

**The Immediate Effects of an External Rotation
Exercise Program Compared with a General
Exercise Program in Patients with Rotator Cuff
Tendinopathy and Healthy Controls: a
Randomised Controlled Trial**

Sara De Reu, Delphine De Roover, Sofie De Schamphelaere

Supervisors: Prof. Dr. Ann Cools, Prof. Birgit Castelein

A dissertation submitted to Ghent University in partial fulfilment of the requirements for the degree
of Master of Science in Rehabilitation and Physiotherapy

Academic year: 2017 – 2018

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In September 2016, we had the opportunity to submit a thesis topic or to choose one of the proposed. We thought it would be a challenge to present our own study. One year earlier, we had already written a literature study about shoulder prostheses with the three of us. This has stimulated us to dedicate our master thesis to the shoulders as well.

This study would not have been possible without the help of some important people.

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LIST OF ABBREVIATIONS

RC = rotator cuff

IR = internal rotation

ER = external rotation

AHD = acromiohumeral distance

PPT = pain pressure threshold

ICC = intraclass correlation coefficient

MDC = minimal detectable change

NRS = numeric rating scale

SD = standard deviation

y = year

m = meter

kg = kilogram

C = matched control group

T = tendinopathy group

NS = not significant

SIS = subacromial impingement syndrome

MTP = myofascial trigger point

1 Abstract

1.1 English

Background: It is clear that exercise therapy is an important part of the rehabilitation of a rotator cuff (RC) tendinopathy. Currently, no consensus is reached about the optimal exercises for subjects suffering from this pathology.

Objectives: This study aimed to examine the short-term effects of two different exercise programs in patients with a RC tendinopathy and in healthy controls.

Study design: Randomised, controlled, non-blinded trial.

Methods: Twenty pain-free healthy persons and 20 patients with a RC tendinopathy participated in this study. Ten subjects of each group performed an exercise program with only external rotation (ER) movements. The other 20 participants accomplished a general exercise program focused on the whole RC. Pressure pain threshold (PPT) of the M. infraspinatus, acromiohumeral distance (AHD) at 0°, 45° and 60° abduction and five viscoelastic properties of the M. infraspinatus (oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time and creep) were measured before and immediately after exercising to determine evolution.

Results: Statistical analysis showed a significant higher PPT and a significant larger acromiohumeral space for the healthy controls compared with the RC tendinopathy patients. Furthermore, there are significant higher values for relaxation time and creep in the control group. At 0° and 45° abduction, a significant higher AHD is measured compared with 60° abduction. No significant differences were found between the two exercise programs and between the pre- and post-measurements.

Conclusion: No significant differences could be demonstrated by comparing pre- versus post-exercise measurements. Therefore, it is not possible to conclude which exercise program is superior. Further research with a larger study population is necessary to draw conclusions.

Keywords: Rotator cuff tendinopathy, general exercise program, external rotation program

1.2 Nederlands

Achtergrond: Het is duidelijk dat oefentherapie een belangrijke plaats inneemt in de revalidatie van een rotator cuff (RC) tendinopathie. Momenteel is er nog geen consensus bereikt over welke oefeningen optimaal zijn voor de behandeling van deze patiëntenpopulatie.

Doelstellingen: Deze studie had als doel om de kortetermijneffecten te onderzoeken van twee verschillende oefenprogramma's bij patiënten met een RC tendinopathie en bij gezonde controles.

Onderzoeksdesign: Gerandomiseerde, gecontroleerde, niet-geblindeerde studie.

Methode: Twintig symptoomvrije personen en 20 patiënten met een RC tendinopathie namen deel aan deze studie. Tien personen van elke groep voerden een oefenprogramma uit met enkel exorotatie-oefeningen. De andere 20 deelnemers vervulde een algemeen oefenprogramma gericht op de volledige RC. De drukpijndrempel van de M. infraspinatus, de acromiohumeraal afstand op 0°, 45° en 60° abductie en de vijf visco-elastische eigenschappen van de M. infraspinatus (oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time en creep) werden gemeten voor en onmiddellijk na het uitvoeren van de oefeningen om de evolutie te registreren.

Resultaten: Uit statistische analyse bleek een significant hogere drukpijndrempel en een significant grotere acromiohumeraal afstand voor de gezonde proefpersonen in vergelijking met de patiënten. Verder zijn er significant hogere waarden voor relaxation time en creep vastgesteld in de controlegroep. In 0° en 45° abductie werd een significant grotere acromiohumeraal afstand gemeten vergeleken met 60° abductie. Noch tussen de twee oefenprogramma's, noch tussen de pre- en post-meetresultaten zijn er significante verschillen gevonden.

Conclusie: Er zijn er geen significante verschillen gevonden bij het vergelijken van de metingen voor en na de oefeningen. Hierdoor is het niet mogelijk om te besluiten welk oefenprogramma superieur is. Verder onderzoek met een grotere studiepopulatie is nodig om conclusies te kunnen trekken.

Sleutelwoorden: Rotator cuff tendinopathie, algemeen oefenprogramma, exorotatie-oefenprogramma

2 Introduction

The rotator cuff (RC) is a multifunctional complex around the shoulder consisting of four different muscles, namely M. supraspinatus, M. infraspinatus, M. subscapularis and M. teres minor¹. These four provide different movements like internal rotation (IR), external rotation (ER) and glenohumeral abduction. On the other hand, the complex provides a high degree of stabilisation. It is the most important dynamic stabilizer² and controls the humeral head translations during activity and movements by compression^{3,4}. It is proven that the RC muscles require sustained contractions, while surrounding muscles with large moment arms produce rotational movements of the humerus with respect to the scapulae⁵. Consequently, an injury of these muscles or the introduction of pain will have a negative effect on the stabilization of the glenohumeral joint and thus more humeral head translations will occur⁶. This is associated with a lack of coordination and neuromuscular balance between the muscles^{1,7,8}.

RC tendinopathy is often determined as a common reason of shoulder pain⁹ and is behold as an 'umbrella term', which includes a variety of diagnoses related to different tendon signs and symptoms (e.g. M. supraspinatus tendinopathy, M. infraspinatus tendinosis...) ¹⁰. These terms are frequently used in clinical settings: tendinopathy is the clinical description of a tendon overuse, a tendinosis is a histopathological description of this problem, and tendinitis does not have a significant role in tendon overuse injuries¹¹.

Various randomised trials proved that the short-term and long-term outcomes in RC tendinopathy patients treated with surgery are comparable to conservative treatment^{12,13,14}. Furthermore Ingwersen et al.¹⁵ recently established a significant improvement in pain, function and strength of both progressive high-load and traditional low-load strength training (with two specific RC exercises) in patients with a RC tendinopathy. Heron et al.¹⁶ showed that different types of exercises (open versus closed chain exercises) were effective in improving strength, functionality and pain in patients with RC tendinopathy. Thus, in general it is clear that traditional exercise therapy, with a focus on strengthening the RC muscles and scapular stabilizing muscles, is effective in patients with this pathology^{10,17}.

In healthy people, Castelein et al.⁶ demonstrated an inhibitory effect of the activity of the M. infraspinatus during arm elevation after applying acute experimental shoulder pain. These results suggest that RC muscle function (including the external rotators) should be an important part of the early management in the rehabilitation of patients with shoulder pain. Thereby, in overhead athletes it has been demonstrated that weak external rotators play a role in the pathomechanics leading to different shoulder pathologies such as RC lesions¹⁸, internal impingement¹⁹...

In the past few years, interest in the role of the external rotators increased and more studies investigated the activity of M. infraspinatus and M. teres minor in healthy, non-athletic populations during different exercises^{20,21}. Both muscles provide ER and abduction movements. At the moment, it has been proven that M. infraspinatus is a more effective external rotator at lower abduction grades while M. teres minor works more efficiently in higher abduction grades³.

At the moment, no consensus is reached about the optimal exercise program for adults suffering from RC tendinopathy¹². Moreover, no studies have investigated the effect of an ER program on patients with this pathology. The aim of this study was to compare short-term effects of two types of exercise programs in a population with RC tendinopathy, one focused on traditional therapy which included the whole RC and one focused specifically on activating external rotators. Outcome parameters were acromiohumeral distance (AHD), pain pressure threshold (PPT), oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time and creep. This comparison has been carried out in a healthy, matched control group as well.

3 Methods

3.1 Study design and data collection

This study is a randomised, controlled, non-blinded trial. The study group, consisting of patients with a RC tendinopathy, was compared to a healthy control group. Two different interventions were examined. For each study group, half of the participants received an exercise program focused on ER and the others followed an exercise training for the whole RC. The randomisation took place through 20 closed envelopes (10 for each intervention) for both groups of which the subject had to pick out one.

Three second year master students of the program of Master of Science in Rehabilitation and Physiotherapy performed all baseline and post-intervention measurements. Before data collection, the students were trained in using the devices by more specialized investigators. The research took place between the 30th of October 2017 and 20th of February 2018. All measurements are executed in the Department of Rehabilitation Sciences and Physiotherapy at the University Hospital of Ghent (Belgium).

The recruitment of subjects began in September 2017. First of all, 150 posters and concomitant letters were distributed mainly in the region of Ghent in sports clubs, practices of general practitioners and physiotherapists... At a later stage the flyer was also shared on social media.

