

The Use of the MyoDK for Mechanical Pressure in the Treatment of Chronic Lateral Epicondylalgia: A Pilot Study

JASON OUTREQUIN¹, FARSHID MOSHIRI², RAHIM KHORASSANI ZADEH³

ABSTRACT

Introduction: Chronic Lateral Epicondylalgia (CLE) is potentially associated with a significant reduction of the patient's quality of life; its treatment by manual Deep Transverse Friction (DTF), although widely accepted, lacks standardization. The purpose of our study was to evaluate the efficacy of the MyoDK device, which allows deep transverse pressure (DTP) monitoring, for treatment of CLE.

Materials and Methods: This is a single centre observational study for treatment of CLE by the MyoDK device. In a given year, all patients who appeared at our institution with a diagnostic of CLE were screened for possible inclusion. Exclusion criteria were: confounding factors on pain and function of the upper limb, cognitive impairment, inability or unwilling to give informed consent or to comply with treatment protocol. Our primary

outcome measure was the pain reduction measured by the VAS pain scale (VAS) at 6 weeks. Our intervention consisted in applying a pressure from 0.5 to 10kg/100mm² for 20 minutes, once a week for 6 weeks, using the MyoDK device.

Results: Thirty patients were screened. Two were excluded for incomplete protocol, remaining 28 for analysis. Mean age was 47.3, 23 were male (82.1%), 24 were affected on their dominant side (85.7%). We had a significant reduction in VAS pain score at 12 weeks (80.8 vs 13.0; p<0.01). There were no side effects reported.

Conclusion: Our study showed the safety of the use of a standard protocol using the MyoDK device for treatment of CLE. We believe that further controlled studies will establish the MyoDK as a reliable option for treatment of CLE.

Keywords: Epicondylalgia treatment, Manual therapy, Transverse pressure

INTRODUCTION

Lateral epicondylalgia (LE), also known as tennis elbow, is a tendinopathy taking place in the insertion of the *extensor carpi radialis brevis* (ECRB), with one third of patients also having *extensor digitorum communis* (EDC) involvement [1]. LE is a very common condition, affecting 1 to 3% of the general population and up to 15% of labour workers in northern European countries [2-5]. This represents a public health issue in terms of work leave of absence, compensation and re-training. LE is an overuse condition, typically caused by repetitive micro traumatic events, resulting from elastic and eccentric loading required by various sports (e.g.: tennis, golf) and manual work. Histologic examination has failed to exhibit the classic features of inflammatory disease, but instead exhibits degenerative changes with a dense population of fibroblasts, vascular hyperplasia and disorganized collagen [6].

Numerous treatments have been proposed: Physical intervention [7], injections of corticoid or platelet rich plasma, immobilization [8], acupuncture, shock-wave therapy [9,10] and surgery. Manipulative therapies are a growing interest in conditions involving chronic pain, especially LE [11,12].

Deep transverse friction (DTF), developed empirically by J.H.Cyriax [13-17] has shown good results. It technically should be referred to as a massage, hence should be precisely applied to the affected soft tissue structure. Four tissues can benefit from DTF: the enthesis, the bulk of the tendon, the musculo-tendinous junction and the muscle belly. Superficial layers will be mobilized with increasing pressure to reach a painful point (estimated around 50 to 100 Newtons), and that pressure must be kept for at least 20 minutes. The expected effects are softening of scar tissues and, at the microscopic level, breaking of pathological collagen cross linking and adhesion. The analgesic effect results from removal of pro-inflammatory substance by the immediate hyperemia, gate control and releases of endogenous opiates.

The technique as described by Cyriax, puts the mechanical stress on the physician's fingers, which over time would result in less effective technical execution, loss of precision and intensity.

Another shortcoming of the manual DTF technique is the lack of standardization in its execution, which is dependent on the physician's physical strength, his or her habits and on patient perception. This lack of standardization leads to inter and intra operator variability which renders its evaluation in clinical trials perilous.

The MyoDK device allows pressure monitoring without putting undue physical stress on the physician. Because the device shields unusually high continuous pressure that are not reached by manual therapy a prospective cases series study should validate its safety and efficacy for a chronic musculoskeletal disease before realization of a randomized control trial.

The purpose of this article is to evaluate the safety and efficacy of the MyoDK device for deep transverse pressure (DTP) in the treatment of Chronic lateral epicondylalgia in a prospective case series pilot study.

