes
- No

Do you suffer Malignancy or have a history of Malignancy?

- Yes
- No

Do you suffer with any of the following condition: Rheumatoid arthritis (RA), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), polymyositis (PM), dermatomyositis (DM), mixed connective-tissue disease (MCTD), Sjögren syndrome (SS), haemophilia, diabetes or heart disease?

- Yes
- No

If you have answered yes to any of the above, please give details.....

Are you on any prescription medications such as beta-adrenoceptor blocking agents or warfarin?

- Yes
- No

If you have answered yes to any of the above, please give details.....

Do you rely on any medication for pain relief such as anti-inflammatory or analgesic drugs?

- Yes
- No

If you have answered yes to any of the above, please give details.....

Please print name .....

Signed ..... Date.....

Appendix 4

Justification for exclusion criteria

"When testing for epicondylitis… the examiner must keep in mind that there may be referral from the cervical spine or peripheral nerve involvement." (Magee, D (2006) Orthopaedic Physical Assessment 4th Ed Saunders. P336) this assess in the questionnaire by asking about any other pain that may implicate the cervical spine (neck) or indication of neurological involvement (pins and needles weakness, numbness and altered sensation. According to Stasinopoulos et al (2006) there are also relative conditions which are contra-indications to physical therapy, including osteoporosis, malignancies, haemophilia and diabetes.

Appendix 5

Inclusion Criteria

Tests that will be performed by the researcher on all participants who have not answered yes to any of the questions on the health questionnaire (Appendix 3).

Tests Include:

Testing

From Magee, D (2006) Orthopaedic Physical Assessment 4th Ed Saunders p336.

Resisted Wrist Extension Test (otherwise known as the Lateral Epicondylitis Test or Cozen's Test)

The patients elbow is stabilised by the examiners thumb, which rests on the patient's lateral epicondyle (figure). The patient is the asked to make a fist, pronate the forearm, and radially deviate and extend the wrist while the examiner resists the motion. A positive sign is indicated by a sudden severe pain in the area of the lateral epicondyle of the humerus. The epicondyle may be palpated to indicate the origin of the pain.

Mill's Test (otherwise known as the Lateral Epicondylitis Test)

While palpating the lateral epicondyle, the examiner passively pronates the patients forearm, flexes the wrist fully and extends the elbow (see figure 1), A positive test is indicated by pain over their lateral epicondyle of the humerus.

Resisted Middle Finger Test (otherwise known as the Lateral Epicondylitis Test)

The examiner resists extension of the third digit of the hand (middle finger) proximal to the interphalangeal joint, stressing the extensor digitorum muscle and tendon (see figure 2). A positive test is indicated by pain over the lateral epicondyle of the humerus

Subjects are included in the studies if they are able to perform test and if two or more tests were positive in that they reproduced pain.

Appendix 6

Participant Information and Consent Form

What is tennis elbow?

The medical term for this condition is lateral epicondylitis because it affects the outside of the elbow bone called the lateral epicondyle. The cause of the problem is damage to a tendon that joins the extensor muscles (move the hand backwards) of the forearm to the upper arm bone.

What is the purpose of this study?

To see if osteopathic treatment will affect symptoms caused by this condition (for example, decrease pain)

What will be involved?

The osteopath will administer treatment directly to the affected forearm; this will need to be exposed in order to do this. You may feel pain or discomfort when this is applied but this is not for a long period and you have the right to withdraw at any time. You will undergo a series of three treatments each one week apart. You will need to attend clinic for approximately two hours on each clinic visit. You will be asked to fill out a questionnaire and undergo testing in this period. You will the be asked to return three months following the last clinic visit in order to complete further testing.

What are the risks?

The osteopathic treatment applied will not cause any detrimental or lasting side effects.

In signing this document I understand that I am giving my consent to partake in this clinical trial. I understand that I will be part of a research study that will aim to investigate the effects of osteopathic technique on tennis elbow. This study is supported by the National Council for Osteopathic Research. I understand that I may have to remove clothing to my upper arm and that will have to attend clinic on four different occasions over the next 4 months. I understand that I may not receive any direct benefit in my involvement with this study however this may be of

benefit to other's suffering this condition. I understand that I can withdraw from this study at any time. If you have any further questions please consult with the researcher.

I hereby certify that I am over the age of eighteen and have read the above information and give my consent to be included in this study.

Please print name .....

Signed..... Date .....

Appendix 7

Intervention procedure

NMT (put how this will be carried out)

Sham group (what this will be and how it will be performed)

1. NMT Technique

The thumb technique employed in NMT enables a wide variety of therapeutic effects to be produced by its different activities. The tip of the thumb imparts a varying degree of pressure via any of four facets. The very tip may be employed or the medial or lateral aspect of the tip can be used to make contact with angled surfaces. For more general (less localized or less specific) contact, of a diagnostic or therapeutic type, the broad surface of the last phalange of the thumb is often used.