3.2 Population

The population of this study consisted of 40 subjects who were divided in two subgroups. One subgroup of 20 patients with a RC tendinopathy and a second group consisting of 20 matched controls. The matching was done based on age, gender, BMI and physical activity. The inclusion criteria of the tendinopathy group were: age between 18 and 65 years old, persevering symptoms for at least one month and three or more of the five positive shoulder tests (painful arc, ER against resistance, test of Jobe, test of Hawkins and test of Neer)²². Reasons for exclusion were a total rupture, a history of systemic disorders, shoulder traumata (luxation, fracture...), surgery of the shoulder and two or more cortisone injections. Patients with small calcifications or partial tears were admitted to the study, on the sole condition that this was proven by echo or MRI. The control group could not present symptoms or a history of shoulder or neck injuries.

There was an extensive selection process to check if the participants met the eligibility criteria by using a questionnaire and carrying out a clinical examination. Included subjects were invited to participate in the current study. All subjects were informed about the aim and method of the study and signed the Informed Consent. The study was approved by the Ethics Committee of Ghent University.

3.3 Outcome measures

3.3.1 PPT of the M. infraspinatus

Patients were positioned in prone with upper arms supported on the table and forearms hung down. Two points were marked with a dermatological pencil on the M. infraspinatus. The first point was situated about two centimetres lateral to the medial scapular border and seven centimetres inferior to the spina scapulae. Point two was located about four centimetres to the medial scapular border and four centimetres inferior to the spina scapulae. During indication of the marks, morphology of participants was taken into account. When a mark was too osseous, the nearest best location was used (maximum two centimetres divergent).



Figure 1: initial position of the subject + position of the algometer

A 'Wagner FPX™ Digital Algometer' was used to objectify the PPT. Participants were instructed to indicate when the feeling changed from pressure to an unpleasant feeling. The sensor of the algometer was placed on a point and pressure was gradually driven up with one Newton per second until the patient said stop (figure 1)²³.

This procedure had an intraclass correlation coefficient (ICC) of 0.945 for point one and 0.953 for point two, which means an excellent intra-rater reliability²⁴. Minimal detectable change (MDC) was for point one 2.939 and for point two 2.577. These values were calculated with a pilot study carried out by the researchers.

3.3.2 AHD

The AHD was measured by an ultrasound device (Colormaster 128 EXT-IZ Telemed UAB, Vilnius, Lithuania). Hereby a linear transducer of 10MHz (HL9.0/40/128Z) was used to capture the ultrasound images²⁵.

The initial position of the subject was a sitting position on a tabouret, feet flat on the floor, a neutral trunk, head straight and arms resting on the thighs with thumbs up. Before the examination, the acromion was indicated with a dermatological pencil. Measurements were performed twice in three different positions of the shoulder, namely 0°, 45° and 60° abduction. For higher abduction grades (45° and 60°) an inclinometer and a belt was used to maintain the right position while the measurements were performed (figure 2)²⁶. The ultrasound images were processed by the three researchers separately. The perpendicular distance between the humeral head and acromion was measured and was used for further analysis (figure 3).



Figure 2: initial position at 0° and 60° abduction + position of the ultrasound probe

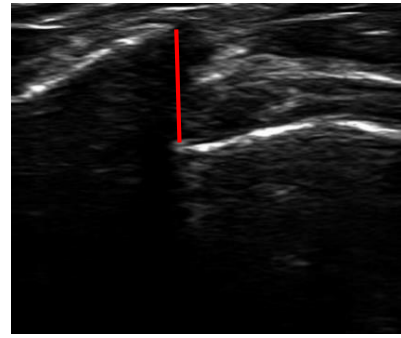


Figure 3: ultrasound image + measured AHD

This procedure had an ICC of 0.945 at 0° abduction, 0.835 at 45° abduction and 0.884 at 60° abduction, which means an excellent intra-rater reliability²⁴. MDC was 1.073, 2.327 and 2.312 at 0°, 45° and 60° abduction respectively. These values were calculated with a pilot study carried out by the researchers.

3.3.3 Oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time and creep of the M. infraspinatus

The MyotonPro measures the state of tension and the biomechanical and viscoelastic properties of muscles. The starting position of the test subject remained the same as for algometry and the probe was placed on the same points. The examiner sat down on a chair next to the patient and held the device firmly in both hands, whilst this two elbows were leaning upon the table and the forearms were positioned vertical to the table. First the MyotonPro was placed perpendicular to the measuring point, then the device tapped 10 times (figure 4)²⁷.

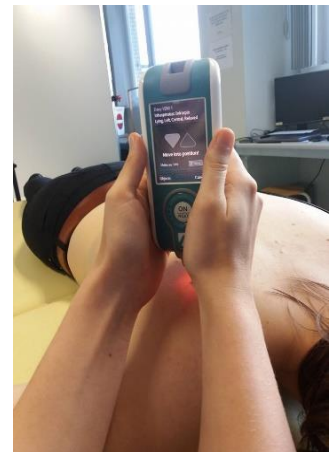


Figure 4: initial position of the subject + position of the MyotonPro

Five different parameters were tested: the oscillation frequency, dynamic stiffness, logarithmic decrement, mechanical stress relaxation time and creep.

In order to register reliable measurements, only parameters with a coefficient of variation less than three percent were included²⁸.

3.4 Intervention

3.4.1 Test procedure

During the test protocol the exercise program was decided by randomisation. Furthermore, a short explanation was given about the goal of the examination and data of intake was checked to see if nothing changed.

At the start of the examination, Numeric Rating Scale (NRS) was completed. Then the volunteers were positioned in supine and marks for algometry and MyotonPro were indicated. Subsequently, investigators performed the measurements with the MyotonPro (two measurements at each point) and algometer (three measurements at each point with ± 15 seconds recuperation). To measure the AHD with the ultrasound, starting position changed from supine to sitting position (two measurements at 0°, 45° and 60° of abduction). All measurements were accomplished on the dominant side (in controls) or the injured side (in patients). After this, the exercise program was explained and dosage was determined (see modalities). The controls executed the exercises on the dominant side and the patients on the injured side, taking into account the established modalities. Immediately after the exercises, the NRS and BORG scale were questioned and PPT, AHD and the five viscoelastic properties were re-evaluated. The entire testing lasted about 45 minutes and each investigator had a predetermined function.

3.4.2 Exercise program 1: ER program

This program consisted of three exercises with an ER component. The first exercise was in prone with a dumbbell in the hand. The subject was lying on the edge of the table with the arm hanging down and moved to ER with abduction (figure 5). The second exercise was executed with a weight and in prone too, though the upper arm was supported on the table. During this exercise, the forearm was moved to an ER position (figure 6). The last exercise was in standing position with feet slightly spread and shoulders relaxed. Elbow was fixated against the body in 90° flexion and the participant performed ER with a theraband (figure 7).



Figure 5: horizontal abduction with ER in prone
Left: initial position, right: end position



Figure 6: ER in prone
Left: initial position, right: end position



Figure 7: ER in standing position
Left: initial position, right: end position

3.4.3 Exercise program 2: general exercise program

This program included three exercises that focused on all muscles of the RC. The first two exercises were performed in standing position with the feet slightly spread and shoulders relaxed. Elbows were bent 90° and fixated against the body. The first exercise was an ER against resistance of the elastic theraband (idem last exercise ER program, figure 7). The second exercise was an IR against resistance with a theraband (figure 8). For the last exercise, the participant did a full elevation in the scapular plane with a dumbbell in a standing position (figure 9).



Figure 8: IR in standing position
Left: initial position, right: end position



Figure 9: elevation in the scapular plane
Left: initial position, right: end position

3.4.4 Modalities

All exercises were performed in three series of 15 repetitions. Between the series there was a rest period of 15 seconds and between the different exercises there was a break of 30 seconds. The dosage of the exercises was determined before the exercise program. The assessors made a table with predicted colour of the theraband and predicted weight of the dumbbell, depending on gender and body weight (appendix 1 and 2). These values were predicted based on scientific literature²⁹ and a pilot study of 30 subjects in the environment of the researchers. This table was just a guide. The researchers tried to estimate if the predicted weight was sufficient for an effort between 11 to 14/20 on the BORG scale and no more than 4/10 on the NRS for pain. Afterwards, the patient had one practice opportunity and there was asked if the suggested weight induced a slightly to somewhat heavy activity. Once started with a weight or a coloured theraband, the series were completed without any change of dosage. Exercises were performed on a quiet standardised pace, controlled with a metronome. ER in prone, ER in stand and IR in stand were performed on a velocity of 35 beats per minute and the two other exercises on a velocity of 25 beats per minute. The execution of the exercises was strictly controlled by the three researchers and corrected if necessary⁶.

3.5 Statistical analysis

First, descriptive statistics were utilised to summarise the data by using means and standard deviations (SD). Afterwards, demographic features were analysed with an independent-samples T-test. Subsequently, four-way interactions in the ANOVA linear mixed models were investigated (group x exercise x time x point/position) for the outcome parameters. If no significant four-way interactions were presented, three- and two-way interactions among the variables of interest were examined. When there was a lack of significant interactions ($\alpha > 0.05$ for ANOVA), main effects were analysed. If a significant difference was found with ANOVA, post hoc analyses were executed using a Bonferroni correction. Before the ANOVA linear mixed models were applied, residuals of the data were found to be normally distributed using the histogram and Q-Q plot. All statistical analyses were performed using the IBM SPSS Statistics version 25 (IBM Corporation, Armonk, NY, USA).