MATERIALS AND METHODS

Study design

All patients gave written informed consent and approval was obtained by local ethics committee. This is a single centre cross sectional, prospective study with inclusion starting from 2007 until 2009, evaluating the efficacy of a standardized protocol of continuous pressure using the MyoDK device for treatment of LE.

Description of the population enrolled: Thirty patients aged 18 to 75, with diagnostic epicondylalgia, presenting at the physical medicine clinic within a period of one year and willing to participate were eligible for a possible inclusion in the study.

Chronic epicondylalgia was defined as pain at the epicondyle insertion of the ECRB either at rest, under palpation or at resisted contraction, for at least 12 weeks (in duration since first symptoms).

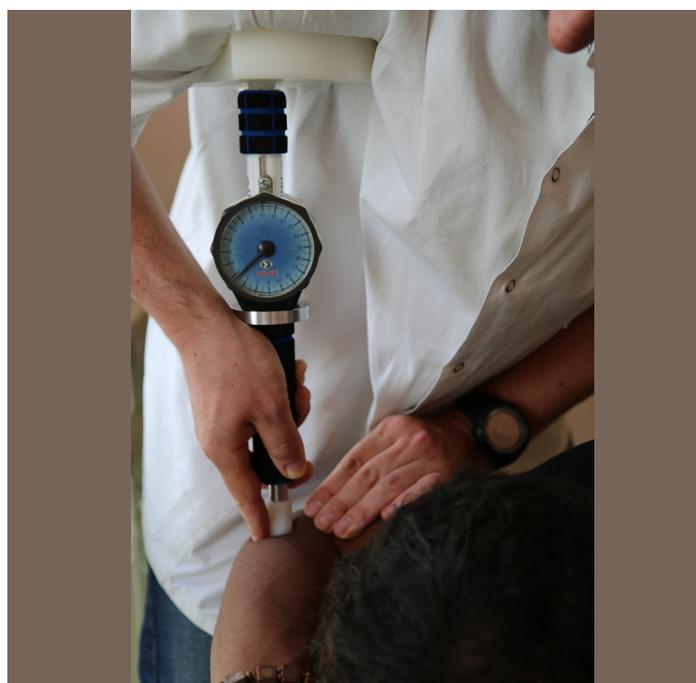
Our Exclusion Criteria were: Patient undergoing a different form of physical treatment at the time of enrollment, mild to severe cognitive impairment, non-French speaker, inability to comply with the follow-

up, inability for the patient or their legal representative to provide informed consent.

Standardized continous pressure protocol: Treatment was administered by a physiotherapist or a medical doctor. A progressively increasing pressure using MyoDK dynamometer was applied to the epicondyle insertion of the ECRB until the pain pressure threshold (PPT), defined as unbearable pain was reached. The PPT minus one third of its value was then sustained for 90 seconds. The common insertion and the bulk of ECRB and ECB were treated.

The process was repeated 10 times to reach a total treatment time of 20 minutes. The pressure applied started at 0.5kg/100mm² and the PPT was usually reached after 3 seconds at 1.5 kg/100mm² with 0.5kg/100mm²/s increments. The initial PPT was used as a reference as the minimal pressure to reach and to surpass in following visits. The patients received treatment once a week for a total of 6 treatment sessions.

Dynamometer: The MyoDK is a medical device that can quantify the amount of pressure (kg/100mm²) applied onto a patient's body using a dynamometer. The Dynamometer is located directly on the divide between the physician and the patient, [Table/Fig-1] with practitioner's body weight used as the pressure source.



[Table/Fig-1]: Dynamometer

Outcome measures: Our primary outcome measure was the difference in the pain during activities the last 2 days between the patient's first clinic visit and his last visit at the end of the treatment period at 6 weeks.

For each evaluation of pain, Visual Analogous Scale (VAS) was used and graded from 0 to 100, 0 representing "no pain" and 100 "the worst pain imaginable".

Primary outcome: Pain by VAS during activities evaluated patient global pain during last 48 hours on activities with VAS Pain Scale.

Secondary outcome measures: Number of patient lost to follow-up, Pain by VAS under pressure evaluated pain during the application of initial PPT at the insertion of ECRB.

Pain by VAS during contraction evaluated pain during a maximal hand grip resisted contraction, VAS Handicap evaluated functional limitation on daily living evaluated by the patient graded from 0 to 100, 0 representing no functional limitation et 100 maximal functional limitation. Our null hypothesis was that there will be no difference in the patient's VAS during activities between their first and last clinic visit at 12 weeks.

