



UHASSELT

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Faculteit Revalidatiewetenschappen

master in de revalidatiewetenschappen en de kinesietherapie

Masterthesis

An evaluation of the inter-rater and intra-rater reliability in volume measurements with a 3D ultrasound apparatus of the musculus multifidus in healthy subjects

**Simon Cornelissen
Max van der Velden**

Scriptie ingediend tot het behalen van de graad van master in de revalidatiewetenschappen en de kinesietherapie, afstudeerrichting revalidatiewetenschappen en kinesietherapie bij musculoskeletale aandoeningen

PROMOTOR :

dr. Anouk AGTEN

COPROMOTOR :

Prof. dr. Frank VANDENABEELE



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www.uhasselt.be
Universiteit Hasselt
Campus Hasselt:
Martelarenlaan 42 | 3500 Hasselt
Campus Diepenbeek:
Agoralaan Gebouw D | 3590 Diepenbeek

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2019



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Acknowledgement

First of all, the authors of this master's thesis gratefully acknowledge the promotor dr. Agten (Ph.D., biomedical sciences) and the co-promotor Prof. dr. Vandenabeele (MD, Ph.D.) for their aid and guidance throughout this research. Furthermore, we want to express our gratitude to drs. Stevens (rehabilitation sciences) for his supervision during the data extraction. We also want to convey our gratefulness to the other thesis duo, Maaïke Withofs and Stijn Nullens, for the pleasant and fluent cooperation during the ultrasound examinations.

Hasselt (Belgium), June 3th

S.C.

Pelt (Belgium), June 3th

M.v.d.V.

CONTEXT OF THE MASTER THESIS

This Master's thesis is part of the musculoskeletal revalidation research domain. It regards an isolated study that has no affiliation with other investigations. Nevertheless, this pilot study may benefit other studies due to the fact that it is a building plot for other examiners that want to use this ultrasound device. It can be an important contribution to the research community by providing information about the reliability of the device for measuring muscle volume, which can contribute to the quality of further investigations. In the past, other studies have been conducted about the inter- and intra-rater reliability of a 3D ultrasound device. All studies concluded that this device was highly reliable in the hands of a trained examiner (Barber, Barrett, & Lichtwark, 2009; Benard, Harlaar, Becher, Huijting, & Jaspers, 2011; Weide et al., 2015; Weller et al., 2007). However, it is not known to this present day whether these findings are still true with untrained examiners. These findings will open plenty of perspectives for future studies examining muscle volume, knowing whether or not to require a trained ultrasonographer. Considering this Master's thesis is not part of a larger study, the master students applied to the ethics committee for approval of this examination. The students prepared this application independently in consultation with another Master's thesis duo who had to submit approximately the same application, for the volume of another muscle. After the application was approved, the authors of this study searched for subjects via local advertisement in collaboration with the other Master's thesis duo. After recruitment was completed, testing was executed conjointly with the other group under the supervision of Dr. Sjoerd Stevens, using the same subjects for all measurements. After collecting all data, the Master's thesis students each began to analyse the data solely and separately. The statistical analysis of the processed data was solely done by the authors. All the academic writing of this Master's thesis was done by the authors Simon Cornelissen and Max van der Velden, and if needed, corrected by the promotors of this study.

This Master's thesis is part two of a two-year thesis, this being the second and last master year of physiotherapy at the University of Hasselt in Diepenbeek. Part one was a literature study in line with this interventional study. It is a pilot study under the guidance of doctor Anouk Agten (Ph.D. biomedical sciences) and professor Frank Vandenabeele (MD, Ph.D.). The research is conducted at BIOMED-REVAL, a rehabilitation research centre at UHasselt. The research aims

to investigate the inter- and intra-rater reliability of a 3D ultrasound device for measuring the muscle volume of the left musculus multifidus in the lumbar area.

The central format was applied for this thesis. For the intervention study, the change of the research question and purpose was approved by promoters doctor Anouk Agten and professor Frank Vandenabeele. This Master's thesis is a dual thesis with authors Simon Cornelissen and Max van der Velden.

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1. ABSTRACT

Background: 3D ultrasound is proven to be a time saving, cost-effective alternative to magnetic resonance imaging (MRI) when measuring muscle volumes of certain muscles. No research has yet been done to evaluate the reliability of a 3D ultrasound apparatus to investigate muscle volume of deeply located trunk muscles, such as the multifidus (MF) muscle, by inexperienced examiners.