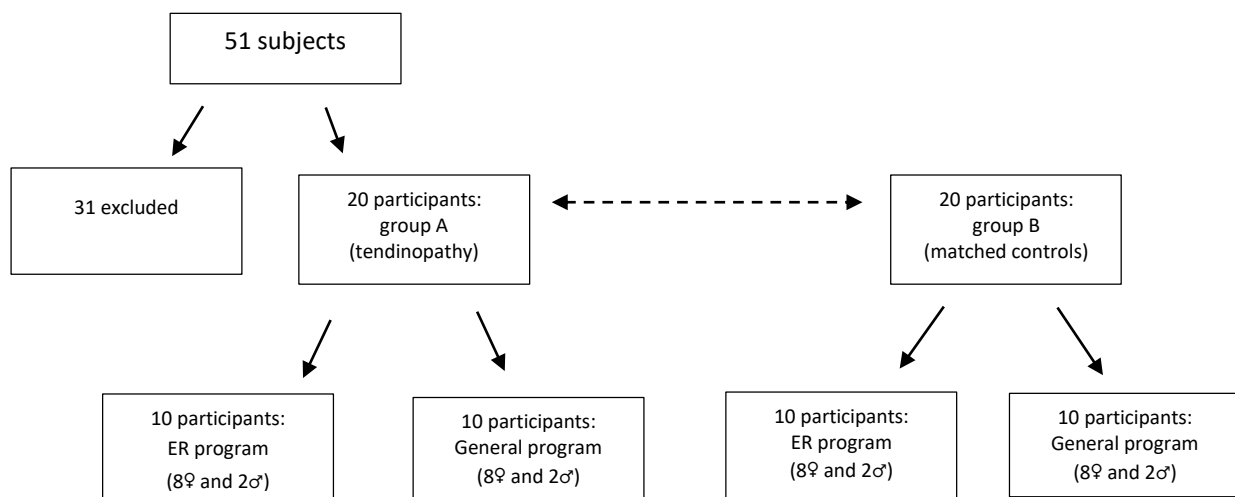
4 Results

4.1 Participants

Fifty subjects with a RC tendinopathy (age range 18y-65y) were screened for eligibility between the 30th of October 2017 and 20th of February 2018, of which 20 met the inclusion criteria (flowchart 1). In the same period, a control group with healthy subjects was composed according to other eligibility criteria. Both groups were matched based on BMI, age and gender. Demographic features of both study groups are summarised in table 1. No significant demographic differences were found for mean age, length, weight and BMI between the two study groups ($\alpha > 0.05$).

Table 1: demographic features

	Group A (Tendinopathy group)	Group B (Healthy control group)
Number of participants	20	20
Gender	4 males, 16 females	4 males, 16 females
Side dominance	18 right, 2 left	16 right, 4 left
Injured side	8 non-dominant, 12 dominant (10 right, 10 left)	/
Mean age (y) \pm SD	44.0 \pm 12.5	44.0 \pm 12.5
Mean length (m) \pm SD	1.680 \pm 0.078	1.694 \pm 0.081
Mean weight (kg) \pm SD	69.2 \pm 11.4	69.9 \pm 10.8
Mean BMI (kg/m ²) \pm SD	24.5 \pm 3.8	24.3 \pm 3.0



Flowchart 1: recruitment

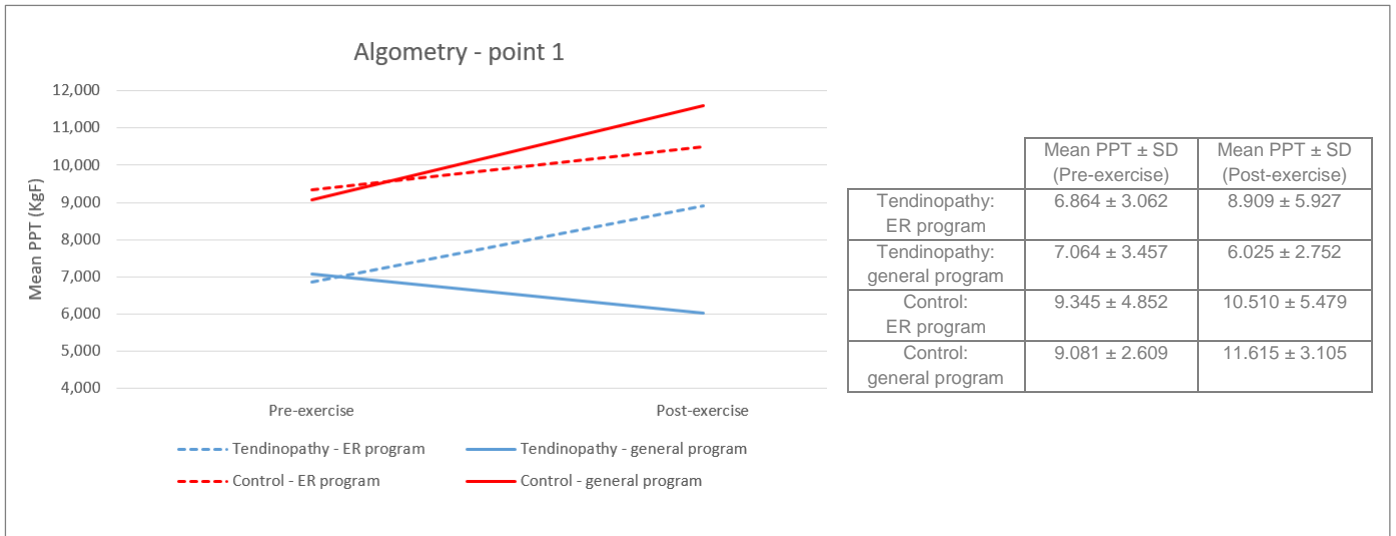
4.2 PPT of the M. infraspinatus

Graphs 1 and 2 summarise the means of the measurements of algometry for the different study groups and the two points. The results of the ANOVA linear mixed models, statistical analysis and post hoc test are described in table 2. Only for the factor group the post hoc test was appropriate, a significant result is found between the two study groups with a higher value for the controls.

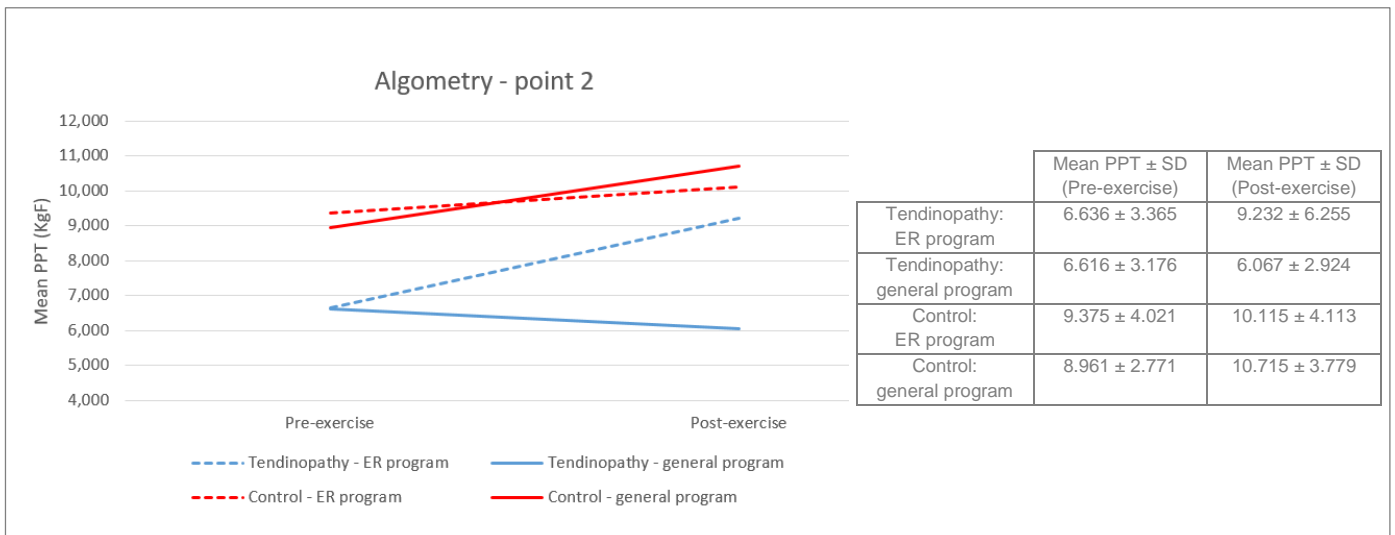
Table 2: results algometry ANOVA linear mixed models

PPT	
Four-way interaction	
Group x exercise program x time x point	NS
Three-way interaction	
Group x exercise program x time	NS
Group x exercise program x point	NS
Group x time x point	NS
Exercise program x time x point	NS
Two-way interaction	
Group x exercise program	NS
Group x time	NS
Group x point	NS
Exercise program x time	NS
Exercise program x point	NS
Time x point	NS
Main effects	
Group	p < 0.001
Exercise program	NS
Time	NS
Point	NS
Post hoc tests (only significant differences are displayed)	
Group	C > T p < 0.001

