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Because not everyone can be mentioned, we want to express a general gratitude to all the people who have been supporting and guiding us through the process of this thesis. Thereby, we want to give special thanks to our relatives and friends, their constant motivation and encouragement have been a great support.

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Research context

As part of our master's degree in Rehabilitation sciences and physiotherapy at University of Hasselt, we present our thesis named 'Test-retest reliability of the elbow muscle strength'. This thesis is situated in the Musculoskeletal Rehabilitation domain.

In 2010, medical Doctor (MD) Carl Dierickx started to evaluate the effect of corticoid infiltration to treat distal biceps tendinopathies, in analogy with other tendinopathies. Patients suffered less pain and regained more force and mobility after treatment. These corticoid infiltrations therefore could serve as an alternative conservative treatment option instead of the golden standard surgical operation. To concretize the subjective patient outcomes, MD Carl Dierickx contacted Dr. Pieter Van Noten to measure force and mobility output of the treated patients. He concluded there was a gain in strength in the m. biceps brachii during elbow flexion and pronation, range of motion and less pain after the corticoid infiltrations. Although, some strength and mobility deficit remained compared to the contralateral side. The findings point out a positive effect of treatment with corticoid injections.

As physiotherapists, we are experts in treating strength and mobility deficits. Yet, to evaluate this treatment, we are interested in developing a parameter to evaluate tendon health. The structural changes in tendinopathy after exercise programs were summarized in our literature study from last year (2017). The idea of developing a tendon specific strength parameter was abandoned after a final consult with MD Carl Dierickx. For that matter we chose to evaluate reliability of strength testing in the elbow joint of healthy subjects. The strength will be measured using the Biodex System 3® as it has been done in the studies mentioned earlier. This is an interesting topic for patients, surgeons and physical therapists as well, who frequently depend on the reliability of the outcome measures of this system.

This master thesis is fulfilled by two last-year students Physical Therapy and Rehabilitation. Both students decided to divide the workload. The patient recruitment was done by the students themselves and all the measurements and tests were performed in the research centre of Hasselt University (REVAL), located in Diepenbeek, under supervision of promotor Dr. Van Noten.

Content

Abstract

Background: Medical Doctor Carl Dierickx started researching the effects of corticoid infiltrations in the treatment of distal biceps tendinopathy with very positive results for strength, joint mobility, and pain. However, the question remained if the perceived strength gain is objective and due to the infiltration itself. Therefore, a reliable and valid device is needed. Isokinetic dynamometers, like The Biodex system 3®, are seen as the golden standard. However, there are limited studies regarding the reliability of the Biodex system 3® involving the elbow joint.

Objectives: In this current study the focus lies on the reliability of strength testing in the elbow joint of healthy subjects using the Biodex system 3®.

Participants: 19 (9 males, 10 females) healthy subjects were selected, with ages varying from 20 to 68 years old. Participants did not have any injuries in one of the upper limbs, in present or past. All completed an informed written consent, approved by the Ethical Committee. There was one dropout during the study.

Measurements: The primary outcome is the reliability of the elbow strength, measured in peak torque (Nm) and was tested during isometric, isokinetic concentric and eccentric contraction at 60°/s while performing elbow flexion and extension, supination and pronation. The secondary outcome is the reliability of range of motion. The participants were measured on two separate days, with an interval of 7 to 14 days in between.

Results: The primary outcome showed significant differences for isokinetic concentric and isometric flexion (respectively P=0.0047 and 0.007) between the two measurement moments. The intraclass correlation coefficient was good to excellent with values ranging from 0.78 to 1. The secondary outcome showed a significant difference for active flexion left arm in range of motion (P=0.0241), with a good to excellent intraclass correlation coefficient (ICC: 0.88-1).

Conclusion: The results show that the Biodex system 3® can be used as a reliable tool for measurements of muscle strength in the elbow joint. This protocol can be used as a tool for clinicians and researchers in future studies of this joint.

Introduction

Distal biceps tendinopathies (DBT) are commonly caused by overload, leading to structural changes in the tendon itself, and are associated with symptoms like pain, loss of strength, and functional problems in the affected limb. DBT therapy, like corticoid infiltrations, therefore require regular muscle strength follow-up to evaluate progression. Elbow flexion and supination are both key aspects of biceps muscle output. However, it is uncertain if maximal elbow strength measured with the Biodex System 3® dynamometer is a reliable clinical tool for evaluating DBT progression.

A frequently used and fast clinical evaluation to assess muscle strength is the manual muscle testing method (MMT), using a scale from 0 to 5. Although, the reliability is still questionable (Clarkson, 2000). The isometric hand-held dynamometer (HHD) is more specific since it assesses force output at a chosen joint angle during an isometric contraction. In other words, strength cannot be measured throughout range of motion but only in a static position. The HHD has a good to excellent reliability in various population groups (Bohannon & Andrews, 1987; Stark et al., 2011). However, the current golden standard in the strength measurement device is an isokinetic dynamometer, for example the Cybex and the Biodex System. Dynamometers evaluate strength (as torque; in Newtonmeter (Nm)) during a dynamic or static contraction, within a chosen range of motion or fixed position (Osternig, 1986; Drouin et al., 2004; Lund et al., 2005). A huge advantage is the ability to measure isokinetic muscle contractions during dynamic movement, since they reflect activities of daily life. Measurements of strength in dynamic exercises where velocity is not controlled, is difficult because the force applied to the muscles alters through the range of motion depending on the velocity. So, from a rehabilitation point of view the development of isokinetic dynamometers are useful because these devices provide data about muscle load and limb velocity throughout a joints range of movement (Osternig, 1986; Yong Seok, 2015). The disadvantages are the high purchase price and the experience and knowledge to operate the equipment.

In general, previous studies stated that the Biodex System is a reliable and valid device to determine position, torque, and velocity measurements (Drouin et al., 2004). Also, it has already been shown that the isokinetic strength measurement in the lower limbs are reliable

in healthy subjects during lower limb multi-joint movement (isokinetic concentric contraction, ICC ≥ 0.75; isometric contraction ICC: 0.82) and during isokinetic concentric knee flexion and extension (ICC> 0.90) (Callaghan et al., 2000; Sole et al., 2007). When evaluating the shoulder joint, Edouard et al. (2013) investigated the isokinetic peak torque during internal and external rotation (IR and ER) at speeds 60°/s and 120°/s for concentric contraction and 30°/s for eccentric contraction in 64 healthy subjects; there was a 7-day interval between evaluations. They started the evaluation with 3 submaximal contractions, followed by 5 maximal repetitions while verbal encouragement was given. The results show a high reliability of concentric and eccentric peak torque during IR (ICC 0.81- 0.97) and ER (ICC 0.87- 0.97).

Only a limited amount of articles are found about the reliability of the Biodex System 3® observing the elbow joint. The first study, Lund et al. (2005), investigated the concentric isokinetic peak torque at speed 60°/s during elbow flexion and extension in 13 healthy subjects; there was a 30 minute and 1-week interval between measurements. No significant differences were noted between the short and the long interval compared to baseline; there was an excellent reliability for elbow flexion (ICC: 0.96) and elbow extension (ICC: 0.95). In the second study, Bassan et al. (2015), investigated the isometric and concentric isokinetic peak torque at speeds 60°/s and 180°/s during elbow flexion and extension in 20 trained male swimmers; there was a 48-72-hour interval between 2 sessions. No significant differences were noted between 2 sessions; there was a moderate to excellent reliability (ICC: 0.79- 0. 92). In the third study; Ekstand, Lexell and Brogardh (2015), investigated the isometric and concentric isokinetic peak torque at speed 60°/s during elbow flexion and extension in 45 subject post stroke; there was a 1-week interval between measures. An excellent reliability (ICC: 0.92- 0.97) was noted. However, these studies have limitations such as sample size: 13-20 subjects, subject population: trained swimmers (Bassan et al., 2015) or stroke patients (Ekstrand, Lexell & Brogardh., 2015) or very short interval between evaluations: 30 minutes (Lund et al., 2005). Moreover, none of the above-mentioned studies investigated the eccentric contraction and no studies examined the reliability of the Biodex System 3® during pronation/ supination of the forearm are found. Thereby, to the best of our knowledge, no study has evaluated the reliability of a complete strength testing protocol of the elbow joint, and more specific the m. biceps brachii, using the Biodex System 3®.