Objectives: The purpose of this Master's thesis is to evaluate the inter-rater and intra-rater reliability of a 3D freehand ultrasound apparatus to measure the muscle volume of the MF. This study investigates the reliability of inexperienced ultrasonographers in particular.

Participants: Ten women and ten men under the age of 60 years were recruited through local advertisement and were screened for eligibility.

Measurements: Measurements of the MF were conducted in a standardized manner by both examiners to calculate intra-rater reliability, and again, by the first examiner to calculate the inter-rater reliability. Subsequently, the obtained ultrasound slices were examined separately by each examiner.

Results: The inter-rater reliability showed poor to good reliability (ICC: 0.718; 95% CI: 0.251-0.894). Intra-rater reliability scored higher with moderate to excellent reliability (ICC: 0.863; 95% CI: 0.670-0.946). Two participants were excluded due to measurement errors.

Keywords: 3D ultrasound, reliability, inter-rater, intra-rater, inexperienced, multifidus muscle, ultrasonographers, imaging

2. INTRODUCTION

Muscle morphology influences muscle function. Different parameters such as fatty infiltration, activation and volume can be obtained via ultrasound (US) that are helpful in determining muscle volume or function. Muscle volume is strongly correlated to strength (Fukunaga et al., 2001). It is useful to know the muscle volume to monitor possible atrophy in neurological diseases or after a surgical procedure that required dissection of certain muscles. On the contrary, hypertrophy can be measured to quantify muscle gains after a rehabilitation protocol or a strength and conditioning program.

To this day, magnetic resonance imaging (MRI) is regarded as the golden standard of muscle volume measurements (Mitsiopoulos et al., 1998). However, the excessive cost of this imaging technique accompanied by greater risk and time consumption demands a more cost-effective alternative in many cases. 3D US might be an excellent substitute to measure muscle volume at certain sites of the lower limb (Barber et al., 2019; Barber et al., 2009; MacGillivray, Ross, Simpson, & Greig, 2009). No such evidence exists regarding the upper limb and trunk muscles after a thorough search on the Pubmed and Web of Science databases.

While 2D US imaging is limited to measurements of width and tissue depth, freehand 3D US has the possibility to create a 3D model accompanied by the actual volume, most often expressed in millilitres. The 3D model is constructed by combining 2D US transverse images while recording the position and orientation of the probe in space (Huang & Zeng, 2017). Consecutively, the examiners outlined the investigated muscle in a sufficient number of frames to complete the 3D model. There have been several studies investigating the inter- and intra-rater reliability of lower limb muscles using 3D US. High correlations were found for the medial gastrocnemius, complete triceps surae, abductor hallucis and rectus femoris (Barber et al., 2019; Barber et al., 2009; Cameron, Rome, & Hing, 2008; MacGillivray et al., 2009).

The purpose of this study was to investigate the inter- and intra-rater reliability for measuring the multifidus (MF) volume with the technique described above. This is the extent to which measurements are able to be reproduced by the same assessor (intra-rater reliability) or different assessors (inter-rater reliability). Adding to this, the researchers were inexperienced in using US. US is known to be reliable when operated by experienced examiners (Hebert,

Koppenhaver, Parent, & Fritz, 2009; Hides, Richardson, & Jull, 1995; Stokes, Hides, Elliott, Kiesel, & Hodges, 2007). However, no values have been published explicitly stating the operators were unfamiliar with this technique. With US becoming more popular in general practice and the possibility of professions such as physiotherapy to follow courses regarding this imaging technique, it's deemed important to investigate this further.

3. METHODS

3.1 PARTICIPANTS

Twenty apparently healthy participants were enrolled in this study with a mean age of 33.75 years old (range 20 to 58 years). The free recruitment was obtained via local advertisement. All subjects signed an informed consent form and were fully aware of the protocol. Subjects with a history of spinal surgery, malignancy and/or a history of low back pain (LBP) (in the past 3 months), diagnosed structural abnormalities such as scoliosis and spondylolisthesis etcetera, history of trauma in the lower back, contra-indications for US use, muscle diseases, neurological symptoms (paraesthesia, motor deficit, sensory changes in lower limbs,...) and long term corticosteroid use were excluded from the study. Participants eligible for the investigation had to be between 18 and 65 years of age. The age, gender, weight and length were gathered from the included subjects. Mean values with standard deviation (SD) are listed in table 1.