C = matched control group; T = tendinopathy group; NS = not significant



Graph 1: algometry - point 1



Graph 2: algometry - point 2

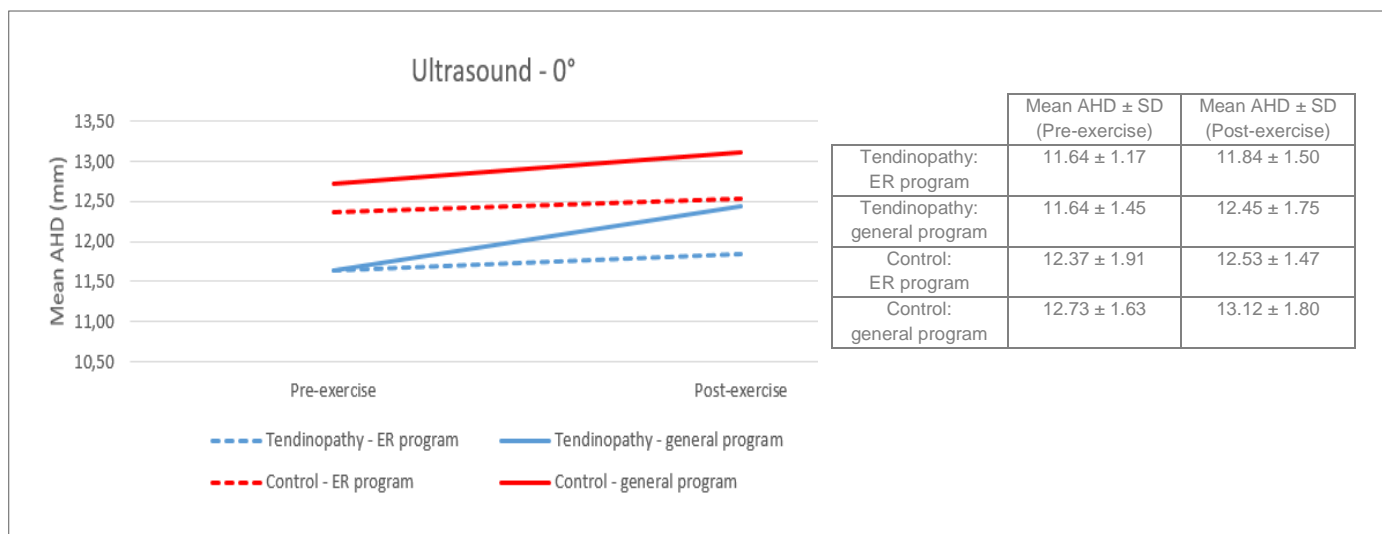
4.3 AHD

Graphs 3 to 5 show the outcome of the ultrasound measured in different elevation positions. Statistical differences are investigated with the ANOVA linear mixed models and post hoc test if admitted. Table 3 indicates significant higher results in favour of the control group. On the other hand a significant lower AHD is measured in 0° and in 45°, both compared with 60°.

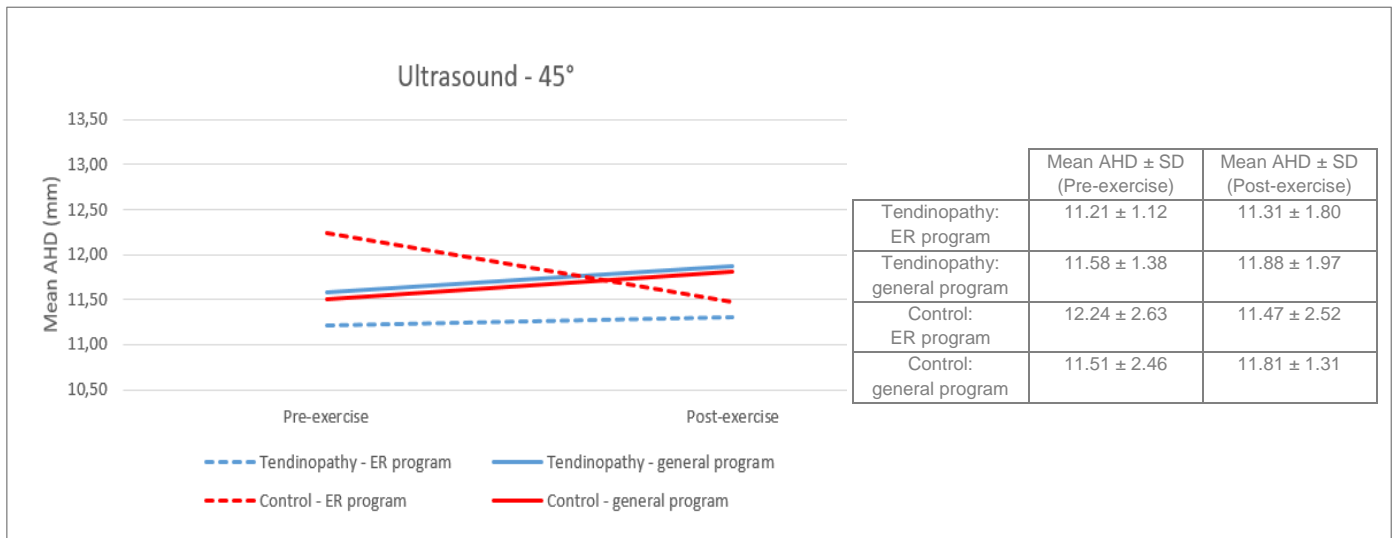
Table 3: results ultrasound ANOVA linear mixed models

Ultrasound	
Four-way interaction	
Group x exercise program x time x position	NS
Three-way interaction	
Group x exercise program x time	NS
Group x exercise program x position	NS
Group x time x position	NS
Exercise program x time x position	NS
Two- way interaction	
Group x exercise program	NS
Group x time	NS
Group x position	NS
Exercise program x time	NS
Exercise program x position	NS
Time x position	NS
Main effects	
Group	p = 0.047
Exercise program	NS
Time	NS
Position	p < 0.001
Post hoc tests (only significant differences are displayed)	
Group	C>T p = 0.047
Position	0° > 60° (p < 0.001) 45° > 60° (p = 0.049)

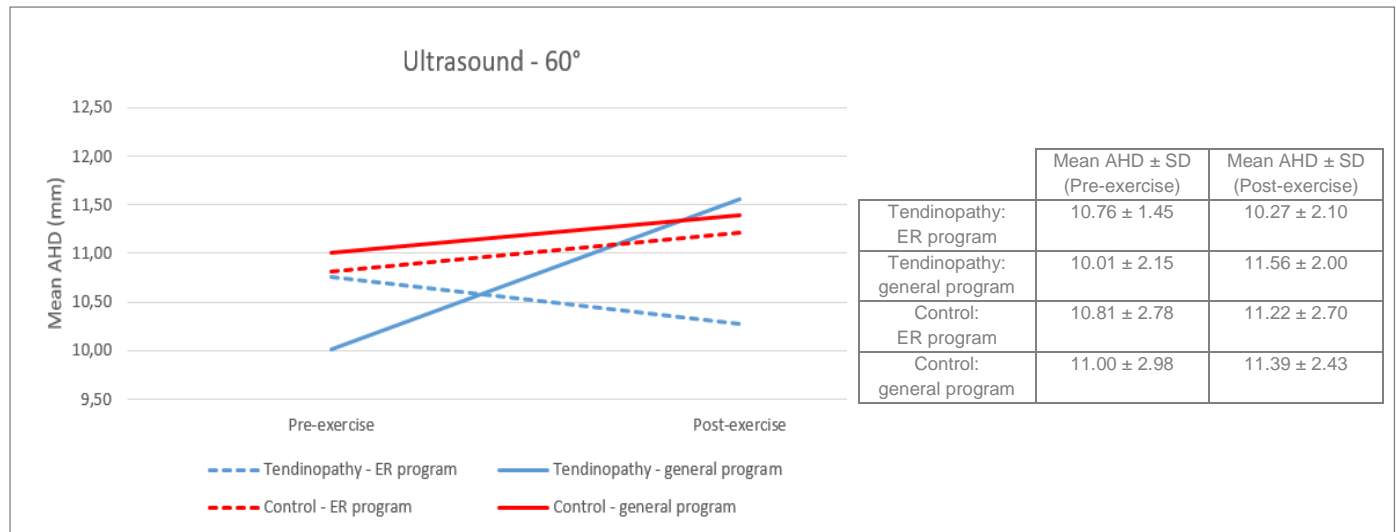
C = matched control group; T = tendinopathy group; NS = not significant



Graph 3: ultrasound - 0°



Graph 4: ultrasound - 45°



Graph 5: ultrasound - 60°

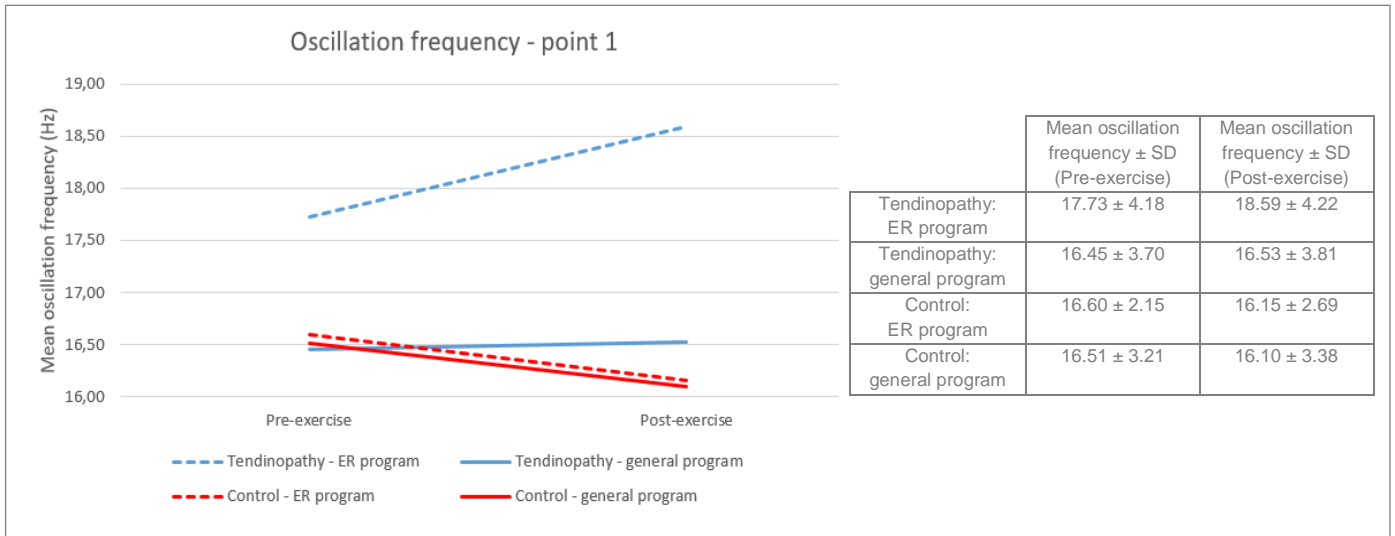
4.4 Oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time and creep of the M. infraspinatus

The five viscoelastic features measured with the MyotonPro device are delineated in 10 different graphs (graphs 6 to 15). Statistical analysis with the ANOVA linear mixed models and post hoc tests were performed if applicable (table 4). Only for relaxation time and creep, significant higher values were found for the control group compared with the RC tendinopathy group.