As shown above, there are limited studies regarding the reliability of the Biodex system 3® involving the elbow joint and among which only limited contraction types are used, particularly eccentric contraction. Therefore, the aim of this study is to evaluate the test-retest reliability of strength measurements in the elbow joint in healthy subjects, using the Biodex system 3® during every possible directions of movement of the elbow joint (flexion, extension, pronation, supination) and in three contraction types (isometric, concentric, eccentric). In this way the present study tries to establish a complete protocol of the elbow joint that can be used as a tool for clinicians and researchers in future studies of this joint.

Method

The study is set up with a test-retest design, evaluating the bilateral maximal strength and mobility of the elbow and forearm joint, with an interval of 7 to 14 days. There was no intervention undertaken between both measurement moments. On both occasions, an identical protocol was implemented. First, all subject completed an informed written consent (appendix 3), approved by the Ethical Committee and a questionnaire, with the intention to gather further information about work and leisure (appendix 2). Active and passive range of motion (ROM) of the elbow was verified using a goniometer; the strength tests were performed with an isokinetic dynamometer, Biodex System 3®. The design and protocol had been approved by the Medical Ethical Committee of Hasselt University (CME2017/774) on 31/01/2018.

Participants

Participants were recruited via a simple add on social media. The inclusion criteria were set to healthy persons, with age between 18 and 70 years old and the cognitive ability to perform the tests. Participants with any complains or dysfunction of the elbow or wrist joint; muscle/tendon tear or muscle/ tendon rupture in one of the upper limbs, in present or past, were excluded for safety reasons. In total 19 subjects were selected, consisting of 9 men and 10 women. None of the subjects ever participated in a previous study involving arm muscle testing. The participants were asked not to perform high loaded strength training and not to load the upper limbs heavily on the day or the day before the test.

Intervention

Measurement of mobility: both active and passive range of motion (ROM) of pronation and supination of the forearm and elbow flexion and extension were always measured by the same examiner, using a goniometer, according to the methods of Clarkson and Gilewich (1989). After a demonstration, active ROM was evaluated by maximal effort of the participant to move the joint as far as possible in the asked direction. Thereafter, a passive overpressure (until end-range) was given by a second examiner to evaluate passive ROM.

For flexion and extension evaluation, the participant stood upright, with the upper arm along the side of the thorax and the wrists in neutral position. The axis of the goniometer was aligned with the lateral epicondyle, the stationary arm of the goniometer was aligned with the

longitudinal axis of the humerus and the movable arm with the longitudinal axis of the radius (Clarkson & Gilewich, 1989). For pronation and supination evaluation, the participant was standing upright, with the elbow in 90° flexion, the forearm in neutral position and a pen gripped in his hand to enhance the measurement. The reference points were capitis metacarpi III (axis of the goniometer), longitudinal axis of the humerus bone (stationary arm of the goniometer) and the extension of the pen (movable arm of the goniometer) (Clarkson & Gilewich, 1989). The researchers were aware and alert of the compensation strategy in the wrist joint; these were corrected if necessary.

Strength testing: the maximum strength outcome (expressed in peak torque; Nm) was tested during isometric, concentric and eccentric contraction while performing elbow flexion, extension, supination and pronation. This was evaluated by an isokinetic dynamometer Biodex System 3®. The participants received a clear explanation of what kind of contraction was needed, followed by 3 warm-up repetitions at 80% of their maximal strength. Then, 5 maximal strength repetitions of every contraction were performed with 20 seconds of rest in between every variety of contraction. During the maximal strength testing the participants were verbally encouraged.

For all force evaluations, participants were seated according to the protocol described in Sardra et al. (2013). They were positioned upright with the trunk fixed to the chair by two straps. For flexion/ extension movement the humerus was fixated with the shoulder positioned in 45° anterior flexion and the wrist in neutral position; a range of motion was set up from 60° to 120° flexion during dynamic contractions; during static contraction the elbow was fixed at 90° flexion. For supination/ pronation the forearm was fixated with the elbow positioned in 90° flexion, a range of motion was set up from 20° pronation to 20° supination during dynamic contractions, during static contractions the forearm was fixed in neutral position. During all dynamic strength measurements, motion was set to 60°/s.

The parameters used for the strength measurements are peak torque and coefficient of variation. Peak torque (Newton*meter) reflects the maximal muscle strength at any time throughout a movement. The coefficient of variation measures the variability among the multiple repetitions as a percentage. Odd measurement outcomes were deleted before the

data-analysis was executed, for example peak torque which resulted in 0.00 Nm and abnormal high coefficient of variation.

Statistics

Data analysis was carried out with JMP 13. Due to a low number of participants, non-parametric tests were used with α- level set at 0.05. All data are presented as mean ± standard deviation. The hypotheses that were formulated and investigated are listed in Appendix 1.

To assess differences in peak torque, coefficient of variation, and range of motion between measurement 1 and measurement 2, a paired Wilcoxon signed ranks test was performed. In the same manner the influence of the dominance of the arm on the peak torque and range of motion was determined. The Friedman two-way ANOVA-analysis was used to investigate the differences in peak torque between the three contraction types of the previously mentioned directions of movement (flexion, extension, pronation, supination). The same ANOVA-analysis was utilized to investigate the difference in stability (known as the coefficient of variation) of the measurement between the contraction types or between the directions of movement. The Intraclass Correlation Coefficient was calculated with a 95% confident interval for reliability between the two measurement moments. This rates values as follows: <0.5 are indicative of poor reliability, between 0.5 – 0.75 moderate, between 0.75 – 0.90 good and 0.9 or higher for excellent reliability.

Results

Subjects

Nineteen subjects (9 men and 10 women) participated in the study. The average age was 28.4, with a range from 21 to 68 years old. 17 participants were right-handed. These demographic characteristics are listed in table 1. Due to poor compliance, the results of measurement 2 is missing from one subject. Further, eccentric elbow extension data from one measurement moment was discarded for one subject, because he held on to the seat. No adverse effects were reported after the measurements.

Table 1. *Demographics*

Total number of subjects	19
Males	9
Females	10
Age (years)	28.4 (21;68)
Dominant arm	
right	17
left	2

Differences between the two measurement moments

Between the two measurement moments, an increase of 2.01 Nm was found in peak torque for concentric flexion ($p=0.0047$) and an increase of 3.32 Nm for isometric flexion ($p=0.007$) (figure 1). After using a Bonferroni correction, these differences were no longer evident (the Bonferroni α- level <0.0042). When calculating the Intraclass Correlation Coefficient (ICC), a good to excellent reliability was found between the two measurement moments for all the different contraction types and directions of movement, with ICC values varying from 0.78 – 1. An increase of 1.53° in range of motion was noticed for active flexion, in the left arm ($p=0.0241$) (figure 2 and 3). These differences were also no longer evident after applying a Bonferroni correction (The Bonferroni α- level <0.0063). After calculating the ICC an excellent reliability was found, with values varying from 0.9666 – 1. There was only a significant difference in coefficient of variation between the two measurement moments for concentric pronation, with a more stable measurement during the second measurement moment ($p=0.0009$).

