Journal of Sports Medicine & Doping Studies
ISSN: 2161-0673
O'Brien and Watson, J Sports Med Doping Stud 2016, 6:3
DOI: 10.4172/2161-0673.1000180
Research Article
Open Access

Deep Oscillation® Therapy in the Treatment of Lateral Epicondylalgia: A Pilot Randomized Control Trial

O'Brien CP[1] and Watson A[2*]

[1]Sports Surgery Clinic, Santry Demesne, Dublin, Ireland
[2]Raglan Sports Medicine, 4 Fitzwilliam Square East, Dublin, Ireland

Abstract

Introduction: DEEP OSCILLATION® therapy has been shown to improve wound healing, inflammation, pain and most prominently its effect on lymphoedema. It has been indicated for use in musculoskeletal injuries but few studies on its effectiveness exist. Therefore, the purpose of this study was to measure the effect DEEP OSCILLATION® (DOT) had on patients with lateral epicondylalgia (LE).

Methods: Twenty subjects aged between 18-55 years who had a diagnosis of LE took part in this trial. Group A (Control) underwent the protocol of injection therapy with 5 mg of Adcortyl and Lignocaine, topical Diclofenac anti-inflammatory gel applied three times per day and supervised rest over a two week period. Patients were then referred for physiotherapy where they completed a baseline PRTEE and were instructed on a home exercise program (HEP) for 4 weeks. Group B, test, received the same protocol from the physician as Group A and referred for physiotherapy where they completed a baseline PRTEE and received the same HEP as Group A. Group B also received DOT consisting of two-25 minute sessions per week for 4 weeks, eight treatment sessions in total. Outcome measures were the PRTEE and VAS to measure pain at baseline and end of treatment at 6 weeks. Further follow-up was performed at 6 months post treatment.

Results: The baseline mean of pain for Group A was 18.9 (SD 4.5) and at 6 weeks the mean was 13(3.09). The baseline mean of pain in Group B was 18.4 (4.5) and at 6 weeks it was 10.3(3.8). Repeated measure ANOVA on Pain showed significant difference between measurement from baseline to 6 weeks ($F(1,18)=530.52$, $p \leq 0.001$). Results for the Time x Group interaction effect was not significant ($F(1,18)=1.76$, $p=0.20$), indicating that the changes in Pain measurements from baseline to 6 weeks were not significantly different for Control and Test groups. The mean function baseline for Group A was recorded as 13 (3.09) and 12.95 (2.76) at 6 weeks. The mean function for Group B was recorded as 22.5 (3.9) and 11.35 (4.10) at 6 weeks. Repeated measure ANOVA on Function showed significant difference between measurement from baseline to 6 weeks ($F(1,18)=98.82$, $p \leq 0.001$). Time x Group interaction effect were found significant ($F(1,18)=10.59$, $p=0.004$), indicating that the changes in measurement from baseline to 6 weeks was significantly different for Control and Test groups.

Conclusion: A significant improvement in patients function at 6 weeks post treatment was found with 70% of the treatment group requiring no further treatment from 6 weeks to 6 months post treatment. DOT is beneficial in the treatment of TE and may further enhance the benefit from local steroid injection. Further research on the use of DOT in musculoskeletal injury and relevant protocols are needed.

Keywords: Lateral epicondylalgia; Tennis elbow; Physiotherapy; Deep oscillation therapy; Sports medicine; Rehabilitation

Introduction

Lateral Epicondylalgia (LE), commonly known as "Tennis Elbow", is a frequent complaint in primary healthcare settings with an occurrence rate of 4-7 per 1000 patients seen per year in general practice [1]. It is one of the most common upper extremity conditions [2] affecting 1-3% of the population with both sexes between 40-60yrs of age being equally susceptible [3]. It is caused by tendinosis of the common extensor tendon complex, primarily the extensor carpi radialis brevis (ECRB) at the lateral humeral epicondyle [4]. As over-use is a common causative factor, approximately 70% of cases are work-related leading to a significant loss of revenue due to sick leave [5].