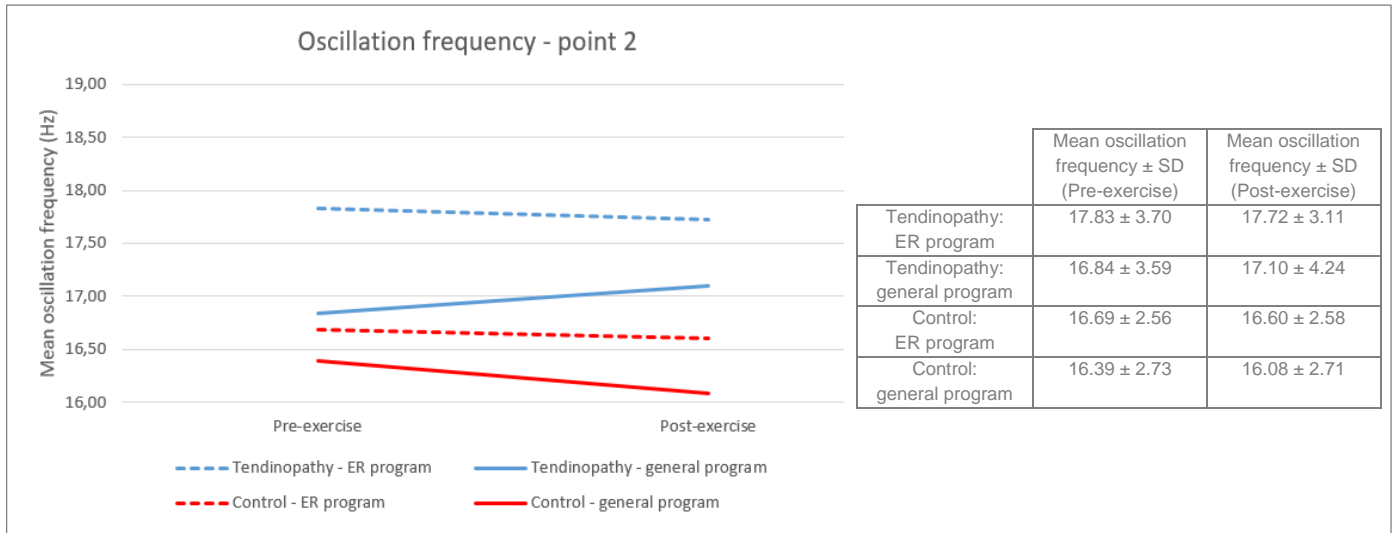
Table 4: results MyotonPro ANOVA linear mixed models

	Oscillation frequency	Dynamic stiffness	Logarithmic decrement	Relaxation time	Creep
Four-way interaction					
Group x exercise program x time x point	NS	NS	NS	NS	NS
Three-way interaction					
Group x exercise program x time	NS	NS	NS	NS	NS
Group x exercise program x point	NS	NS	NS	NS	NS
Group x time x point	NS	NS	NS	NS	NS
Exercise program x time x point	NS	NS	NS	NS	NS
Two-way interaction					
Group x exercise program	NS	NS	NS	NS	NS
Group x time	NS	NS	NS	NS	NS
Group x point	NS	NS	NS	NS	NS
Exercise program x time	NS	NS	NS	NS	NS
Exercise program x point	NS	NS	NS	NS	NS
Time x point	NS	NS	NS	NS	NS
Main effects					
Group	NS	NS	NS	p = 0.044	p = 0.026
Exercise program	NS	NS	NS	NS	NS
Time	NS	NS	NS	NS	NS
Point	NS	NS	NS	NS	NS
Post hoc tests (only significant differences are displayed)					
Group	NS	NS	NS	C > T p = 0.044	C > T p = 0.026

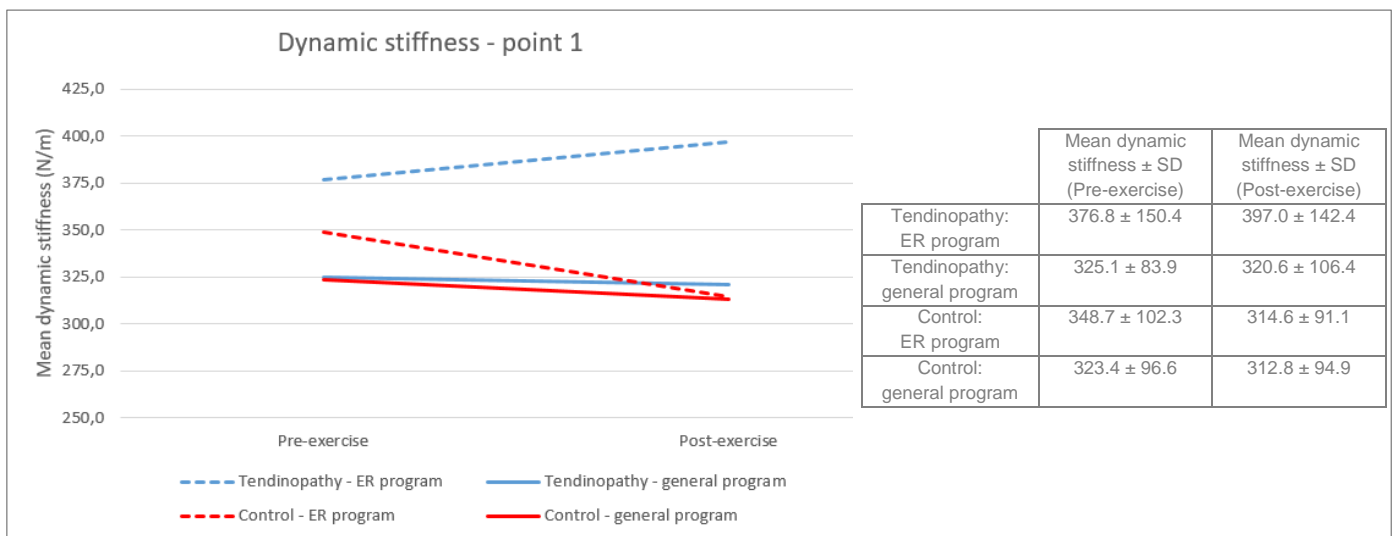
C = matched control group; T = tendinopathy group; NS = not significant



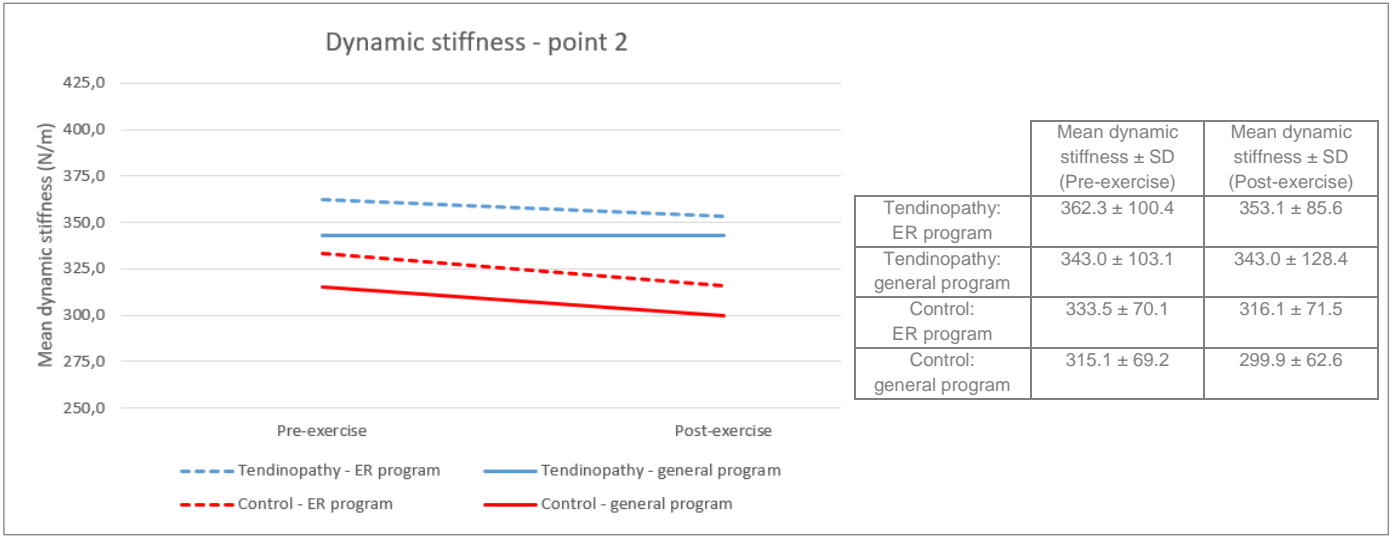
Graph 6: oscillation frequency – point 1