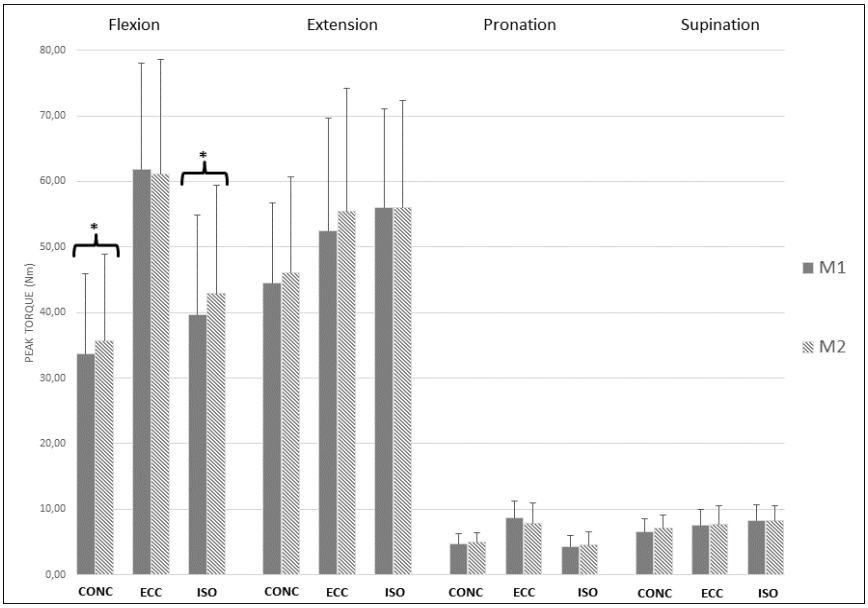

***Figure 1**: Mean ± 1 SD of peak torque between the two measurements within the different contraction types and directions of movement. M1: measurement 1; M2: measurement 2; Nm: Newtonmeter; CONC: concentric contraction; ECC: Eccentric contraction; ISO: isometric contraction; *: p<0.05.*

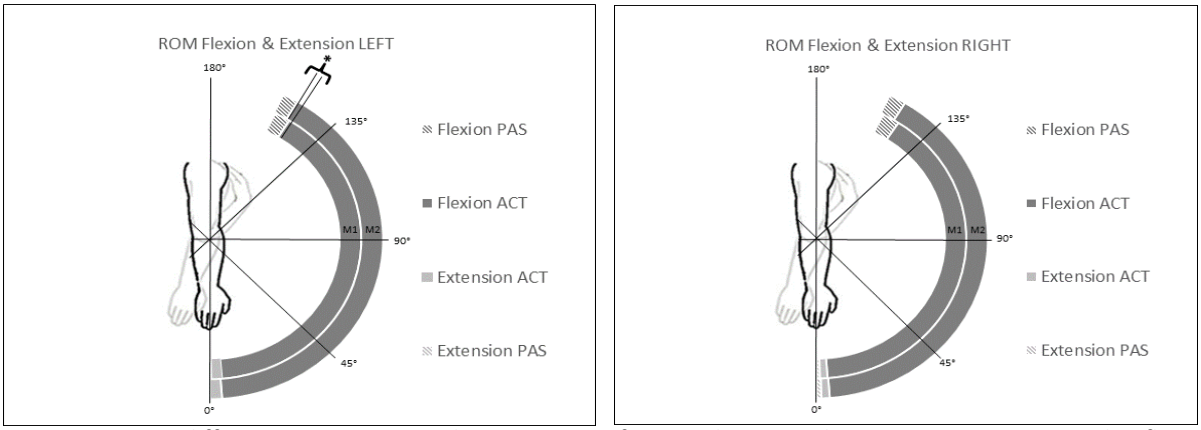

***Figure 2**: Mean differences in passive and active range of motion between the two measurements within flexion and extension; M1: measurement 1; M2: measurement 2; PAS: passive; ACT: active; *: p<0.05.*

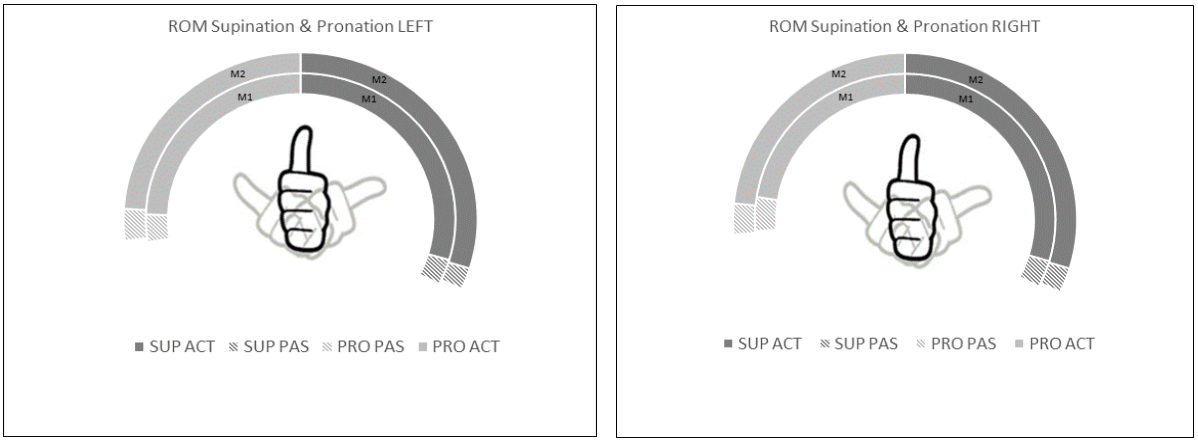

***Figure 3**: Mean differences in passive and active range of motion between the two measurements within supination and pronation; M1: measurement 1; M2: measurement 2; PAS: passive; ACT: active; PRO: pronation; SUP: supination; *: p<0.05.*

Comparison of contraction types

Between the various contraction types, the results show a difference with a p-value <0.0001. Only for the following results the p-value differs: between isometric and eccentric supination (p=0.0498), between eccentric and concentric supination (p=0.0176) and between isometric and eccentric extension (p=0.0315). No difference was found between concentric and isometric pronation. The results show that more torque could be delivered in eccentric and isometric contraction than in concentric contraction. In flexion and pronation, the delivered peak torque is higher in eccentric contraction than in isometric contraction. In extension and supination, peak torque is higher in isometric contraction than in eccentric contraction (figure 4).

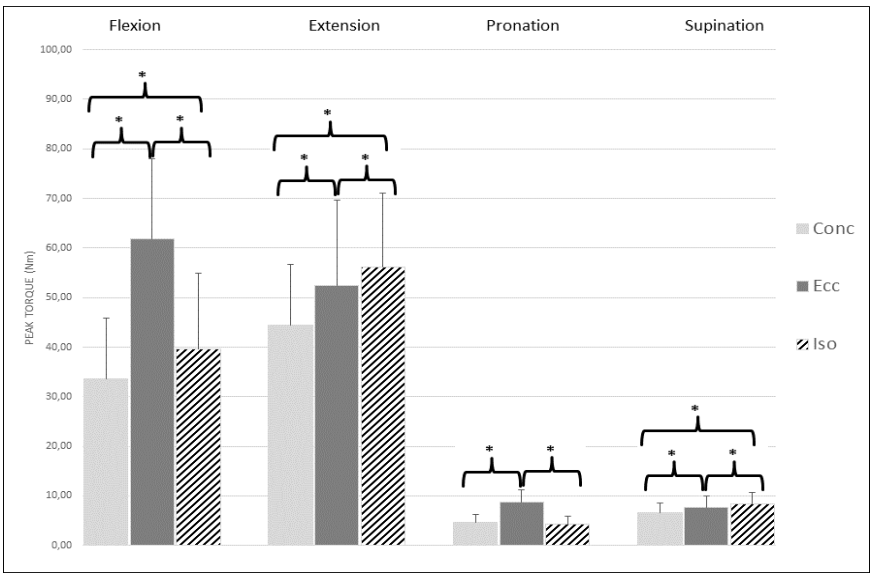

***Figure 4**: Mean ± 1 SD of peak torque between the contraction types within the different directions of movement during measurement 1; *: p<0.05.*

Influence of dominance

The dominant arm is stronger than the non-dominant arm, with an average difference of 5.97 Nm during concentric flexion (p=0.0002), 4.41 Nm during isometric flexion (p=0.0195), 4.86 Nm during eccentric extension (p=0.0055), and 4.41 Nm during eccentric pronation (p=0.0452) (figure 5). When looking at range of motion, the non-dominant arms show an average of 2.26° wider range during active flexion (p=0.0214), 6.10° during active pronation (p=0.0262), and 5.79° for passive pronation (p=0.0019) (figure 6).