DATA COLLECTION AND ANALYSIS

Data regarding demographics, activity level, patient's history, previous treatment received were collected upon first clinical encounter. VAS was collected at the first patient visit, at 3 weeks and at 6 weeks. The need to switch to another treatment modality was assessed at the final follow-up visit.

Data analysis was completed using SYSTAT® 9 for Windows®.

Results will be expressed as a mean for continuous variables (VAS pain score at each time point, age, BMI, height, weight) and as a percentage for categorical variables (gender, laterality).

To assess a difference in our primary outcome measure, we used a paired T-test comparing the mean of the differences between the initial VAS and VAS at 3 and 6 weeks. A value of $p < 0.05$ was considered statistically significant.

RESULTS

During a one year period, we enrolled 30 patients, 2 patients were lost to follow-up between their initial visit and their 6 week visit and were not included in the statistical analysis. The mean age was 47.3 (ranging from 30 to 64), mean BMI was 25.2 (ranging from 19 to 37.3). Twenty-three (82.1%) were male, 26 (92.8%) were affected on the right side and 24 (85.7%) were affected on their dominant side [Table/Fig-2]. VAS, Handicap, PPT at the initial visit, 3 weeks and 6 weeks is shown in [Table/Fig-3]. The results of our comparison between endpoints are summarized in [Table/Fig-4]. No patients needed or asked to be switched to another treatment modality.

	Values
Gender (% Male)	82.1%
Age (years)	47,3 ± 9.2 [30 ; 64]
Weight (kg)	70 ± 15.2 [45 ; 100]
Height (cm)	166 ± 10.7 [154.194]
BMI	25.2 ± 4.4 [19 ; 37.3]
Side (% right)	92.08%
Dominant Hand affected (% right)	85.7%

[Table/Fig-2]: Baseline characteristics

	Initial (n=28)	3 weeks (n=28)	6 weeks(n=28)
VAS during activities	80.8 ± 19.6 [25 ; 100]	35.4 ± 17.1 [4 ; 76]	13.0 ± 10.1 [2 ; 54]
VAS Pain under pressure	87.3 ± 14.3 [54 ; 100]	47.8 ± 13.0 [25 ; 78]	13.2 ± 8.5 [2 ; 34]
VAS Pain during contraction	76.6 ± 21.1 [19 ; 98]	33.8 ± 16.6 [8 ; 80]	10.6 ± 7.1 [1 ; 29]
VAS Handicap	70.8 ± 20.0 [28 ; 98]	30.6 ± 17.3 [11 ; 64]	8.5 ± 8.2 [2 ; 30]
PPT	0.4 ± 0.3 [0 ; 1]	2.2 ± 1.5 [0 ; 4.1]	3.7 ± 2.1 [0.5 ; 8.2]

[Table/Fig-3]: Comparison of VAS during activities, VAS Pain under pressure, VAS Pain during contraction, VAS Handicap and PPT at the initial visit with visit at 3 weeks and at 6 weeks time period (mean ± SD ; [range])
No patients needed or asked to be switched to another treatment modality

	Initial-3 weeks	3 weeks-6 weeks	Initial-6 weeks
VAS during activities	- 44.5*	- 23.5*	- 66.2*
VAS Pain under pressure	- 39.0*	- 35.4*	- 73.2*
VAS Pain during contraction	- 39.4*	- 23.7*	- 62.0*
VAS Handicap	-22.8*	-22.7*	-61.2*

[Table/Fig-4]: Comparison in VAS at rest between endpoints (by mean of the differences)
* $p < 0.01$

DISCUSSION

A recently updated meta-analysis by Loew [17] does not find sufficient evidence in favor of DTF on pain, improvement of grip strength and functional status. One randomized controlled trial with 40 patients with lateral epicondylalgia was included in the analysis and did not show statistically significant result in favor DTF. Many

studies are excluded from analysis for insufficient methodological quality but no studies include a DTP technique in their protocol.

Our pilot study show a significant benefit of the use of the MyoDK for DTP in lateral epicondylalgia. We were able to show a significant reduction in pain using DTP at both 3 and 6 weeks follow ups. Moreover, only 2 patients were lost to follow-up and no patient asked or needed to be switched to another treatment modality, which make the use of the MyoDK for a standardized DTF protocol a very well tolerated and accepted treatment.