Various treatment methods have been proposed in the management of lateral epicondylalgia. Labelle and colleagues [6] found evidence for approximately 40 treatment modalities with no one specific treatment proving to be superior. In 1936, Cyriax suggested that lateral epicondylalgia would spontaneously resolve in 8-12 months [7], a statement that has yet to be disproven. In many review papers, long-term follow up of 12 months or more, show little difference between placebo groups and intervention [8] with "wait and see" groups performing as good as groups that received physiotherapy or other treatment methods at 12 months follow-up.

Three treatment methods in particular have become the most common intervention for the management of lateral epicondylalgia. Local steroid injection has been shown to reduce pain and increase function in the acute stages of the pathology, particularly at 4 week follow up [9-13]. Work by Burnham et al., [14] showed topical diclofenac to be beneficial in reducing pain when applied directly to the site of pain for one week in patients with lateral epicondylalgia. The influence of exercise therapy has also been shown to give long-term improvement with a combination of stretching and strengthening helping to improve outcome measures of pain and function [15]. DEEP OSCILLATION® therapy has been shown to improve wound healing, [16] inflammation, pain [17] and most prominently its effect on lymphoedema [18]. The mechanism by which the therapy is achieving results is due to the

***Corresponding author:** Mr. Andrew Watson, Head Athletic Therapist and Chartered Physiotherapist, Raglan Sports Medicine, 4 Fitzwilliam Square East, Dublin, Tel: 353 1 661 2180; E-mail: info@raglansportsmedicine.com

Received January 29, 2016; **Accepted** May 02, 2016; **Published** May 09, 2016

Citation: O'Brien CP, Watson A (2016) Deep Oscillation® Therapy in the Treatment of Lateral Epicondylalgia: A Pilot Randomized Control Trial. J Sports Med Doping Stud 6: 180. doi:10.4172/2161-0673.1000180

mobilisation of interstitial fluids therefore enhancing the body's natural lymphatic drainage reducing inflammation [19] and activation of mechanoreceptor cells causing a reduction in pain sensitivity. It has been indicated for use in musculoskeletal injuries but few studies on its effectiveness exist.

Therefore, the purpose of this study was to measure the effect DEEP OSCILLATION® (DOT) had on patients with lateral epicondylalgia (LE).

Materials and Methods

Twenty subjects aged between 18-55 years took part in this trial from patients whom attended a sports medicine physician at the Sports Surgery Clinic, Dublin for the treatment of lateral elbow pain over the course of 12 months. A consultant physician with over 25 years of expertise in the area made the diagnosis of LE. The diagnostic criteria included an appropriate subjective history of the injury and an objective physical examination. To make a diagnosis of LE a positive Stoddard's test, pain on palpation of the origin of ECRB at the lateral epicondyle and pain at the lateral epicondyle with resisted wrist extension were all required. Exclusion criteria included patients whom had a negative Stoddard Test and did not have pain from either palpation or resisted wrist extension or had a pathology that was causing lateral elbow pain that was not related to tendinosis of the common extensor origin. Any subject with an underlying pathology that DOT treatment was contraindicated was also excluded. Ethical approval was granted through the ethics board at the Sports Surgery Clinic, Dublin and written consent was received from all participants.

Subjects individually completed a Patient Rated Functional Tennis Elbow Evaluation (PRTEE) [20] to assess their baseline perceived pain and function levels using a ten point Visual Analogue Scale (VAS) with 0 indicating no pain and 10 indicating the worst pain possible.

A baseline measure of grip strength was also collected by all subjects using a Baseline Hydraulic Hand Dynamometer (Fabrication Enterprises Inc, New York). This was recorded with the subject standing, elbow flexed to 90 degrees and wrist in a neutral position. Subjects were then randomised into two groups, Group A, control and Group B, intervention. Randomization was performed using random order allocation using SPSS software with subjects stratified for age and sex.

Group A (Control) underwent the protocol of injection therapy with 5 mg of Adcortyl and Lignocaine, patients were advised to apply approximately 1inch of topical Diclofenac anti-inflammatory gel themselves three times per day and undergo supervised rest over a two week period. Patients were then referred for physiotherapy where they completed a baseline PRTEE and were instructed on a home exercise program (HEP) for 4 weeks. The HEP consisted of stretching of the forearm extensors with the elbow extended, holding for 30 seconds for 2 sets twice per day. Wrist extension and radial deviation strength exercises performed with resistance band were performed for 3 sets of 10 repetitions each.