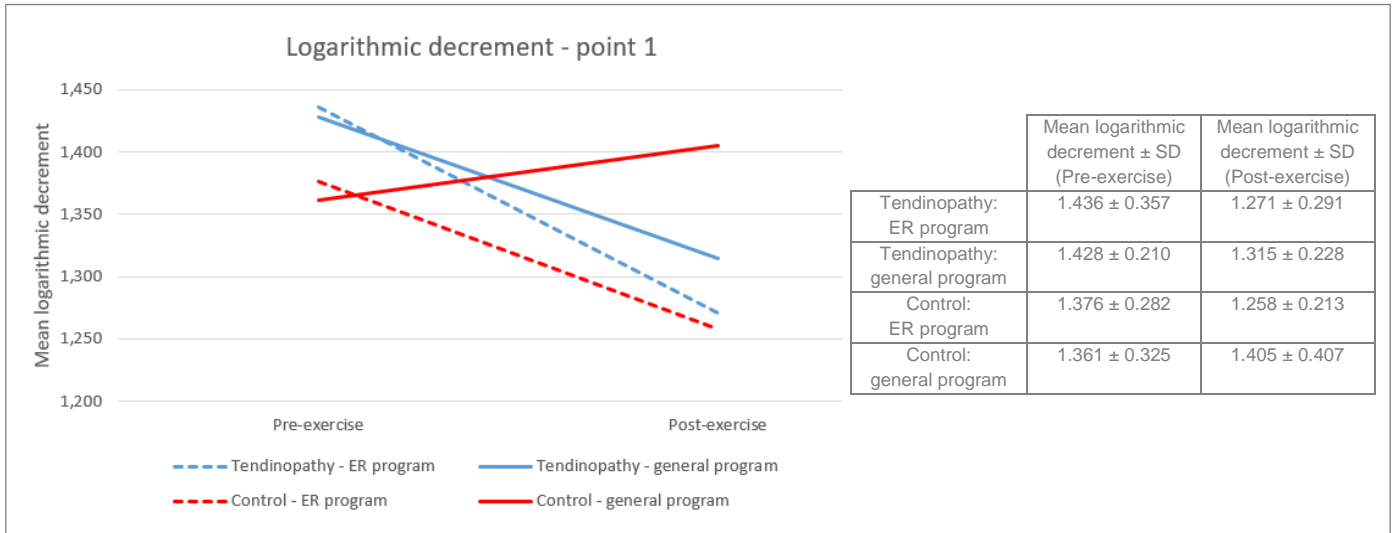
Graph 7: oscillation frequency – point 2



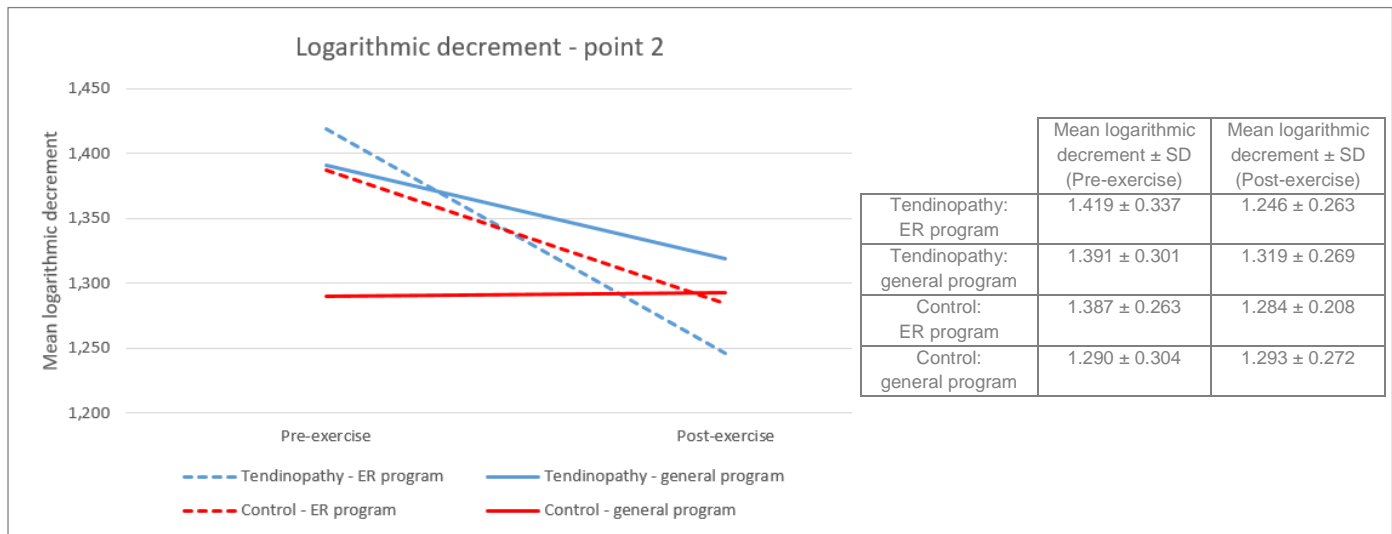
Graph 8: dynamic stiffness – point 1



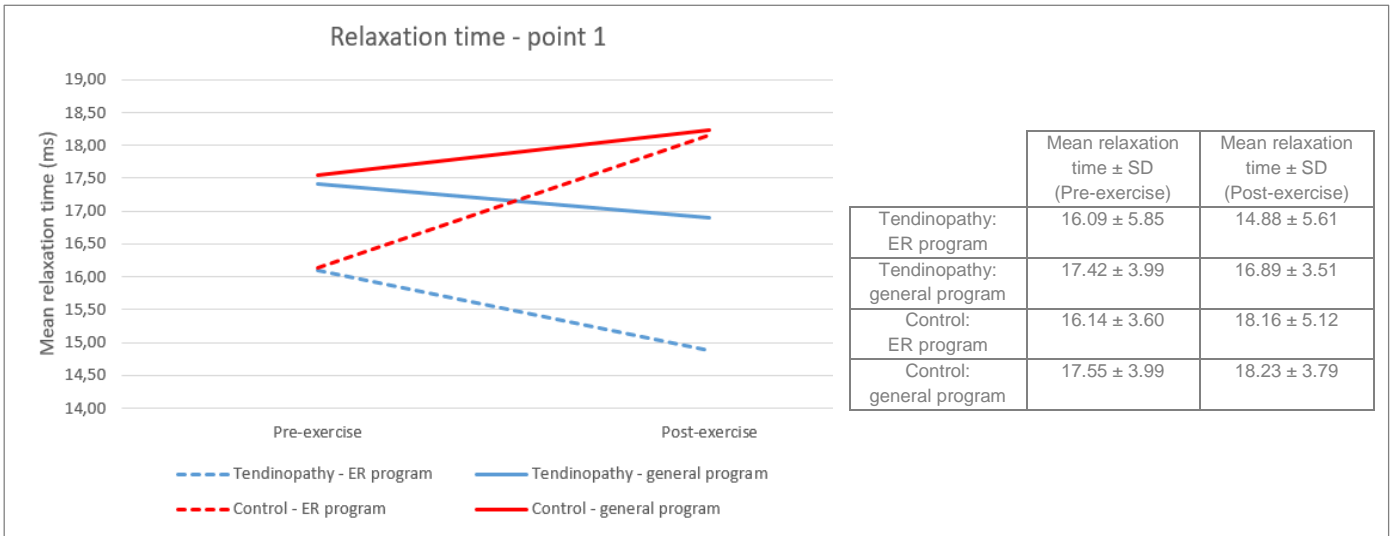
Graph 9: dynamic stiffness – point 2



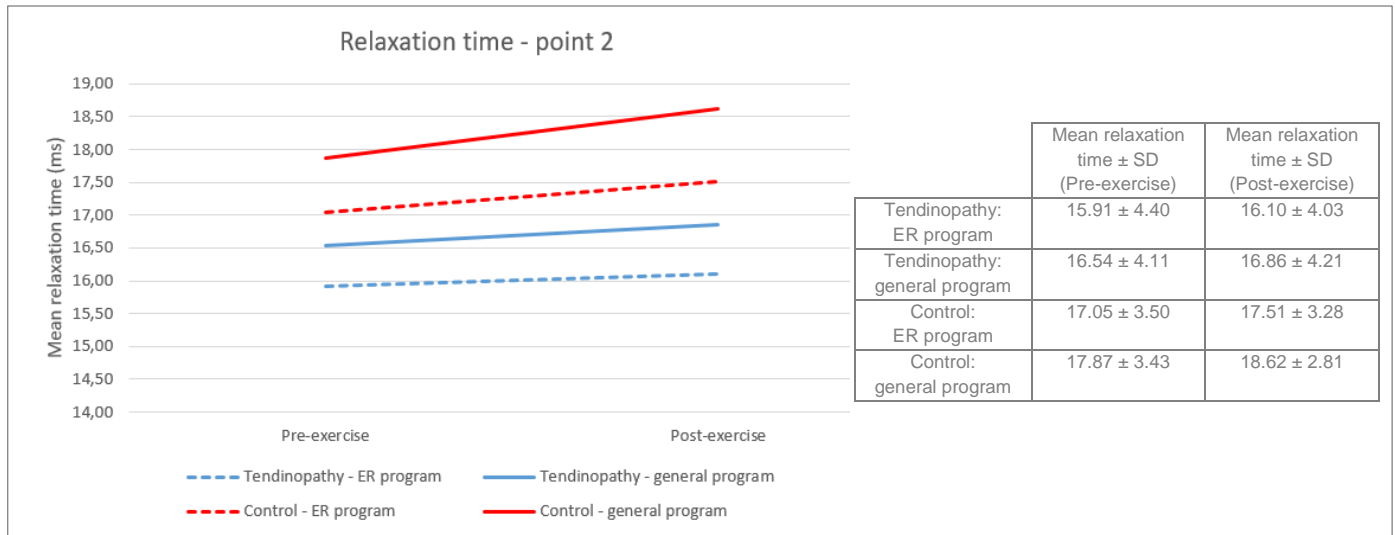
Graph 10: logarithmic decrement – point 1