3.2 PROCEDURE

This study with code number B9115201838341 was approved by the committee of medical ethics (CME) UHasselt on the 11th of December 2018. All participants were examined at the UHasselt BIOMED-REVAL site in Diepenbeek, Belgium.

3.2.1 OUTCOMES

The primary and single outcome measures are the inter- and intra-rater reliability between the two examiners, determined by the intraclass correlation coefficient (ICC).

3.2.2 3D ULTRASOUND SYSTEM

The US system used was from the company Telemed, UAB, Darlaus, Ir Gireno 42, Vilnius, 02189, Lithuania, with type Echo blaster 128 CEXT-1Z, REV:CS. The freehand probe connected to the system was followed by an optic tracking system (OTS) to appoint position and orientation of the obtained 2D transverse slices in space. The OTS followed four spheres the probe was equipped with to determine location. The probe was visible at all times by the OTS to ensure no interruption while visualising the MF. The software used to collect the 2D cross-

sections was the latest version of Stradwin (5.4a), Medical Imaging Group, Engineering Department, Cambridge University, Cambridge, United Kingdom. This program was capable of putting cross-sectional slices in space with the help of the OTS. Furthermore, the object of interest could be identified in a series of 2D slices to create a 3D muscle volume model. The specifications of the laptop and operating system are processor Intel(R) Core (TM) i5-8250U CPU @1.60GHz 1.80GHz, 8 GB installed RAM (7.85 GB usable), 64-bit operating system, x64-based processor. The device analysed at a frequency of 20MHz.

3.2.3 3D ULTRASOUND FREEHAND SCANNING AND BASELINE MEASUREMENTS

The 3D US device has been calibrated via the protocol described in another study (Cenni et al., 2016). Patients were placed in a prone position on the treatment table in a standardized manner. The head facing the OTS to prevent the gluteal region from disturbing the signal between the probe and the OTS. The height of the table remained constant throughout every assessment. Subjects were asked to wear shorts which were lowered just caudal to the PSIS, to ensure a proper margin for the swipe. Rodisonic contactgel (ingredients: water, carbomer, sodium hydroxide, methylparaben, propylparaben) was applied in adequate amounts to guarantee a decent induction of the US waves. The scanning site for further analysis was the left paraspinal area of the spinous processes L5 through L1. The researchers hypothesised that the MF sufficed a single swipe from the spinous process (SP) L5 to L1, which was later confirmed. Both examiners confirmed the fifth lumbar SP palpatorily and via US guidance. The operators agreed 100% on the location of the SP. When the consensus was reached an “x” was placed contralaterally at the height of the L5 SP as a reference point. The starting point was slightly distal of the “x” and the probe was swiped until the lower thoracic vertebrae, to ensure the examiners included L1-5 in the swipe. The examiners determined L1 and L5 separately when scanning the slices in Stradwin for volume measurements. The laptop was in sight at all times with near live feedback via Stradwin (figure 1). For the assessment, two operators were present. One controlling Stradwin for the start and end of the measurement, verbally cued by the operator holding the probe. The probe and the cable attached were held as seen in figure 2. When finishing the measurement, the recorded swipes were reviewed in sequence to affirm equitable images. When in doubt, the measurement was repeated. Origins of error were - for example - movement of the subject, disturbances in signal or conductance, freezing of software, etc. The duration of a single measurement was approximately two

minutes and was repeated immediately by the second examiner. Subjects were measured (centimetres) and weighed (kilograms, numbers rounded to tenths) before the second assessment while the operators examined another subject, to minimise the learning curve via diminished recall. This way, there was a sufficient amount of time between the first and second assessment of the first operator. When all measurements were completed, the examiners outlined the MF once every 20 slides in Stradwin to construct a 3D muscle model with the corresponding volume expressed in millilitre. The researchers were blinded from each other's volume measurements per subject. For intra-rater reliability, the files were randomized to annul recall prior to the volume analyses. The scanning process in Stradwin can be seen in figure 3.

3.3 DATA-ANALYSIS

The statistical reliability analysis was conducted with IBM SPSS Statistics (version 25). A Two-way mixed model was used with an absolute agreement for multiple raters and a 95% confidence interval. The single outcome measure was the average ICC value for inter-rater reliability and the single ICC value for intra-rater reliability. The decision of the correct statistical model was determined with the help of figure 4 (Koo & Li, 2016). The exact mathematical model used in SPSS was as followed:

$$MS_R - MS_E / \left(MS_R + \frac{MS_C - MS_E}{n} \right)$$

MSR = mean square for rows; MSE = mean square for error; MSC = mean square for columns;
n = number of subjects.