Group B (Test) received the same protocol from the physician as Group A and referred for physiotherapy where they completed a baseline PRTEE and received the same HEP as Group A. Group B also received DOT consisting of two-25minutes session per week for 4 weeks, eight treatment sessions in total. All subjects received one-to-one treatment and therefore had no interaction with other subjects.

The extensor tendon and the extensor muscle mass were both treated with two applicator heads using a custom protocol stored on the Evident Clinical Unit, designed and supplied by Physiomed Elektromedizin AG, Germany.

Protocol

The DOT treatment protocol consisted of 10minutes @ 200Hz-250Hz, 5minutes @ 40Hz-65Hz and a final 10minutes @ 85Hz. Intensity was set as close to 100% manually based on patients' response and sensitivity. Application was performed using two 5 cm diameter treatment heads using effleurage strokes treating the extensor mass of the affected forearm from distal to proximal with a proximal end point of 3 cm proximal to the lateral epicondyle. The mode was set to 2:1. Protocol design was customized by the authors and was based on parameters stored within the Evident unit and literature provided by manufacturers on effects of varying frequency ranges. High frequency oscillations for pain reduction, low frequency for reduction of scar tissue due to the deeper oscillations and medium frequency to reduce inflammation by mobilizing interstitial fluid. Do date; no current evidence is available on specific protocols for specific soft tissue injuries.

Follow-up

After the four week protocol and 6 weeks from the start of the treatment with the consultant physician, both groups returned for follow up PRTEE, grip strength and further assessment. At 6 months, information on any further treatment was recorded through telephone and email correspondence. The purpose of this was to ascertain if the subjects still had symptoms and did they seek further treatment since the 6 week follow up.

Statistical analysis

Data recorded on the PRTEE was collected from the groups. Pain scores were added to give a figure out of a maximum of 50 and the sum of the function scores were divided by 2 to also give a figure out of 50. Grip strength scores were recorded from baseline and at 6 weeks post treatment to analyze for comparison. Statistical analysis was performed using SPSS version 20 software for Windows. Data was tested for normality and analysis was performed using a repeated measure ANOVA to assess the significant difference between groups' pain and function from baseline to 6 weeks. Significance levels report at $p < 0.05$ with a confidence interval of 95%.

Results

Twenty subjects, 14 females and 6 males, between the age of 18 and 55 years with a mean age of 38.8 yrs (± 12.02) took part in the study and met the criteria. The remaining subjects were randomized into control and intervention groups with equal number of males and females per group. Descriptive statistics for the groups are displayed in Table 1.

Due to insufficient grip strength data at 6 weeks being recorded, there was no benefit in analyzing the collected results. This was due to a number of subjects being unable return to the test center at the allocated time therefore PRTEE data was recorded via email and telephone correspondence.

Descriptive statistics above show mean age to be 38.8 yrs with a SD of 12.02. Sex has a mean of 0.3 indicating 30% of the subjects were male. A mean of 0.5 indicates equal numbers in each group. The baseline mean of pain for Group A was 18.9 (SD 4.5) and at 6 weeks the mean was 13 (3.09). The baseline mean of pain in Group B was 18.4 (4.5) and at 6 weeks it was 10.3 (3.8). The results of the repeated measure ANOVA on Pain showed significant difference between measurement from baseline to 6 weeks ($F(1,18)=530.52$, $p \leq 0.001$). However, Results for the Time x Group interaction effect was not significant ($F(1,18)=1.76$, $p=0.20$),

	N	Minimum	Maximum	Mean	Std. Deviation
Age:	20	18	55	38.8	12.016
Sex:	20	Female	Male	0.3	0.47
Group:	20	Group A	Group B	0.5	0.513
Subject:	20	1	20	10.5	5.916
Valid N (list wise)	20				

Table 1: Descriptive statistics.

indicating that the changes in Pain measurements from baseline to 6 weeks were not significantly different for Control and Test groups. This is also shown in the Figure 1.