The treatment is safe because perpendicular application of pressure causes no shear stress on the different layers of tissue with therefore very low risk of lesion. Moreover this can also explain why this treatment modality is much more tolerated than DTF. After a few sessions pressure superior to 6 kg/100mm² could be applied.

Our study is the first to address the problem of pressure measurement during treatment in epicondylalgia. By defining and recording the pain threshold at the location of the epicondylalgia, at each visit, we were able to apply consistent pressure and show the patient his progress. The procedure has allowed great adherence of the patients with low rate lost to follow up. There hasn't been any adverse effect reported although the treatment protocol was reaching pain thresholds at each study. To our knowledge the maximum amount of pressure that can be reached by applying pressure perpendicularly to a tendon hasn't been study. However Kukulka has reached 10 kg (N/mm²) on Achille tendon [18]

Having a numeric value for the pressure applied allows for low inter and intra operator variability, which is fundamental for the evaluation of new techniques, and solves for a major shortcoming in the evaluation of any manual therapy.

High pressure are difficult to reach for the therapist because they put tremendous pressure on his/her hands, most notably the trapeziometacarpal joint and can result in trapeziometacarpal joint degenerative disease over the long term [19]. Moreover those high are rarely reached and most probably never sustained because of human biomechanic physiological limitation. The MyoDK device allows the application of high pressure on the treatment area using the physician's body weight and eliminating pressure from the physician's hand. This is of significant importance in the treatment of obese patients or athletes with high muscular density, and to avoid physician chronic hand pain.

Our pressure protocol is similar to DTF but is less painful because there are no transverse friction and is therefore closer to manual ischemic compression. The emergence of the myofascial trigger point concept as a potential generator of myofascial pain in epicondylalgia was reviewed by Shmushkevich [20] and offers a insightful approach to the relevance of ischemic compression technique for the treatment of musculo-skeletal pain. Contrary to ischemic compression the device allows modulation of the pressure applied during the treatment, probably modulating ischemic pressures.

Perpendicular pressure or DTF has the ability to modify tissue intrinsic property by increasing tolerance to stretch. At the microscopic level those techniques probably modifies collagen cross-linking [6]. At the difference of stretching manipulation (as in the gliding technique) direct pressure techniques probably have the potential to modify collagen hydration and collagen unfolding [21,22].

Physical therapy literature offers one pilot study by McLean and al., [23], that aimed to physically evaluate the pressure required to produce analgesia during manual therapy. The manipulative treatment aimed to realize a lateral glide and was to be associated with voluntary movement of the patient. They found the best results were obtained with higher pressure applied. Similarly, each treatment in our study aimed to reach higher pressure and was a criterion for follow-up during the course of the treatment.

Kukulka and et al., [18] found that by doing perpendicular pressure on Achille tendon, H reflex was decreased in soleus muscle but there was not difference between 5 and 10 kg pressure [18].

Pain regulating mechanism i.e diffuse noxious inhibitory control by treating arm at different locations, are present but we believe there is poor if any neurological sustained effect [18,20,24].

In this study, the use of the MyoDK for DTF in the treatment of LE had favorable results as we were able to significantly improve patient pain using a reliable and reproducible protocol. In this study chronic patient can be considered their own control if we consider the length of symptoms. Our next steps in the evaluation of this new technique are to compare the MyoDK for DTP to other treatments modalities in a randomized-controlled trial and allow us to better define the indications for this intervention

CONCLUSION

The use of the MyoDK for DTF of chronic lateral epicondylalgia showed good tolerability with no side effect. Besides significant pain reduction at 3 and 6 weeks were observed. The use of MyoDK allows reproducible pressure application for standardization of treatment, while significantly reducing stress to the physician's hand.

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PARTICULARS OF CONTRIBUTORS:

1. Medical Practitioner, Department of Musculo-skeletal Rehabilitation, Leukerbad Clinic, Leukerbad, Switzerland.
2. Hospital Surgeon, Department of Orthopedic Surgery and Traumatology, Centre Hospitalier dArgenteuil, Argenteuil, France.
3. Faculty, Department of Internal Medicine, LSU Shreveport, USA.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Jason Outrequin,
Leukerbad Clinic, Willy-Spuler Strasse 2, 3954 Leukerbad.
E-mail: Outrequin@gmail.com

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