4. RESULTS

Two subjects were excluded due to errors in the measurements. The data of eighteen participants (9 male, 9 female) were analysed. These subjects had a mean age of 34.16 years (range 20 to 58 years), height 172.8 ± 9.82 cm (range 156 to 195 cm), weighed 72.37 ± 11.98 kg (range 53.4 to 96.3 kg) and had a BMI of 24.12 ± 2.63 . Single sweep freehand 3D US scans of the MF were performed on 18 subjects. The inter-rater reliability showed poor to good reliability (ICC: 0.718; 95% CI: 0.251-0.894). Within rater or intra-rater reliability, scored higher with moderate to excellent reliability (ICC: 0.863; 95% CI: 0.670-0.946). The qualitative interpretation of the data is based on an intraclass coefficient guideline (Koo & Li, 2016). A visual representation of this qualitative classification can be found in the supplementary data (figure 5).

5. DISCUSSION

This study investigated the inter-rater and intra-rater reliability of a 3D US measuring muscle volume. The researchers explored the reliability of measuring the volume of a deep trunk muscle, the MF. According to our findings, inexperienced ultrasonographers have a moderate to excellent intra-rater reliability. The inter-rater reliability appeared to be poor to moderate, questioning the usage of the device for this subgroup of examiners. To the researcher's knowledge, the current study is the first to investigate reliability in 3D US volume measurements of the MF, meaning no published standardized protocols are available to this day. This study could thus be regarded as a pilot study in the field.

This paper has several limitations. The protocol was not pre-trial registered at clinicaltrials.gov. This means the researchers cannot prove there was no deviation of the predetermined protocol. Additionally, the power was not calculated before commencing the study. In the statistical outcomes, the authors found moderately acceptable ICC values. However, for the inter-rater reliability, the 95% confidence interval is rather wide. This phenomenon can be attributed to the high variance in volumes and some extremely low and high discrepancies in ICC values. Experienced ultrasonographers could minimize this interval, however, this was not the objective of the study. Another explanation would be the heterogeneous population. The study contains a rich spread of age, length, weight, and gender. It might be interesting to investigate homogenous populations in the future to see the possible impact on the results. In US research, different confounding variables may come into play. Therefore, it's possible that the reliability of the measurements was highly dependent on certain confounding variables and proxies such as swipe speed, experience, focus, learning curve, the curvature of the lower back, subtle movements by the subject, etc. Usually, reliability studies for US devices are done by radiologists or experienced examiners. This was not the case when carrying out this study. The researchers had zero experience conducting an US examination, as well as the overseeing examiner. With no experienced examiner present during the measurements, it is possible mistakes were made during the assessment of the MF. The authors again had no experience with analysing the US results in Stradwin, which is necessary to correctly define the MF on the obtained slices. It's plausible to assume that results would be positively altered if raters assessed the same scan in this software. This could

influence the inter- and intra-rater reliability. Future studies could try to shed some light on this hypothesis. However, in standard private practice, the ultrasonographer is likely to be the one assessing the structures within the scan so the usefulness of such a study could be questioned.

It is important to keep in mind that each assessment is highly dependent on skill, motivation and other confounding variables of the investigator, which makes the data specific to the raters of interest. This unique combination makes external validity limited even if other raters have similar characteristics.

The main strength of this paper is the robust and reproducible method. This study makes way for further investigations building on these findings. Furthermore, eligibility criteria were specified preliminary to ensure morphological changes due to pathology, age or other factors would not interfere with the accuracy of measuring the MF. All recruited people were measured, and 90 percent of the obtained data was suitable for the analysis. This Master's thesis was a single-blinded study. Meaning the assessors were blinded from each other's volume results. Both researchers thus analysed the data separately. This way they were not influenced by one another. Furthermore, for the intra-rater reliability, the examiner was blinded from his previous results and volume data was obtained in a randomized order. This ensures that the investigator is not biased by his prior findings. An equal amount of men and women participated in this research, enhancing the external validity for this matter.