The figure above shows the Mean difference between 1 (baseline) and 2 (6-weeks post) for each group. The mean function baseline for Group A was recorded as 13 (3.09) and 12.95 (2.76) at 6 weeks. The mean function for Group B was recorded as 22.5 (3.9) and 11.35 (4.10) at 6 weeks. The results of the repeated measure ANOVA on Function showed significant difference between measurement from baseline to 6 weeks ($F(1,18)=98.82$, $p \leq 0.001$). Furthermore, the results for the Time x Group interaction effect were found significant ($F(1,18)=10.59$, $p=0.004$), indicating that the changes in measurement from baseline to 6 weeks was significantly different for Control and Test groups. This is also shown in the Figure 2.

The figure above indicates the mean scores for both groups for function at 1. (baseline) and at 2. (6 weeks post). On follow up at 6 months, 7 of the 10 subjects in Group A required further treatment between 6 weeks and the 6 month period. Only 3 subjects from Group B required further treatment within the same period. The methods of further treatment was not considered in the study design but data collected ranged from further physiotherapy, injection therapy and continued topical ketoprofen gel use.

Discussion

The results of this pilot study show the benefit both groups received from the treatment intervention given but that Group B reported better outcomes on follow-up. Both groups pain significantly reduced in the 6 week period which is supported by research by Bisset et al. [9]. They compared mobilization techniques, injection therapy and "wait and see" in 65 patients with TE. Corticosteroid injection was found to give the best results at 6 weeks compared to the other modalities. They also found a high regression rate with 47 out of the 65 patients' symptoms regressing between 6 and 52 weeks post injection. Work by Ozturan et al., [10], Verhar et al., [12] and Price et al., [13]; all found corticosteroid injection therapy to give the most benefit in the treatment of TE from baseline to 6 weeks but they also found approx 50% of these patients symptoms would regress in the weeks following. This finding was similar in this current study with 7 of the 10 patients in Group A requiring further treatment between 6 week and 6 months.

The current study did not show a statistically significant difference in pain of Group A compared to Group B on 6 week follow-up. However, the significant improvement of Group B's function over Group A may have been the deciding factor in patient's recovery. Only 3 out of the 10 subjects (30%) in Group B required further treatment from 6 weeks to 6 months compared to 7 out of the 10 (70%) in Group A. As both groups received the same protocol except for the eight DOT treatment

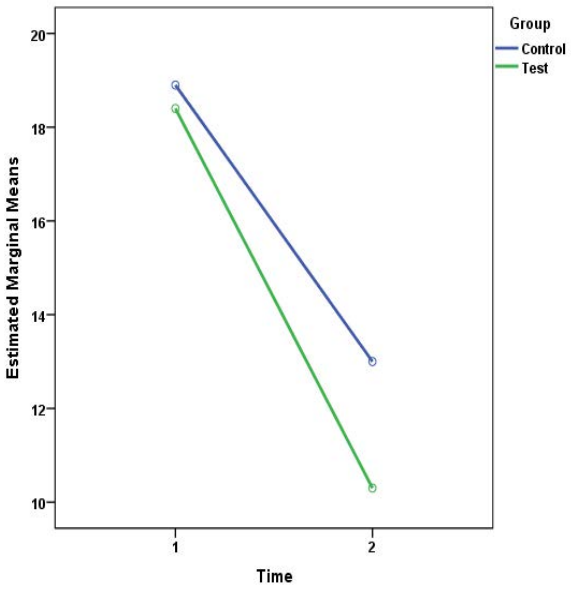

Figure 1: Results of pain difference between groups.

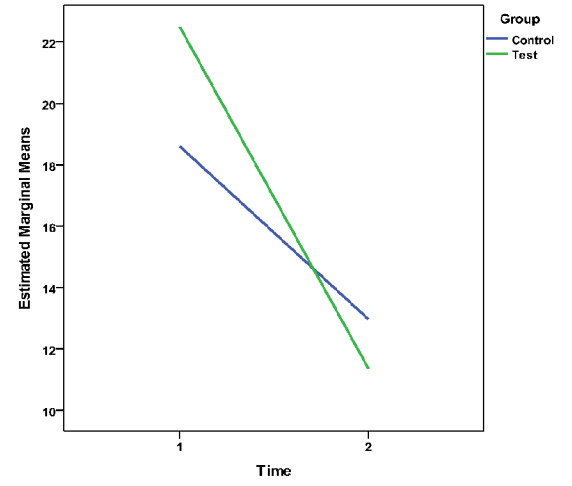

Figure 2: Results of function difference between groups.