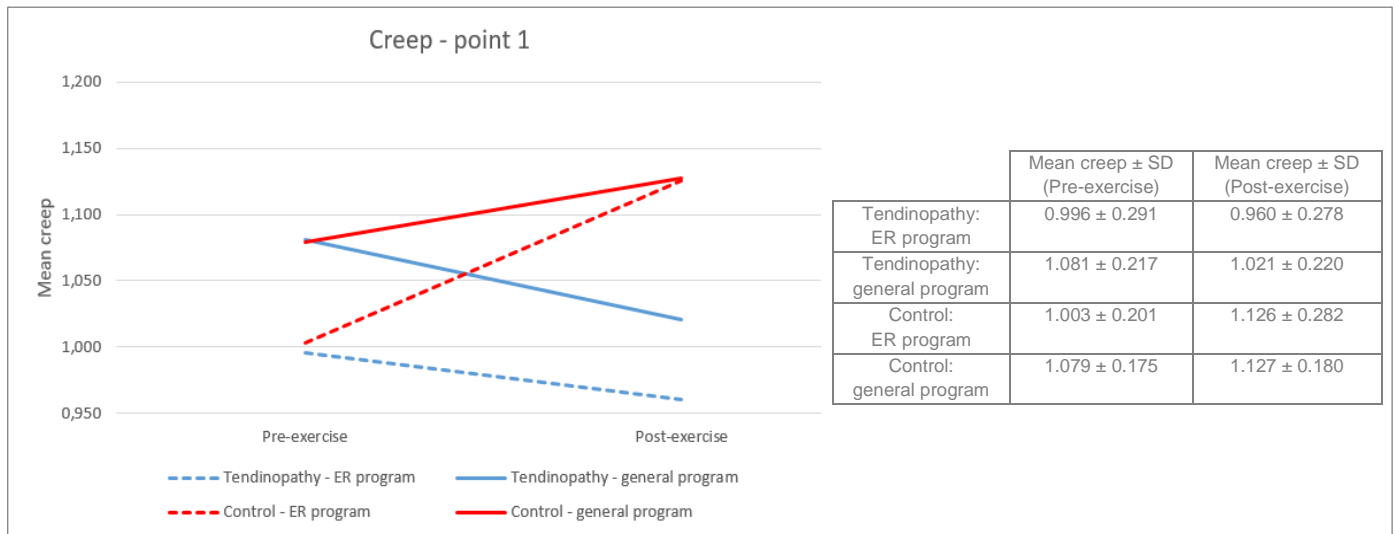
Graph 11: logarithmic decrement – point 2



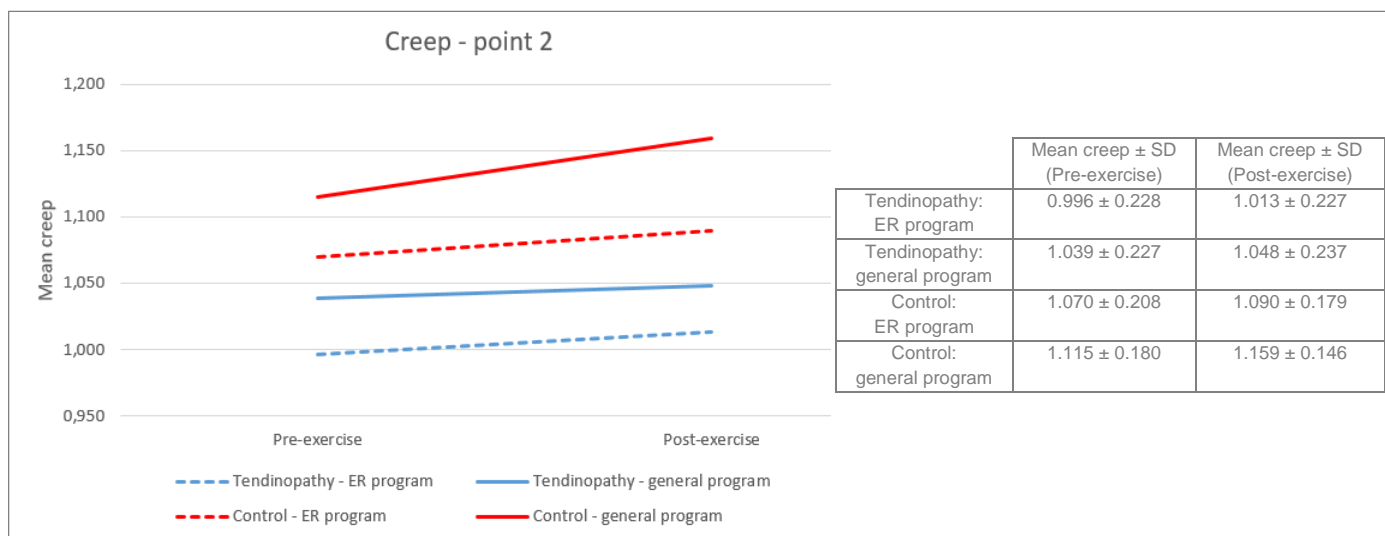
Graph 12: relaxation time – point 1



Graph 13: relaxation time – point 2



Graph 14: creep – point 1



Graph 15: creep – point 2

5 Discussion

The aim of the study was to examine the short-term effects of two different exercise programs in patients with a RC tendinopathy compared with healthy controls. PPT of the M. infraspinatus, AHD at 0°, 45° and 60° abduction and five viscoelastic properties of the M. infraspinatus were measured before and immediately after exercising.

5.1 PPT of the M. infraspinatus

In our study, it was found that the RC tendinopathy group had a significant lower average PPT in comparison with the control group independent of time, interventions and the two measuring points. This corresponds with the literature. Hidalgo-Lozano et al.³⁰ published a randomised controlled trial in which the PPT of the M. infraspinatus was significant lower for the subacromial impingement syndrome (SIS) group in comparison with a healthy control group. A possible explanation according to the researchers could be that measurements were taken on or nearby a myofascial trigger point (MTP). Albuquerque-Sendín et al.³¹ established a significant greater amount of MTPs in the M. infraspinatus in patients with SIS compared with healthy controls. Another study searched for the relationship between active and latent MTPs in the M. infraspinatus. On the painful side, more active MTPs could be found in patients with unilateral shoulder pain³². In addition, a significant negative correlation was found between the number of MTPs and the PPT in a study which compared SIS patients with healthy controls. A greater number of MTPs is related with a lower PPT and a greater pain intensity³⁰.

No significant differences were found in this short-term study after both exercise programs compared with the initial measurements. This differs from the study of Camargo et al.³³ who provided some evidence about augmenting the PPT in the M. infraspinatus after exercising. However, this study looked into long-term effects in SIS patients.

5.2 AHD

In this research, AHD was significant larger in the healthy controls compared with the patients. This is similar to the study of Navarro-Ledesma et al.³⁴ which showed a significant narrower AHD in patients with RC related shoulder pain at 60° abduction in comparison with non-symptomatic shoulders. However, no significant differences could be demonstrated at 0° abduction between both groups. Comparable results were found in the study of Cholewinski et al.³⁵ which showed a significant narrower AHD in patients with SIS compared with healthy people. Although it was unclear in which arm position the measurements were taken. Nevertheless, no consensus could be reached yet because Michener et al.³⁶ proved no significant differences in AHD in SIS patients compared with healthy controls.

In this study, a significant larger AHD is measured at 0° abduction and 45° abduction, both compared with 60° abduction. Scientific literature showed similar results. A significant smaller AHD was found at 60° compared with 0° and 45° in the study of Maenhout et al.³⁷. However, the study was carried out in overhead athletes. Another study of Leong et al.³⁸ established that there was more reduction of the subacromial space during early arm abduction (0° to 30° abduction) in overhead athletes with a RC tendinopathy compared with healthy athletes.

Furthermore, both interventions of this study did not significantly change the AHD in the two study groups. According to scientific research, various results were found for AHD with regard to exercising. A study of McCreesh et al.³⁹ found that AHD narrowed following exercises in patients with a RC tendinopathy, taking into account that the exercises were performed until the fatigue level was reached. Another study showed a significant larger AHD after a rehabilitation program in patients with subacromial pain syndrome. Hereby, this program lasted six weeks and included RC strengthening exercises in combination with other interventions⁴⁰. The researchers of this study suspected that a general exercise program caused more activation of the entire RC in comparison with the ER program that mainly focused on the M. infraspinatus. However, another study of Leong et al.⁴¹ showed that a smaller AHD was related with weaker ER strength in volleyball players. Therefore, the ER program can be useful at long-term.

5.3 Oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time and creep of the M. infraspinatus

This is the first study investigating five viscoelastic properties (oscillation frequency, dynamic stiffness, logarithmic decrement, relaxation time and creep) in the M. infraspinatus. As a consequence, the obtained data could not be supported by literature. Three studies investigated the reproducibility of the MyotonPro device and concluded that this is different for various subgroups^{42,43,44}. As a result, the data in this study population must be interpreted with caution and further research about the reproducibility of the MyotonPro device is needed.

The primary parameter of the MyotonPro device was the relaxation time, which includes the time for a muscle to restore the shape from deformation. The healthy participants showed a significant longer relaxation time in comparison with the patient group independent of time, interventions and the two measuring points. The creep is the gradual elongation of a muscle over time²⁸. Statistics showed that the control group had significant higher average values than the tendinopathy group independent of time, interventions and points.