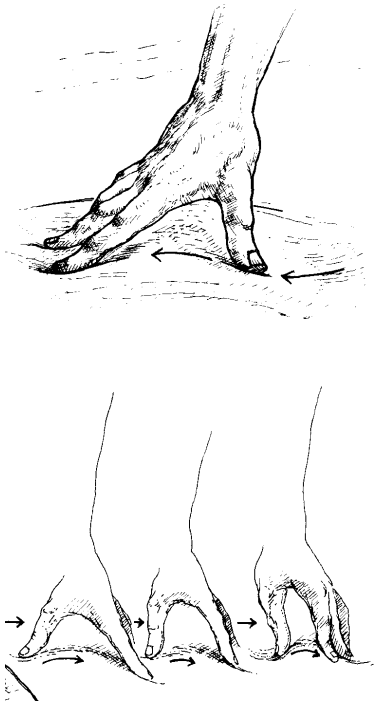


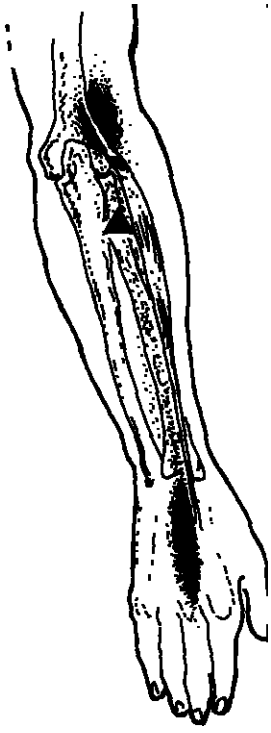
Figure 1

The hand is always spread so that the direction of the thumb stroke runs towards one of the fingertips (as seen in figure 1). During the stroke, which covers between two and three inches (5-8cm), the fingertips act as a fulcrum point. The chief force is imparted to the thumb tip by the operator leaning onto the thumb in a controlled manner. The thumb thus never leads the hand but always trails behind the fingers, the tips of which rest just beyond the end of the stroke.

The extreme versatility of the thumb enables it to modify the direction of imparted force in accordance with the indications of the tissue being treated. As the thumb glides across and through those tissues it is an extension of the operator’s brain in the assessment of what is being palpated, change in the tissue can be felt and reacted to.

The thumb and hand seldom impart their own muscular force except in dealing with small localized contractures or fibrotic 'nodules'. In order that the force is transmitted directly to its target, the weight being imparted from the shoulder should travel in as straight a line as possible. To this end the arm should not be flexed at the elbow or the wrist by more than a few degrees. The positioning of the operator's body in relation to the area being

treated is also of the utmost importance in order to facilitate economy of effort and comfort. In this regard both the optimum height vis-à-vis the various body areas must be considered.
The degree of pressure will depend upon the nature of the tissue being treated. The thumb will allow for a greater variety of changes in pressure during its strokes across and through the tissues. The patient should not feel acute pain but a general degree of discomfort is usually acceptable as the thumb is seldom stationary. A stroke or glide of two to three inches (5-8cm) will usually take four to five seconds, seldom more unless a particularly obstructive indurated area is being dealt with.
Of course, if reflex pressure techniques are being employed, a much longer stay on a point will be needed, but in normal diagnostic and therapeutic use the thumb continues to move as it probes, decongests and generally treats the tissues. It is not, therefore, possible to state the exact pressures necessary. Attention should also be paid to the relative sensitivity of different areas and different patients. The thumb is not just mechanically stroked across or through tissue but is an intelligent extension of the operator's diagnostic sensitivities and it should feel to the patient as though it is assessing every fibre of his soft tissues. Pain should be transient and no bruising should result if the above advice is followed.



The application of this technique will be applied to the extensor muscles and tendons in picture 2 above. This will be applied in upward direction (as highlighted in figure 2). The duration of this procedure can not be specified, it will continue until the operator has assessed a change to the tissues; however this will not be applied for any longer then 10 minutes on each participant.

2. The Sham Treatment

This will be applied by the same operator. Very gentle brushing of the skin will be applied in the same direction as the above technique for 6 minutes, using the thumb as the applicator (as above).

Figure 2

Reference

Chaitow, Leon (2003) Modern neuromuscular techniques. .Edinburgh : Churchill Livingstone.

Appendix 8

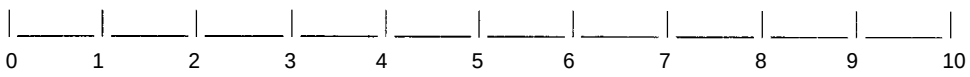
10cm VAS system

The line corresponds with the amount of pain sensation being experienced.

1 indicates no pain, and 10 is the worst pain imaginable.

Please indicate on the scale your current level of pain.

No Pain Distressing Unbearable



Name .....

Date .....