sessions, it can be hypothesized that the improvement in function and in pain scores was due to the treatment effect. Similar effects were found in research by Jahr et al. [18] in which DOT was also found to reduce pain and increase function when used in conjunction with lymphatic drainage massage to patients with secondary lymphoedema following breast surgery. Twenty one subjects were used in total with the treatment group of 11 subjects receiving 12 treatments of DOT lymphatic drainage massage. The control group received lymphatic massage without the aid of DOT. The treatment group received 45min sessions 2-3 times per week performed at 100Hz for 30mins and 30Hz for 15mins. As the control group did not receive any placebo or sham DOT, the benefit in the treatment group of this study may be due to the placebo effect in having a new treatment. This was also a limitation of this current study.

As the mean function difference of Group B was larger than

Group A, the difference can be assumed to be the impact DOT had on the corticosteroid injection therapy each patient received. We have hypothesised that the oscillation of the tissue increases permeability of the target tissue increasing the therapeutic effect of the corticosteroid and lignocain solution. There is no literature to the authors' knowledge that supports this claim other than comparing the therapy to iontophoresis which it is not. DOT has been shown to mobilise interstitial fluid which may help to disperse the corticosteroid throughout the target tissue. In this current study, it was found that patients whom received DOT closer to their time of injection described a greater reduction of pain post treatment session. This observation may be a consideration in further study designs.

The Patient Rated Tennis Elbow Evaluation (PRTEE) as designed by MacDiarmuid et al. [20] was used to assess pain and function in this trial. Martinez-Silvestrini et al., [21] indicated in their work that as the PRTEE specifically focuses on the forearms pain and function it is therefore the best tool for studying lateral epicondylitis. Poltawski and Watson [22] showed in their work using the PRTEE that what may indicate a statistical difference may not yield a compelling clinic difference. They set the minimal clinical importance difference (MCID) at 11/100 on the PRTEE, defined as "much better" or "completely recovered". Taking this information into account, when the pain and function results are combined in order to mark the score out of 100, Group A improved by 11.55/100 and Group B improved by 19.25/100. This would indicate that both groups showed a clinical difference with Group B showing a greater clinical improvement overall. However, it was the intention to also measure grip strength to further correlate subject improvement of symptoms as Nilsson et al., [15] among others have done, but as enough follow-up data could not be collected, the small amount of collected data was not presented in this work.

There are some limitations with this work. Low subject numbers do not give the ability to make any substantial claims about the effectiveness of DOT in the treatment of TE. The significant improvement in such a small number does however give strong indication that the therapautic benefit could be even more significant on a larger test group. As the trial was not a double blind design, the impact of placebo effect of the test group receiving DOT over the control must be taken into consideration. As very little research on DOT and particularly effective protocols for different pathologies exist, the possibility that the protocol used in this current research may not be optimal for TE. The protocol was based on set protocols stored in the Evident Clinical Unit and practitioner experience of the therapy and not on published results.

Conclusion

This pilot study indicates the potential benefit DOT has in musculoskeletal pathologies such as TE and how it can be used in conjunction with injection therapy to improve on results already gained. A significant improvement in patients function at 6 weeks post treatment was found with 70% of the treatment group requiring no further treatment from 6 weeks to 6 months post treatment. DOT is beneficial in the treatment of TE and may further enhance the benefit from local steriod injection. Further research on the use of DOT in musculoskeletal injury and relevant protocols are needed.

Ethical Approval

Ethical approval was granted through the ethic committee of the Sports Surgery Clinic, Santry Demesne, Dublin 9, Ireland.

Funding

The research paper was funded by the authors.

Sponsors

Equipment was provided on loan for the duration of the testing in the trial by Physiomed Elektromedizin AG, Germany.