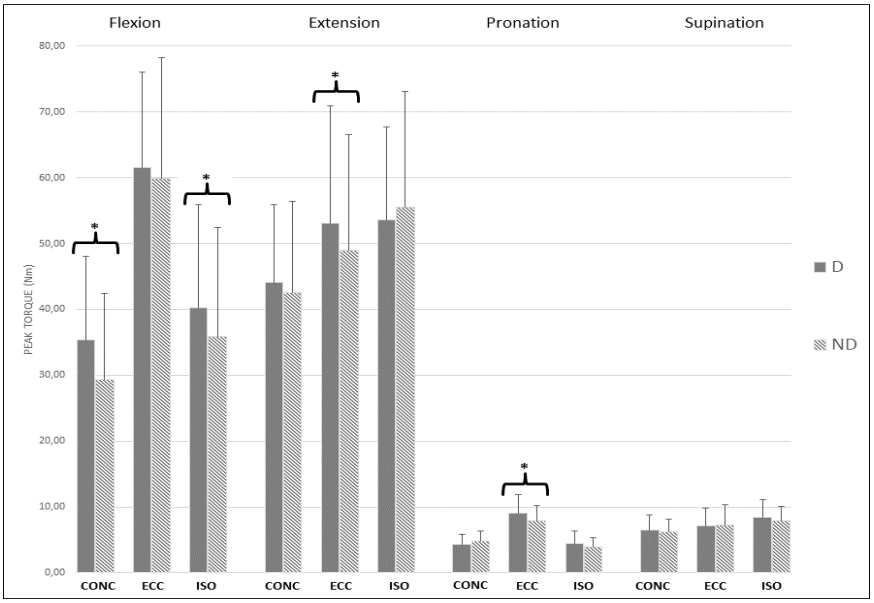

***Figure 5**: Mean ± 1 SD of peak torque between dominant and non-dominant arm within the different directions of movement and contraction types during measurement 1; D: dominant-arm; ND: non-dominant arm; *: p<0.05.*

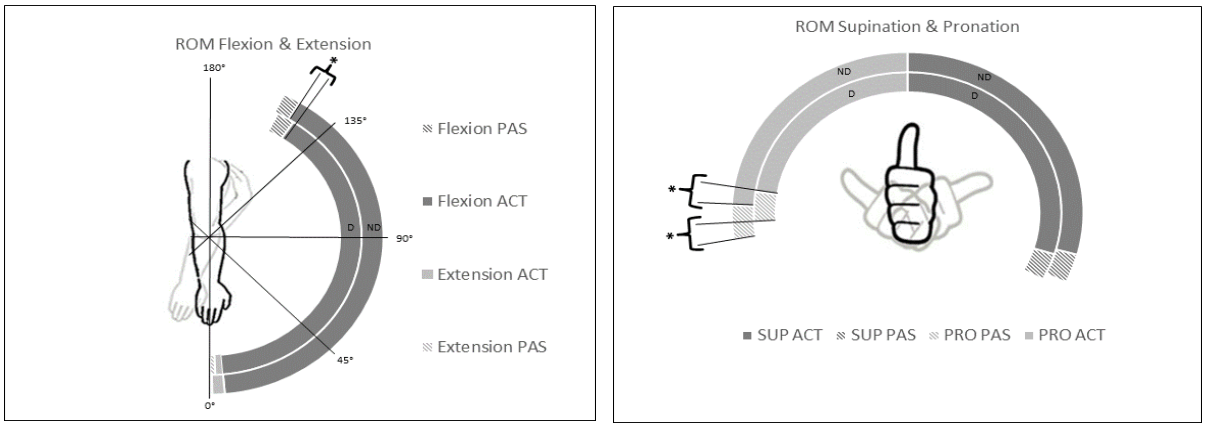

***Figure 6**: Mean differences in passive and active range of motion between dominant and non-dominant arm during measurement 1; D: dominant-arm; ND: non-dominant arm; *: p<0.05.*

Stability of the measurements

The results show that isometric contractions (p=0.0001) and concentric contractions (p=0.0034) were less variable than eccentric contractions during pronation. Isometric contractions showed lower variability than concentric contractions during supination (p=0.0433). During extension and flexion, all the contraction types were equally variable. Pronation was more variable than flexion, extension and supination during concentric and isometric contractions (p<0.0001). Supination was more variable than flexion during eccentric contraction (p<0.0001) and more variable than extension during eccentric and isometric contraction (p=0.0002) (figure 7).

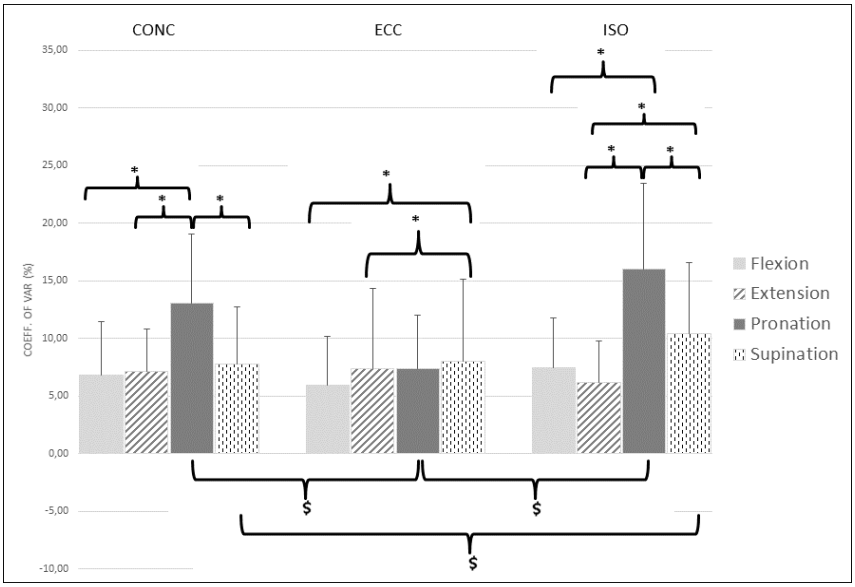

***Figure 7**: Mean ± 1 SD of coefficient of variation during measurement 1; *: p<0.05 between the contraction types within the different directions of movement; $: p<0.05 between the different directions of movement within the contraction types.*

Discussion

The main focus of this study was to compare the muscle strength delivered in the elbow joint between two measurement moments using the Biodex system 3® in healthy subjects. The results show a slight increase when comparing peak torque, for concentric and isometric flexion.

Reliability of peak torque measurements

A possible explanation for the differences between two measurement moments could be found in differences in subject compliance (as following the preset instructions, delivering maximal force or avoiding strength training), subject motivation, fatigue or a learning effect. Difference in compliance and motivation could lead to a difference in strength delivered during the tests, since the subjects are expected to deliver their maximum force. To improve subject compliance, the researchers could have repeated the measurements for subjects who scored a coefficient of variation of 10% or higher. This method was used in Lund et al. (2005), to ensure the subjects delivered their maximal force during all repetitions. In the present study a coefficient of variation close to 10% was found for isometric and concentric flexion (respectively 7.27% and 9.16%). These values are close enough to the cut-off (10%) of Lund et al. (2005), making differences in compliance a viable explanation. To control the effect of subject motivation (the subjects competitive drive to improve their first measurement score), the results of measurement one were not communicated with the subjects.

When considering fatigue of the subjects as a potential explanation (e.g. the first measurement being in the morning and the second after a full day of work), the question remains why only a difference in concentric and isometric flexion was found. Nogueira et al. (2012) noticed that the elbow flexor muscles are influenced in a higher degree by resting time, which could be interpreted as fatigue, than the elbow extensor muscles. This could explain the unlikely reasoning of fatigue only influencing flexion measurements. However, it is unclear why only concentric and isometric contractions during flexion were significant different.

During the second measurement, the subjects could be more familiar with the exercises they needed to perform, this could lead to a learning effect. Lund et al. (2005) found that a clear instruction before test performance is a necessary prerequisite for avoiding a learning effect. The current study tried to limit this learning effect by giving the same clear instructions before

every measurement and by including trial sessions before testing, thus making the explanation of a learning effect influencing the results less plausible. When looking at other studies with the same design using the Biodex system 3®, one study found similar results. Ekstrand, Lexell and Brogardh (2015) also tested the elbow flexion in stroke patients using the Biodex system 3® with a test-retest design. Their study also noticed an increase in muscle strength in isokinetic elbow flexion measured during the second test. They interpreted this result as a learning effect.

The results could also be influenced by the measurement device itself. Due to the various body lengths and extremities, especially the arm lengths, every subject was seated in an individually adjusted position. The seat height of the Biodex is not able to alter which made it more difficult to position shorter people in an ideal set-up, with the result that not all participants could be seated with 45° shoulder anteflexion. Because the m. biceps brachii and m. triceps brachii are biarticular muscles, the variation of shoulder flexion angles has significant influence on elbow flexion peak torques. For elbow extension peak torque, the degree of shoulder flexion had less influence. Thus, a variance in seat positioning between two measurement moments may also be responsible for the difference in flexion peak torques as Guenzkofer et al. (2012) showed that more shoulder flexion leads to significant lower elbow flexion torques.