Appendix 9

Grip strength

This will be tested using a hand held computerized dynamometer. Using a computerized isometric dynamometer to test the maximal grip strength at setting II. Participant will be asked to repeat testing three times. The mean value of the three reading will be used.

Appendix 10

Patient- Related Forearm Evaluation Questionnaire (PRFEQ) by Newcomer et al (2005)

Patient- Related Forearm Evaluation Questionnaire (PRFEQ)

Name ..... Date.....

The questions below will help us understand the amount of difficulty you have had with your arm in the past week. You will be describing your average arm symptoms over the past week on a scale 0-10. Please provide an answer for all questions. If you did not perform an activity because of pain or because you were unable ,then you should circle a "10". If you are unsure please estimate to the best of your ability. Only leave items blank if you never perform that activity. Please indicate this by drawing a line completely through the question.

1. Pain in your affected arm

Rate the average amount of pain in your arm over the past week by circling the number that best describes your pain on a scale from 0-10. A zero (0) means that you did not have any pain and a ten (10) means that you had the worst pain imaginable.

Rate your pain:											
When your are at rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with repeated arm movement	0	1	2	3	4	5	6	7	8	9	10
When carrying a plastic bag of groceries	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its least	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its worst	0	1	2	3	4	5	6	7	8	9	10

2. Functional disability

A. specific activities

Rate the amount of difficulty you experienced performing each of the tasks listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficult you were unable to do it at all.

Turn a doorknob or key	0	1	2	3	4	5	6	7	8	9	10
Carry a grocery bag or briefcase by the handle	0	1	2	3	4	5	6	7	8	9	10
Lift a full coffee cup or glass of milk to your	0	1	2	3	4	5	6	7	8	9	10

mouth											
Open a jar	0	1	2	3	4	5	6	7	8	9	10
Pull up pants	0	1	2	3	4	5	6	7	8	9	10
Wring out a washcloth or wet towel	0	1	2	3	4	5	6	7	8	9	10

B. Usual activities

Rate the amount of difficulty you experienced performing your usual activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed before you started having a problem with your arm. A zero (0) means you did not experience any difficulty and a ten (10) means it was so difficulty you were unable to do any of your usual activities.

Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10
Recreational or sporting activities	0	1	2	3	4	5	6	7	8	9	10

Comments:

.....

.....

.....

Scoring Instructions

Minimize non-response by checking forms when patients complete them. Make sure that the patient left an item blank because they could not do it, that they understand that should have recorded this item as a "10". If patients are unsure because they have rarely performed an activity in the past week, then they should be encouraged to estimate their average difficulty. This will be more accurate than leaving it blank. If they never perform an activity they will not be able to estimate and should leave it blank. If items from a subscale are left blank, then you can substitute the average score from that subscale.

Pain Subscale – Add up 5 items: Best score= 0; Worst score = 50

Specific Activities – Add up 6 items: Best Score= 0; Worst Score = 60

Usual Activities – Add up 4 items: Best Score= 0; Worst Score = 40

Function Subscale – (Specific Activities + Usual Activities)/2: Best score= 0; Worst score = 50

Total Score = Pain Subscale + Function Subscale Best Score= 0 Worst Score = 100. Pain and disability contribute equally to score.

Reliability of subscales and total score are sufficiently high that both subscales and total are reportable.

Appendix 11

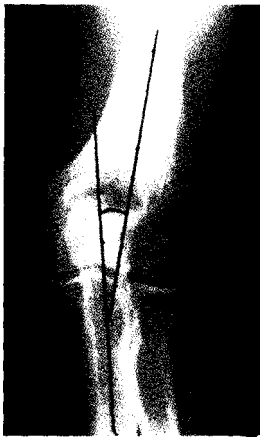
Data collection sheets

Test	1st Intervention	2nd Intervention	3rd Intervention	4th Intervention
Grip Strength	1.	1.	1.	1.
	2.	2.	2.	2.
	3.	3.	3.	3.
	Mean =	Mean =	Mean =	Mean =
VAS pre-intervention	__/100	__/100	__/100	__/100
VAS post-intervention	__/100	__/100	__/100	__/100
Mean VAS	__/100	__/100	__/100	__/100
RFEQ	__/100	__/100	__/100	__/100

Participant name.....

Appendix 12

Carrying Angle



According to Magee (2006) the carrying angle is the formed by the long axis of the humerus and the axis of the ulna and is most evident when the elbow is straight and the forearm is fully supinated (Figure 1). In the adult, this would be a slight valgus deviation between the humerus and the ulna when the n is supinated and the elbow is extended. In males the normal carrying angle is 5° to 10°; in females, to 15°.

Figure 1

Appendix 13

Power Analysis

Definition

“A procedure for estimating (a) the likelihood of committing a Type II error, or (b) sample size requirements” (Polit, Denise F et al. (2001) p468).

Sample Size can be estimated through power analysis, illustrated by Polit, Denise F et al. (2001) p244.

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