References

1. Hamilton PG (1986) The prevalence of humeral epicondylitis: a survey in general practice. J R Coll Gen Pract 36: 464-465.
2. Allander E (1974) Prevalence, incidence, and remission rates of some common rheumatic diseases or syndromes. Scand J Rheumatol 3: 145-153.
3. Putnam MD, Cohen M (1999) Painful conditions around the elbow. Orthop Clin North Am 30: 109-118.
4. Nirschl RP1 (1992) Elbow tendinosis/tennis elbow. Clin Sports Med 11: 851-870.
5. Kivi P (1983) The etiology and conservative treatment of humeral epicondylitis. Scand J Rehabil Med 15: 37-41.
6. Labelle H, Guibert R, Joncas J, Newman N, Fallaha M, et al. (1992) Lack of scientific evidence for the treatment of lateral epicondylitis of the elbow. An attempted meta-analysis. J Bone Joint Surg Br 74: 646-651.
7. Cyriax JH (1936) The pathology and treatment of tennis elbow. J Bone Joint Surg Am 4: 921-940.
8. Hong QN, Durand MJ, Loisel P (2004) Treatment of lateral epicondylitis: where is the evidence? Joint Bone Spine 71: 369-373.
9. Bisset L, Beller E, Jull G, Brooks P, Darnell R, et al. (2006) Mobilisation with movement and exercise, corticosteroid injection, or wait and see for tennis elbow: randomised trial. BMJ 333: 939.
10. Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I (2010) Autologous blood and corticosteroid injection and extracoporeal shock wave therapy in the treatment of lateral epicondylitis. Orthopedics 33: 84-91.
11. Newcomer KL, Laskowski ER, Idank DM, McLean TJ, Egan KS (2001) Corticosteroid injection in early treatment of lateral epicondylitis. Clin J Sport Med 11: 214-222.
12. Verhaar JA, Walenkamp GH, van Mameren H, Kester AD, van der Linden AJ (1996) Local corticosteroid injection versus Cyriax-type physiotherapy for tennis elbow. J Bone Joint Surg Br 78: 128-132.
13. Price R, Sinclair H, Heindrich I, Gibson T (1991) Local injection treatment of Tennis Elbow-hydrocortisone, triamcinolone and lignocaine compared. Br J Rheumatol 30: 39-44.
14. Burnham R, Gregg R, Healy P, Steadward R (1998) The effectiveness of topical diclofenac for lateral epicondylitis. Clin J Sport Med 8: 78-81.
15. Nilsson P, Thom E, Baigi A, Marklund B, Månsson J (2007) A prospective pilot study of a multidisciplinary home training programme for lateral epicondylitis. Musculoskeletal Care 5: 36-50.
16. Mikhalchik E, Titkova S, Anurov M, et al. (2005) Wound healing effects of DEEP OSCILLATION. 1st International Conference on Skin and Environment, Moscow, St Petersburg, Russia.
17. Janik H et al. (2010) Treatment of patients with fibromyalgia syndrome with vibration massage by deep oscillations. Eur J Phys Rehabil Med 46: 42.
18. Jahr S, Schoppe B, Reisshauer A (2008) Effect of treatment with low-intensity and extremely low-frequency electrostatic fields (Deep Oscillation) on breast tissue and pain in patients with secondary breast lymphoedema. J Rehabil Med 40: 645-650.
19. Gasbarro V, Bartoletti R, Tsolaki E, Sileno S, Agnati M, et al. (2006) Role of Hivamat (Deep Oscillation®) in the treatment for the lymphedema of the limbs. Eur J Lymphol 16: 13-15.
20. Macdermid J (2005) Update: The Patient-rated Forearm Evaluation Questionnaire is now the Patient-rated Tennis Elbow Evaluation. J Hand Ther 18: 407-410.
21. Martinez-Silvestrini JA, Newcomer KL, Gay RE, Schaefer MP, Kortebein P et al., (2005) Chronic Lateral Epicondylitis: Comparative effectiveness of a home exercise program including stretching alone versus stretching supplemented with eccentric or concentric strengthening. J Hand Ther 18: 411-420.
22. Poltawski L and Watson T (2011) Measuring clinically important change with the Patient-rated Tennis Elbow Evaluation. J Hand Ther 16: 52-57.