However, as the difference between the two measurement moments is minimal (2.01 Nm for concentric and 3.32 Nm for isometric flexion), these results could be assumed as not clinical relevant and can be due to a type I error. When using the Bonferroni correction, the results were no longer evident. This means these differences could be explained by a type I error, since the Bonferroni correction is used to avoid this error with the use of multiple comparison tests. To add on this, ICC calculations pointed out a good to excellent reliability of the test-retest results during all contraction types and directions of movement.

Reliability of range of motion measurements

When examining the range of motion between the two measurement moments, the results show a wider range of motion for active flexion of the left arm during the second measurement ($p=0.0241$). Other studies also investigated test-retest reliability of range of motion measurements; Greene and Wolf (1989), Armstrong et al. (1998) and Chapleau et al. (2011) showed a high reliability of the active range of motion of the elbow and/or forearm

joint, measured with a universal goniometer. Rothstein et al. (1983) only investigated the passive elbow joint range of motion, with a high reliability as result. Goodwin et al. (1992) and Santos et al. (2012) do not support these findings; these studies show a moderate to high reliability and low to high reliability.

When applying the Bonferroni correction, these differences were also no longer evident, meaning these differences could also be explained by a type I error. Again, ICC calculations indicate an excellent reliability of the range of motion measurements and the minimal difference between the measurement moments (1.53°) might indicate that the significant differences are not clinically relevant.

Validity

A recent systematic review (Kotte et al., 2018) made an overview of the normative values of the isometric elbow strength (in flexion, extension, pronation and supination) of healthy adults. Besides, Jakobe Brynard wrote a masterthesis about normative data of peak torque in isometric and concentric elbow flexion and supination. The average peak torques measured in the present study are similar to these normative values. Furthermore, they were comparable to the results (concentric elbow flexion and extension) of Lund et al. (2005). Thus, our measurements of peak torque with the Biodex system 3® can be considered as valid. Unfortunately, no (normative) data were found for eccentric elbow torque measurements.

Normative data of the elbow range of motion in healthy subjects were established in Zwerus et al. (2017). The average active and passive range of motion in the different directions of movement measured in the current study were comparable to these of Zwerus et al. (2017) and thus, our range of motion measurements can also be considered as valid.

Contraction types

When looking at the maximum strength delivered in the different contraction types in each direction of movement for the elbow joint, the results of the current study show that more force has been delivered during eccentric and isometric contraction than during concentric contraction. Furthermore, more force has been delivered during eccentric contraction than during isometric contraction when measuring flexion and pronation, this was also found in the

study of Chapman, Newton and Nosaka (2005). It is shown that muscles which contract eccentrically, use less oxygen, a smaller amount of ATP, and less motor-unit involvement than muscles contracting concentrically (Doss & Karpovich, 1965). As described by A.V. Hill in 1938, the force created by a muscle is different across various speeds, called the force-velocity relationship. This relationship states that in concentric actions, the produced force decreases with increasing velocity of shortening. Force is zero at maximum velocity and maximal at zero velocity (being an isometric contraction). In eccentric actions, the force the muscle can resist increases with increasing velocity of lengthening (Hageman, Gillaspie & Hill, 1988, Walmsley, Pearson & Stymiest, 1986; Rodgers & Berger, 1974). These findings confirm the fact that during repeated isokinetic testing the eccentric torques are higher than isometric torques, while concentric torques decline with varying slopes with increasing speed of shortening.

When measuring extension and supination, more force has been delivered in isometric contraction than during eccentric contraction, which is contradictory with the measurements during flexion and pronation. Before starting the extension and supination measurement, only 20 seconds resting interval was induced. The rest interval before the pronation measurement was higher (>60 seconds) because the construction of the Biodex system had to be adjusted before this measurement. It is evident that before starting the flexion measurement (the first measurement), there was no fatigability due to the measurement exercises yet. It has been shown that the influence of muscle fatigability is higher in eccentric than in isometric contractions due to metabolic strain (Ryschon et al., 1997). This could explain why during extension and supination less force is produced during eccentric than during isometric contractions. Parcell et al. (2002) found that a resting period of 60 seconds or more between sets during maximal isokinetic force production is sufficient for the recovery of force production in healthy subjects. Again, a shorter resting interval could have allowed fatigability to influence the results in extension and supination. The reason why the current study found no difference between concentric and isometric pronation is unknown. However, it is remarkable that the force production during pronation is very low in general. To date, no other studies investigated the difference between contraction types during a pronation measurement. Perhaps, this measurement is not clinically relevant because of the low force production during this movement.

Dominance

When comparing the results of peak torque between the dominant and non-dominant arm, a significant difference was found in favor of the dominant arm during concentric and isometric flexion, eccentric extension and eccentric pronation. Other studies confirm these results; Carpes et al. (2012) investigated maximal isometric and concentric contraction torque during elbow flexion and extension. A higher maximal peak torque in the dominant arm was found in concentric and isometric flexion torque at 90°. Gallagher et al. (1997) also found significant higher levels of peak torque in the dominant arm during concentric flexion. In these studies, the outcomes were explained by the preference to use the dominant arm in daily life activities causing an asymmetry. The studies Frontera et al. (1991) and Wittstein et al. (2010) did not find any significant difference during maximal elbow and forearm joint testing between the dominant and the non-dominant arm. Matsuoka et al. (2006) tried to explain this due to the sequence of the protocol; in this study the subjects were tested first on the dominant side, followed by the non-dominant side, which could lead to familiarization. This learning effect may have influenced the peak torque and therefore explain the contradictory results with the current study, since the subjects were randomly tested on the dominant and non-dominant side.

When comparing the results for range of motion, a larger range of motion in the non-dominant arm was found in active flexion, active pronation and passive pronation. Other studies confirm this difference in range of motion between both sides. Gunal et al. (1996) found a significant higher active and passive elbow flexion and extension and active and passive forearm supination on the non-dominant arm. Macedo and Magee (2008), also found significant higher ROM between both arms in passive and active supination, and in active elbow flexion in the non-dominant upper limb. Wang et al. (2016) also found a larger range of motion in the non-dominant arms during flexion, extension, and also during pronation and supination. A plausible explanation was given to muscle tightness of the antagonists or a larger muscle mass, where the dominant arms are used more frequently leading to an increased muscle tension and muscle volume which cause a decrease in range of motion. In the current study, there was only a difference noticed in elbow flexion and pronation, which could be linked to physical activities and hobbies of the subjects. These factors determine which

muscles are used more often in the dominant arm and hence which direction of movement is more restricted.

Coefficient of variation

The current study compared outcomes of coefficient of variation between the two measurement moments. Results show that concentric pronation was more stable during measurement 2 than during measurement 1. No previous studies were found investigating the same outcome. The results could be explained by increase in motivation, whereby the subjects performed a more stable measurement on measuring moment 2.

This study also analyzed the variability of each contraction type in the different directions of movement. The results show that isometric contractions and concentric contractions were less variable than eccentric contractions during pronation. Isometric contractions showed lower variability than concentric contractions during supination and during extension and flexion, all the contraction types were equally stable. This suggests an influence of contraction types on stability of movement. Christou and Carlton (2002) demonstrated that eccentric contractions are more variable compared with isometric and concentric contractions in knee-extension task. They reasoned that the difference in variability can be explained by the hypothesis that eccentric contractions are influenced uniquely by the central nervous system compared to concentric and isometric contractions. No clear explanation could be found for the contradictory results in the current study. The current study also noticed a difference in coefficient of variation depending on direction of movement in each contraction type. Pronation was more irregular than flexion, extension and supination during concentric and isometric contractions. Supination was more variable than flexion and extension during eccentric and isometric contractions. These findings are most likely explained by differences in discharge rate characteristics and motor unit recruitment of different muscles. Each muscle has a specific recruitment of motor units and discharge rate. Variability is influenced in an important manner by the sequential recruitment of motor units, first the small motor units and then the larger and by the difference in discharge rates characteristics of these motor units (Christou, Grossman & Carlton, 2002).