For the oscillation frequency, no significant differences were found between both groups, exercise programs, pre-measurements compared with post-measurements and measuring points. Despite this, the investigators hypothesized that there would be a slightly increase in oscillation frequency. The higher the oscillation frequency, the higher the muscle tone⁴². Additional to this, it had been shown that there is a higher muscle tone in the presence of pain⁴⁵. No significant differences in dynamic stiffness and logarithmic decrement were identified between exercise programs, pre-measurements in comparison with post-measurements, two study groups and measuring points. The logarithmic decrement represents the muscle elasticity, which is inversely proportional to this. So, the smaller the value of decrement, the higher the muscle's elasticity^{28,42}.

5.4 Limitations

To interpret the results of the current study correctly, it is necessary to take into account the most important limitations.

First of all, the population consisted of only 40 subjects of whom 10 in each subgroup. This number of participants makes it a rather small group, future research should focus on bigger samples. Each member of the injured group met the inclusion criteria but only 18 of them effectively had a medical diagnosis.

Another weakness to take into account is that the researchers were three Master's students in physiotherapy whose study program provided no practical education about the use of ultrasound, MyotonPro and algometry. Experts within the application of these devices gave some explanations about the functioning of the devices, but the researchers had to train these skills independently. This may have had an influence on the reliability of the results. Besides, validity and reliability of the MyotonPro have not yet been tested on the population of this study.

Before the actual measurements took place the marks on the M. infraspinatus had to be indicated. The researchers tried to standardise as good as possible but if the mark was too osseous, a small margin of a few millimetres to two centimetres was accepted.

The last limitation is about the suggestion of the weights and colours of the theraband which was done by the investigators, but a number of participants did not follow the proposed dosage. It seemed that estimating the load-capacity was difficult for a few people. Because of the under- or overestimation, nine subjects did not reach the predetermined interval of 11-14/20 on the Borg-scale.

Nevertheless, it is the first study which investigated short-term effects after an ER program compared with a general program. This can be an inducement for further research in the future.

6 Conclusion

In this study, no significant differences could be demonstrated by comparing pre- versus post-exercise measurements. Therefore, it is not possible to conclude which exercise program is superior. However, significant differences in terms of AHD (between 0°-60° and 45°-60° abduction), PPT, relaxation time and creep has been shown between the groups with higher values for the healthy ones. Further research about this topic is needed in a larger population to draw conclusions.

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Abstract in lektentaal

Oefentherapie vormt tegenwoordig een belangrijk aspect in de revalidatie van een schouderpeesontsteking. Momenteel is er geen consensus omtrent welke oefeningen zorgen voor een betere outcome. Het doel van deze studie was om kortetermijneffecten te onderzoeken na het uitvoeren van twee verschillende oefenprogramma's, bij gezonden en patiënten.

Twintig gezonde proefpersonen en 20 patiënten met een schouderpeesontsteking namen deel aan deze studie. De helft van elke groep voerde drie oefeningen uit gericht op één soort schouderbeweging, de anderen drie oefeningen gericht op verschillende schouderbewegingen. Er werden meerdere parameters onderzocht voor en onmiddellijk na het oefenen met betrekking tot pijn, morfologie en vijf spiereigenschappen.

Na grondige analyse bleek dat gezonden een hogere pijndrempel hebben vergeleken met patiënten gemeten op één specifieke spier ter hoogte van het schouderblad (M. infraspinatus). De ruimte waar mogelijks aangedane pezen (bij een schouderpeesontsteking) doorheen lopen is kleiner in de patiëntengroep. Dit wordt kleiner naarmate je de arm zijwaarts meer omhoog brengt tot ongeveer 60°. Daarnaast is er een positief effect op twee van de gemeten spiereigenschappen.

Na het oefenen werden positieve veranderingen opgemerkt voor beide programma's, maar deze konden onvoldoende wetenschappelijk onderbouwd worden. Hierdoor is het onmogelijk om het beste oefenprogramma te bepalen. Verder onderzoek is nodig om conclusies te kunnen trekken.

Approval Ethics Committee



Afz: Commissie voor Medische Ethiek



**COMMISSIE VOOR MEDISCHE
ETHIEK**

REVAKI
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UW KENMERK	ONS KENMERK 2017/0994	DATUM 17-nov-17	KOPIE Zie "CC"

BETREFT

Advies voor monocentrische studie met als titel:
Onderzoek naar het onmiddellijk effect van een algemeen programma versus een specifiek programma (gericht op M. Infraspinatus) bij patiënten met rotator cuff tendinopathy en een gezonde controlegroep.

Belgisch Registratienummer: B670201733241

- * Adviesaanvraagformulier (volledig ontvangen dd. 29/08/2017)
- * (Patiënten)informatie- en toestemmingsformulier
- * Antwoord onderzoeker dd. 06/10/2017 (ontv. dd. 10/10/2017) op opmerkingen EC dd. 25/09/2017
- * Rekruteringsmateriaal: Flyer
- * Antwoord onderzoeker dd. 16/11/2017 (ontv. 17/11/2017) op opmerkingen EC dd. 15/11/2017

Advies werd gevraagd door:

Prof. dr. A. COOLS ; Hoofdonderzoeker

**BOVENVERMELDE DOCUMENTEN WERDEN DOOR HET ETHISCH COMITÉ BEOORDEELD.
ER WERD EEN POSITIEF ADVIES GEGEVEN OVER DIT PROTOCOL OP 17/11/2017. INDIEN DE STUDIE NIET WORDT OPGESTART
VOOR 17/11/2018, VERVALT HET ADVIES EN MOET HET PROJECT TERUG INGEDIEND WORDEN.**

Vooraleer het onderzoek te starten dient contact te worden genomen met Bimetra Clinics (09/332 05 00).

**THE ABOVE MENTIONED DOCUMENTS HAVE BEEN REVIEWED BY THE ETHICS COMMITTEE.
A POSITIVE ADVICE WAS GIVEN FOR THIS PROTOCOL ON 17/11/2017. IN CASE THIS STUDY IS NOT STARTED BY 17/11/2018, THIS
ADVICE WILL BE NO LONGER VALID AND THE PROJECT MUST BE RESUBMITTED.**

Before initiating the study, please contact Bimetra Clinics (09/332 05 00).

**DIT ADVIES WORDT OPGENOMEN IN HET VERSLAG VAN DE VERGADERING VAN HET ETHISCH COMITE VAN 21/11/2017
THIS ADVICE WILL APPEAR IN THE PROCEEDINGS OF THE MEETING OF THE ETHICS COMMITTEE OF 21/11/2017**

- o *Het Ethisch Comité werkt volgens 'ICH Good Clinical Practice' - regels*
- o *Het Ethisch Comité beklemt oont dat een gunstig advies niet betekent dat het Comité de verantwoordelijkheid voor het onderzoek op zich neemt. Bovendien dient U er over te waken dat Uw mening als betrokken onderzoeker wordt weergegeven in publicaties, rapporten voor de overheid enz., die het resultaat zijn van dit onderzoek.*
- o *In het kader van 'Good Clinical Practice' moet de mogelijkheid bestaan dat het farmaceutisch bedrijf en de autoriteiten inzage krijgen van de originele data. In dit verband dienen de onderzoekers erover te waken dat dit gebeurt zonder schending van de privacy van de proefpersonen.*
- o *Het Ethisch Comité benadrukt dat het de promotor is die garant dient te staan voor de conformiteit van de anderstalige informatie- en toestemmingsformulieren met de nederlandsstalige documenten.*
- o *Geen enkele onderzoeker betrokken bij deze studie is lid van het Ethisch Comité.*
- o *Alle leden van het Ethisch Comité hebben dit project beoordeeld. (De ledenlijst is bijgevoegd)*

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Vervolg blz. 2 van het adviesformulier betreffende project EC UZG 2017/0994

- *The Ethics Committee is organized and operates according to the 'ICH Good Clinical Practice' rules.*
- *The Ethics Committee stresses that approval of a study does not mean that the Committee accepts responsibility for it. Moreover, please keep in mind that your opinion as investigator is presented in the publications, reports to the government, etc., that are a result of this research.*
- *In the framework of 'Good Clinical Practice', the pharmaceutical company and the authorities have the right to inspect the original data. The investigators have to assure that the privacy of the subjects is respected.*
- *The Ethics Committee stresses that it is the responsibility of the promotor to guarantee the conformity of the non-dutch informed consent forms with the dutch documents.*
- *None of the investigators involved in this study is a member of the Ethics Committee.*
- *All members of the Ethics Committee have reviewed this project. (The list of the members is enclosed)*


Namens het Ethisch Comité / On behalf of the Ethics Committee
Prof. dr. D. MATTHYS
Voorzitter / Chairman

CC: De heer T. VERSCHOORE - UZ Gent - Bimetra Clinics
FAGG - Research & Development; Victor Hortaplein 40, postbus 40 1060 Brussel

Appendix

1 Intensity for men

	60-69 kg	70-79 kg	>80 kg
1. External rotation and abduction in prone	1 kg	2 kg	3 kg
2. External rotation in prone	1 kg	2 kg	3 kg
3. External rotation in stand	Green	Blue	Black
4. Internal rotation in stand	Green	Blue	Black
5. Full can in stand	2 kg	3 kg	4 kg

2 Intensity for women

	50-59 kg	60-69 kg	>70 kg
1. External rotation and abduction in prone	0.5 kg	1 kg	1.5 kg
2. External rotation in prone	0.5 kg	1 kg	1.5 kg
3. External rotation in stand	red	green	blue
4. Internal rotation in stand	red	green	blue
5. Full can in stand	1 kg	1.5 kg	2 kg