Strengths and limitations

The biggest strength of the current study is that this is a unique study measuring the reliability of a complete strength testing protocol of the elbow joint, using the Biodex System 3®, in all possible directions of movement (flexion, extension, pronation and supination) and contraction types (concentric, eccentric, isometric). Another important strength is the diversity of the subject population, it consists both genders (9 men and 10 women), ages varying between 20 to 68 and differences in physical activity level; this reduces selection bias and promotes generalization of results. Further, no adverse effects were reported after the protocol. So, it can be stated that measurements with the Biodex system 3® are safe and feasible. To increase reliability, all tests were performed by the same researcher and to reduce experimenter bias, this researcher was observed by another clinician. Last, the measurements were performed at the same location for all the subjects, this location was secluded, with minimal distractions reducing the possibility of external variables influencing the results e.g. concentration loss. The weaknesses of this study include the small number of investigated subjects and the dropout of one subject for the second measuring moment; this remains a downside for generalization of the results even though its diversity of the subject population. An important weakness is that certain results were not usable for four subjects e.g. eccentric pronation and eccentric supination. The strength measured in these conditions was 0 Nm. A plausible reasoning for these results lies in the functioning of the measurement tool (minimum strength needed to obtain results: 7 Nm) or difficulties in performance of the task. Eccentric pronation and supination at maximum torque are not frequently performed during daily life. The lack of these results is an important deficit for the strength of this study and for judging the test-retest outcome of eccentric pronation and supination.

Conclusion

This study shows that the Biodex system 3® can be used as a reliable tool for measurements of muscle strength in the elbow joint; ICC shows good to excellent reliability. Thereby the current study succeeded to set up a reliable and complete strength testing protocol of the elbow joint without occurrence of any complications. This protocol can be used for muscle strength evaluation to follow-up therapy progression. The results of this study could lead to more interest for using the Biodex system 3® as a measuring tool for the elbow joint and to more research and attention for afflictions involving the elbow joint and its treatment options. However, to confirm these results, further research is needed with bigger sample sizes.

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Appendix

1. Hypotheses

Inquiry 1:	Is there a difference in peak torque between the two measurement moments for each specific combination of contraction type (concentric, eccentric, isometric) and direction of movement (flexion, extension, supination, pronation)?
Hypothese:	H_0: peak torque measurement 1 = peak torque measurement 2 for each specific combination of contraction type and direction of movement H_1: peak torque measurement 1 $\neq$ peak torque measurement 2 for each specific combination of contraction type and direction of movement

Inquiry 2:	Is there a difference in coefficient of variation between the two measurement moments for each specific combination of contraction type and direction of movement?
Hypothese:	H_0: coefficient or variation measurement 1 = coefficient or variation measurement 2 for each specific combination of contraction type and direction of movement H_1: coefficient or variation measurement 1 $\neq$ coefficient or variation measurement 2 for each specific combination of contraction type and direction of movement

Inquiry 3:	Is there a difference in range of motion between the two measurement moments for each specific combination of movement pattern (active, passive) and direction of movement?
Hypothese:	H_0: Range of motion measurement 1 = Range of motion measurement 2 for each specific combination of movement pattern and direction of movement H_1: Range of motion measurement 1 $\neq$ Range of motion measurement 2 for each specific combination of movement pattern and direction of movement

Inquiry 4:	Is there a difference in peak torque between the various contraction types, within a certain direction of movement?
Hypothese:	H_0: peak torque during concentric contraction = peak torque during eccentric contraction = peak torque during isometric contraction (in flexion / extension, pronation / supination) H_1: peak torque concentric ≠ peak torque eccentric ≠ peak torque isometric (in flexion / extension, pronation / supination)

Inquiry 5:	Does the dominance of the arm affect the peak torque that can be delivered?
Hypothese:	H_0: Peak torque dominant arm = peak torque non-dominant arm for each specific combination of contraction type and direction of movement H_1: Peak torque dominant arm ≠ peak torque non-dominant arm for each specific combination of contraction type and direction of movement

Inquiry 6:	Does the dominance of the arm affect the range of motion of the directions of movement?
Hypothese:	H_0: Range of motion dominant arm = range of motion non-dominant arm for each specific combination of movement pattern and direction of movement H_1: Range of motion dominant arm ≠ range of motion non-dominant arm for each specific combination of movement pattern and diretion of movement

Inquiry 7:	Is there a difference in stability of the measurement (coefficient of variation) depending on the type of contraction?
Hypothese:	H_0: coefficient of variation during concentric contraction = coefficient of variation during eccentric contraction = coefficient of variation during isometric contraction H_1: coefficient of variation during concentric contraction ≠ coefficient of variation during eccentric contraction ≠ coefficient of variation during isometric contraction

Inquiry 8:	Is there a difference in stability of the measurement (coefficient of variation) depending on the direction of movement?
Hypothese:	H_0: coefficient of variation during flexion = coefficient of variation during extension = coefficient of variation during pronation = coefficient of variation during supination H_1: coefficient of variation during flexion ≠ coefficient of variation during extension ≠ coefficient of variation during pronation ≠ coefficient of variation during supination

2. *Subject questionnaire*

	Sex	Age	Proffesion	Hobby	Active days/week	Heavy load arm(s) during job/ hobby	Complaints upper limb(s) in present/ past
1)	F	24	Student	Running	0-1	No	No
2)	M	22	Student	Basketball, referee	3-4	No	No
3)	F	24	Student	Running	3	No	No
4)	F	25	Student	Fitness	1	No	No
5)	F	26	Physical Therapist	Fitness, cycling, running	4-5	No	No
6)	M	26	Doctor	Gaming	1	No	No
7)	F	24	Physical Therapist	Volleyball	3	Yes	No
8)	M	21	Student	Fitness	3	No	No
9)	F	26	Doctor	Running	2	No	No
10)	M	28	Employee	Volleyball, stepping	2	Yes	No
11)	M	26	Industrial engineer	Cycling	7	No	No
12)	M	21	Student	Soccer, referees	5	No	No
13)	F	24	Student	Volleyball	3	Yes	No
14)	M	21	Student	Horse riding, cycling	4	No	No
15)	M	28	student	Soccer, running	1	No	No
16)	F	24	Student	Running, skating, fitness	2-3	No	No

17)	F	25	Student	Running, tennis, cycling	2	No	No
18)	M	63	Doctor	Horse riding	2	No	No
19)	M	68	Retired	Chores, cycling	5	No	No
20)	F	55	Nurse	Reading	0	No	No

3. *Informed consent*

Geïnformeerde toestemming

Titel van de studie: Intra-beoordelaarbetrouwbaarheid van een ultrasonografische peesdikte-meting bij personen met een tendinopathie van de distale bicepspees na corticosteroïde infiltratie en bij gezonde personen.

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Ethisch comité: Ethische Toetsingscommissie Jessa Ziekenhuis en Comité voor Medische ethiek Uhasselt (CME Uhasselt)

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I. Noodzakelijke informatie voor uw beslissing om deel te nemen

Inleiding

Als u aan deze studie deelneemt, moet u weten dat:

De behandeling die de arts-onderzoeker u in overeenstemming met de huidige aanbevelingen heeft voorgesteld niet zal veranderen door uw deelname aan deze studie.

Deze klinische studie is opgesteld na evaluatie door één of meerdere ethische comités.

Uw deelname is vrijwillig; er kan op geen enkele manier sprake zijn van dwang. Voor deelname is uw ondertekende toestemming nodig. Ook nadat u hebt getekend, kan u de arts-onderzoeker laten weten dat u uw deelname wilt stopzetten.

De gegevens die in het kader van uw deelname worden verzameld, zijn vertrouwelijk. Bij de publicatie van de resultaten is uw anonimiteit verzekerd.

Er is een verzekering afgesloten voor het geval dat u schade zou oplopen in het kader van uw deelname aan deze klinische studie.

Indien u extra informatie wenst, kan u altijd contact opnemen met de arts-onderzoeker of een medewerker van zijn/haar team.

Aanvullende informatie over uw "Rechten als deelnemer aan een klinische studie" vindt u in bijlage 3 (pagina 5).

Doelstellingen en verloop van de studie

Deze klinische studie is georganiseerd om de betrouwbaarheid van een peesdikte-meting na te gaan, uitgevoerd met een ultrasonografie/ echografie toestel. Peesdikte is een van de belangrijke parameters die de belastbaarheid van de pees bepalen; hoe hoger deze factor, hoe meer krachten de pees kan weerstaan. Een verandering in peesdikte wordt gezien bij personen met een tendinopathie, bijgevolg wordt deze factor frequent onderzocht wanneer men het effect van een behandeling op een pees met tendinopathie wil nagaan. Daarbij is het van belang te weten wat de intra-beoordelaarbetrouwbaarheid is van een meting van de peesdikte met een ultrasonografie toestel is.

Wij stellen u voor om aan deze klinische studie deel te nemen omdat uw arts u een cortoicoïde infiltratie t.h.v. een chronische tendinopathie of partiële scheur in de distale bicepspees heeft toegediend in het kader van uw klinische situatie.

Aan deze klinische studie zouden een veertiental patiënten deelnemen en een viertiental gezonde personen. De duur van uw deelname aan deze studie bestaat uit twee onderzoeksmomenten tijdens dewelke uw arts-onderzoeker een ultrasonografie-meting zal uitvoeren. De uitvoering zal gebeuren in het Biomedisch onderzoekscentrum REVAL te Diepenbeek. Vervoerskosten worden vergoed op vertoon van een eenmalig vervoerskostenbewijs (bus, auto).

Beschrijving van de risico's en van de voordelen

Zoals hierboven vermeld, stemt de behandeling die u werd voorgesteld en de procedures voor diagnose en opvolging overeen met de goede medische praktijken. Uw deelname aan deze studie houdt geen gekende gezondheidsrisico's in. Verder zal uw deelname aan deze studie u geen persoonljke voordelen opleveren. Uw deelname aan dit onderzoek zou ons kunnen helpen om aan te tonen dat een peesdikte-meting met een ultrasonografie toestel betrouwbaar is en bijgevolg bruikbaar is in verder klinisch onderzoek waarin peesdikte onderzocht wordt. U helpt dan enigszins de medische wetenschap en mogelijks andere patiënten.

Intrekking van uw toestemming

U neemt vrijwillig deel aan deze studie en u hebt het recht om uw toestemming voor gelijk welke reden in te trekken. U hoeft hiervoor geen reden op te geven. Als u uw toestemming intrekt, zullen de gegevens bewaard blijven die tot op het ogenblik van uw stopzetting werden verzameld. Dit om de geldigheid van de studie te garanderen. Er zal geen enkel nieuw gegeven aan de opdrachtgever worden gegeven.

Als u aan deze studie deelneemt, vragen wij om:

Ten volle mee te werken voor een correct verloop van de studie.

Geen informatie over uw gezondheidstoestand, de geneesmiddelen die u gebruikt of de symptomen die u ervaart te verzwijgen.

Uw arts-onderzoeker op de hoogte te brengen als men u voorstelt om aan een andere studie deel te nemen zodat u met hem kan bespreken of u aan deze studie kunt deelnemen en of uw deelname aan de huidige klinische studie moet worden stopgezet.

Contact

Als u bijkomende informatie wenst, maar ook ingeval van problemen of als u zich zorgen maakt, kan u contact opnemen met de arts-onderzoeker Prof. Dr. Carl Dierickx (carl.dierickx@uhasselt.be). Als u vragen hebt met betrekking tot uw rechten als deelnemer aan de studie, kan u contact opnemen met de ombudsdienst in uw ziekenhuis op het telefoonnummer: 011 30 84 00 (Ombudsdienst Jessa Ziekenhuis, Campus Virga Jesse). Indien nodig kan de ombudsdienst u in contact brengen met het Ethisch Comité.

II Geïnformeerde toestemming

Deelnemer

Ik verklaar dat ik geïnformeerd ben over de aard, het doel, de duur, de eventuele voordelen en risico's van de studie en dat ik weet wat van mij wordt verwacht. Ik heb kennis genomen van het informatiedocument en de bijlagen ervan.

Ik heb voldoende tijd gehad om na te denken en met een door mij gekozen persoon, zoals mijn huisarts of een familielid, te praten.

Ik heb alle vragen kunnen stellen die bij me opkwamen en ik heb een duidelijk antwoord gekregen op mijn vragen.

Ik begrijp dat mijn deelname aan deze studie vrijwillig is en dat ik vrij ben mijn deelname aan deze studie stop te zetten zonder dat dit mijn relatie schaadt met het therapeutisch team dat instaat voor mijn gezondheid.

Ik begrijp dat er tijdens mijn deelname aan deze studie gegevens over mij zullen worden verzameld en dat de arts-onderzoeker en de opdrachtgever de vertrouwelijkheid van deze gegevens verzekeren overeenkomstig de Belgische wetgeving ter zake.

Ik stem in met de verwerking van mijn persoonlijke gegevens volgens de modaliteiten die zijn beschreven in de rubriek over het verzekeren van de vertrouwelijkheid (bijlage 3, pagina 6). Ik geef ook toestemming voor de overdracht naar en verwerking van mijn gecodeerde gegevens in andere landen dan België.

Ik ga ermee akkoord / Ik ga er niet mee akkoord (doorhalen wat niet van toepassing is) dat de studiegegevens die voor de hier vermelde studie worden verzameld, later zullen worden verwerkt, op voorwaarde dat deze verwerking beperkt blijft tot de context van de hier vermelde studie voor een betere kennis van de ziekte en de behandeling ervan.

Ik ga ermee akkoord / Ik ga er niet mee akkoord (doorhalen wat niet van toepassing is) dat mijn huisarts of andere specialisten die zich met mijn gezondheid bezighouden, indien nodig worden gecontacteerd om aanvullende informatie over mijn gezondheid te verkrijgen.

Ik heb een exemplaar ontvangen van de informatie aan de deelnemer en de geïnformeerde toestemming.

Naam, voornaam, datum en handtekening van de deelnemer:

Arts-onderzoeker

Ik ondergetekende Dierickx Carl, arts-onderzoeker, verklaar de benodigde informatie inzake deze studie mondeling te hebben verstrekt evenals een exemplaar van het informatiedocument aan de deelnemer te hebben verstrekt.

Ik bevestig dat geen enkele druk op de deelnemer is uitgeoefend om hem/haar te doen toestemmen met deelname aan de studie en ik ben bereid om op alle eventuele bijkomende vragen te antwoorden.

Ik bevestig dat ik werk in overeenstemming met de ethische beginselen zoals vermeld in de "Verklaring van Helsinki", de "Goede klinische praktijk" en de Belgische wet van 7 mei 2004 inzake experimenten op de menselijke persoon.

Naam, Voornaam,

Prof. Dr. Carl Dierickx

Datum en handtekening van de arts-onderzoeker:

III Aanvullende informatie

1: Aanvullende informatie over de organisatie van de studie

Het onderzoek houdt in dat er twee metingen zullen plaatsvinden met een ultrasonografie toestel waarbij de dikte van uw pees wordt nagegaan. Deze zal uitgevoerd worden door Prof. Dr. Carl Dierickx en zal uitgevoerd worden in *het Biomedisch onderzoekscentrum REVAL te Diepenbeek.* Vervoerskosten worden vergoed op vertoon van een eenmalig vervoerskostenbewijs (bus, auto).

2: Aanvullende informatie over de risico's die verbonden zijn aan de deelname aan deze studie:

Er zijn geen gekende gezondheidsrisico's verbonden aan de deelname aan deze studie.

3: Aanvullende informatie over de bescherming en de rechten van de deelnemer aan een klinische studie

Ethisch comité

Deze studie werd geëvalueerd door een onafhankelijk ethisch comité, namelijk de Ethische Toetsingscommissie van het Jessa Ziekenhuis in Hasselt, dat een gunstig advies heeft uitgebracht, en na raadpleging van het ethisch comité van medische ethiek van de Uhasselt. De ethische comités hebben als taak de personen die aan klinische studies deelnemen te beschermen. Ze controleren of uw rechten als patiënt en als deelnemer aan een studie gerespecteerd worden, of de studie wetenschappelijk relevant en ethisch verantwoord is.

Hierover brengen de ethische comités een advies uit in overeenstemming met de Belgische wet van 7 mei 2004.

U dient het positief advies van de Ethische Comités in geen geval te beschouwen als een aansporing om deel te nemen aan deze studie.

Vrijwillige deelname

Aarzel niet om alle vragen te stellen die u nuttig vindt voordat u tekent. Neem de tijd om er met een vertrouwenspersoon over te praten, als u dit wenst.

U heeft het recht om niet deel te nemen aan deze studie of met deze studie te stoppen zonder dat u hiervoor een reden hoeft te geven, zelfs al hebt u eerder toegestemd om aan deze studie deel te nemen. Uw beslissing zal in geen geval uw relatie met de arts-onderzoeker en de voortzetting van uw therapeutische behandeling veranderen. Als u aanvaardt om aan deze studie deel te nemen, ondertekent u het toestemmingsformulier. De arts-onderzoeker zal dit formulier ook ondertekenen en zal zo bevestigen dat hij u de noodzakelijke informatie voor deze studie heeft gegeven. U zult het voor u bestemde exemplaar ontvangen.

Kosten in verband met uw deelname

De arts-onderzoeker en zijn team worden niet vergoed voor hun tijd die ze aan deze studie besteden. Het betreft immers een niet gesponsorde studie waarbij het initiatief volledig ligt bij de vernoemde arts-onderzoeker, twee studenten Revalidatiewetenschappen en Kinesitherapie en een doctor-assistent in de Revalidatiewetenschappen en Kinesitherapie. U zult ook geen vergoeding krijgen voor uw deelname aan deze studie. Uw deelname zal echter voor u geen bijkomende kosten met zich meebrengen. Vervoerskosten worden door het onderzoekersteam vergoed op vertoon van een eenmalig vervoerskostenbewijs (bus, auto).

Vertrouwelijkheidgarantie

Uw deelname aan de studie betekent dat u ermee akkoord gaat dat de arts-onderzoeker gegevens over u verzamelt en die gebruikt voor onderzoek en in het kader van wetenschappelijke en medische publicaties.

U hebt het recht om aan de arts-onderzoeker te vragen welke gegevens hij/zij over u heeft verzameld en waarvoor ze gebruikt worden in het kader van de studie. Deze gegevens hebben betrekking op uw huidige klinische situatie maar ook op uw medische voorgeschiedenis en op de resultaten van onderzoeken die werden uitgevoerd voor de behandeling van uw gezondheid volgens de geldende zorgstandaard. U hebt het recht om deze gegevens in te kijken en om verbeteringen te laten aanbrengen indien ze foutief zouden zijn[1].

De arts-onderzoeker is verplicht om deze verzamelde gegevens vertrouwelijk te behandelen.

Dit betekent dat hij zich ertoe verbindt om uw naam nooit bekend te maken in het kader van een publicatie of een conferentie, en dat hij uw gegevens zal coderen (uw identiteit zal worden vervangen door een identificatiecode in de studie) voordat hij ze eventueel doorgeeft aan de

1 Deze rechten zijn bepaald door de wet van 8 december 1992 tot bescherming van de persoonlijke levenssfeer ten opzichte van de verwerking van persoonsgegevens en door de wet van 22 augustus 2002 betreffende de rechten van de patiënt.

beheerder van een databank. Op dit moment is het team niet van plan om de gegevens door te geven aan een firma of een databank.

De arts-onderzoeker en zijn team zullen gedurende de volledige klinische studie de enige personen zijn die een verband kunnen leggen tussen de overgedragen gegevens en uw medisch dossier [2].

De overgedragen persoonlijke gegevens omvatten geen combinatie van elementen waarmee het mogelijk is u te identificeren. [3]

Om de kwaliteit van de studie te controleren, kan uw medisch dossier worden ingekeken door personen die gebonden zijn aan het beroepsgeheim zoals vertegenwoordigers van de ethische comités, van de opdrachtgever van de studie of een extern auditbureau. Dit kan enkel gebeuren onder strikte voorwaarden, onder de verantwoordelijkheid van de arts-onderzoeker en onder zijn/haar toezicht (of van één van zijn/haar onderzoeksmedewerkers).

De (gecodeerde) onderzoeksgegevens kunnen doorgegeven worden aan Belgische of andere regelgevende instanties, aan de ethische comités, aan andere artsen en/of instellingen die samenwerken met de opdrachtgever.

Ze kunnen ook doorgegeven worden aan andere sites van de opdrachtgever in België en in andere landen waar de normen inzake de bescherming van persoonsgegevens verschillend of minder strikt kunnen zijn. Dit gebeurt dan steeds in gecodeerde vorm zoals hierboven uitgelegd [4] (hier niet van toepassing).

Uw toestemming om aan deze studie deel te nemen betekent dus ook dat u akkoord gaat dat uw gecodeerde medische gegevens gebruikt worden voor doeleinden die in dit informatieformulier staan beschreven en dat ze worden overgedragen aan bovenvermelde personen en/of instellingen (hier niet van toepassing).

De opdrachtgever verbindt zich ertoe om de verzamelde gegevens enkel in het kader van deze studie te gebruiken.

Indien u uw toestemming tot deelname aan de studie intrekt, zullen de gecodeerde gegevens die al verzameld waren vóór uw terugtrekking, bewaard worden. Hierdoor wordt de geldigheid van de studie gegarandeerd. Er zal geen enkel nieuw gegeven aan de opdrachtgever worden doorgegeven.

[2] De wet verplicht om voor klinische studies dit verband met uw dossier gedurende 20 jaar te bewaren.

3 De database met de resultaten van de studie zal dus geen elementen bevatten zoals uw initialen, uw geslacht en uw volledige geboortedatum (dd/mm/jjjj).

4 De opdrachtgever verbindt zich ertoe om het bindend karakter van de Europese richtlijn en van de Belgische wetgeving inzake bescherming van de persoonlijke levenssfeer te respecteren.

Verzekering

De opdrachtgever is, ook indien er geen sprake is van fout, aansprakelijk voor de schade die u als deelnemer - of in geval van overlijden uw rechthebbenden - oplopen en die rechtstreeks of onrechtstreeks te wijten is aan de deelname aan deze studie. Hiervoor heeft de opdrachtgever/ arts-onderzoeker een verzekeringscontract afgesloten (Ethias).

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KNOWLEDGE IN ACTION

VOORTGANGSFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDTEKENINGEN
13/07/2017	Overleg Ethische Commissie	Promotor: Copromotor: Student(e): Hocqué Student(e):
17/01/2018	Bespreking in vreand met wranderingen onderzoeksprotocol	Promotor: Copromotor: Hocqué Student(e): Student(e):
12/01/2018	Bespreking en uitwerking methode	Promotor: Copromotor: Hocqué Student(e): Student(e):
25/01/2018	Bespreking en uitwerking methode	Promotor: Copromotor: Hocqué Student(e): Student(e):
31/01/2018	Bespreking en uitwerking methode	Promotor: Copromotor: Hocqué Student(e): Student(e):
8/03/2018	Bespreking statistische analyse en werking JMP via Skype	Promotor: Copromotor: Hocqué Student(e): Student(e):
13/03/2018	Bespreking statistische analyse via Skype	Promotor: Copromotor: Hocqué Student(e): Student(e):
23/03/2018	Bespreking statistische analyse via Skype	Promotor: Copromotor: Hocqué Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):
		Promotor: Copromotor: Student(e): Student(e):

Auteursrechtelijke overeenkomst

Ik/wij verlenen het wereldwijde auteursrecht voor de ingediende eindverhandeling:
Test-retest reliability of elbow muscle strength

Richting: **master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij musculoskeletale aandoeningen**
Jaar: **2018**

in alle mogelijke mediaformaten, - bestaande en in de toekomst te ontwikkelen - , aan de Universiteit Hasselt.

Niet tegenstaand deze toekenning van het auteursrecht aan de Universiteit Hasselt behoud ik als auteur het recht om de eindverhandeling, - in zijn geheel of gedeeltelijk -, vrij te reproduceren, (her)publiceren of distribueren zonder de toelating te moeten verkrijgen van de Universiteit Hasselt.

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Ik verklaar tevens dat ik voor het materiaal in de eindverhandeling dat beschermd wordt door het auteursrecht, de nodige toelatingen heb verkregen zodat ik deze ook aan de Universiteit Hasselt kan overdragen en dat dit duidelijk in de tekst en inhoud van de eindverhandeling werd genotificeerd.

Universiteit Hasselt zal mij als auteur(s) van de eindverhandeling identificeren en zal geen wijzigingen aanbrengen aan de eindverhandeling, uitgezonderd deze toegelaten door deze overeenkomst.

Voor akkoord,

Bocqué, Marthe **Luyck, Sophie**

Datum: **5/06/2018**