Due to the fact that this Master's thesis is a pilot study, it is difficult to link back to other similar studies regarding this subject. Most 3D US reliability studies examining muscle volume, measure the size of the calf muscles in vivo and in patients with cerebral palsy. One study measured quadriceps volume in vivo. They collectively agreed that freehand 3D US offers good clinical utility compared with MRI, considering the low cost and time efficiency (Barber et al., 2019; Barber et al., 2009; MacGillivray et al., 2009). One study looked at the ICC values for 3D US versus volume measurements for the distal semitendinosus muscle after dissection in cadavers. An excellent ICC of 0.96 was found, confirming the validity of 3D US (Haberfehlner et al., 2016). There is a significant difference comparing the reliability results with the results of these other studies. These studies examined validity by comparing to MRI scans or dissection results, while the current study only compared the 3D US within and between raters. The reliability of the other investigations is higher, presumably on the grounds that the

examiners were radiologists or had reasonable experience with performing and interpreting US scans, although this cannot be stated with certainty. Another contributing factor for the disagreement between the other investigations is that the MF is a more profound muscle with an arguably more complex origin and insertion, while the gastrocnemius, rectus femoris and semitendinosus are more superficial muscles. Apart from these two main differences, there were several similarities between this investigation and the other studies. All investigations included ten to twenty participants and patients with a history of any injury in the measured muscle or area were excluded. All studies had a standardized protocol of measuring, and the devices were calibrated beforehand. All post-scanning processing was performed in Stradwin.

For future studies, it will be interesting to see the reliability in different levels of expertise, compared to MRI results to determine validity. Knowing the aforementioned study would require a vast amount of resources and a compelling precedent evidence base, studies looking at the reproducibility of the previously achieved ICC values - in different inexperienced raters - would be a required prior step. Attempting to examine more neighbouring structures such as the m. quadratus lumborum and m. erector spinae could possibly enhance the usefulness of such a device in practise. Accomplishing this, an informed decision could be made regarding the clinical applicability for 3D US of the MF in less experienced hands. The authors encourage more research in this field.

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8. SUPPLEMENTARY DATA

Table 1. BASELINE MEASUREMENTS

<i>Variables</i>	<i>M (SD)</i>
Sex (male)	50%
Age	34.16 (15.28)
Height (cm)	172.8 (9.82)
Weight (kg)	72.37 (11.98)
BMI	24.12 (2.36)

Notes: M = mean; SD = standard deviation; cm = centimetres; kg = kilograms; BMI = body mass index

Table 2. COMPARISON OF VOLUME MEASUREMENTS

<i>Participant</i>	<i>Scan 1 (ml)</i>		<i>Scan 2 (ml)</i>
	<i>Rater 1</i>		<i>Rater 2</i>
	<i>1st</i>	<i>1st</i>	<i>2nd</i>
1	81.009	121.964	123.736
2	113.363	127.856	157.905
3	70.104	67.069	75.912
4	113.715	105.018	111.241
5	64.409	81.512	65.134
6	77.159	86.986	71.25
7	134.241	108.021	116.432
8	61.58	75.679	82.273
9	79.42	99.157	102.817
10	109.86	119.738	109.898
11	102.682	109.647	108.175
12	106.61	111.782	107.257
13	142.867	83.062	76.313
14	74.576	71.957	71.389
15	74.551	82.59	87.293
16	76.795	84.578	82.672
17	65.223	70.375	86.889
18	73.715	85.472	72.054

Notes: ml = millilitres

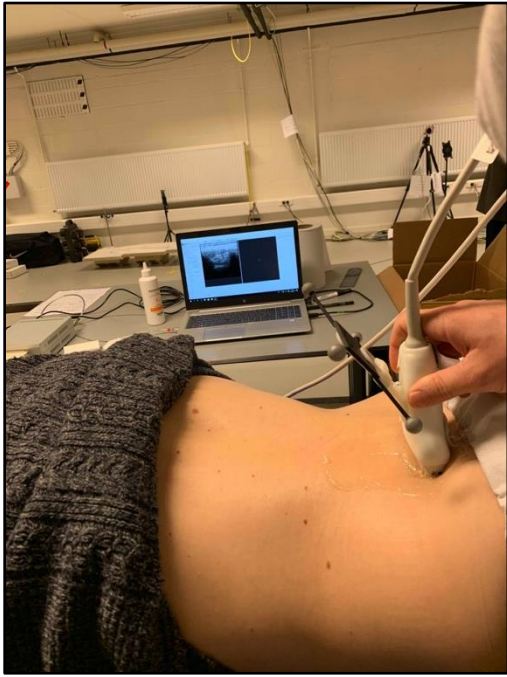


FIGURE 1



FIGURE 2

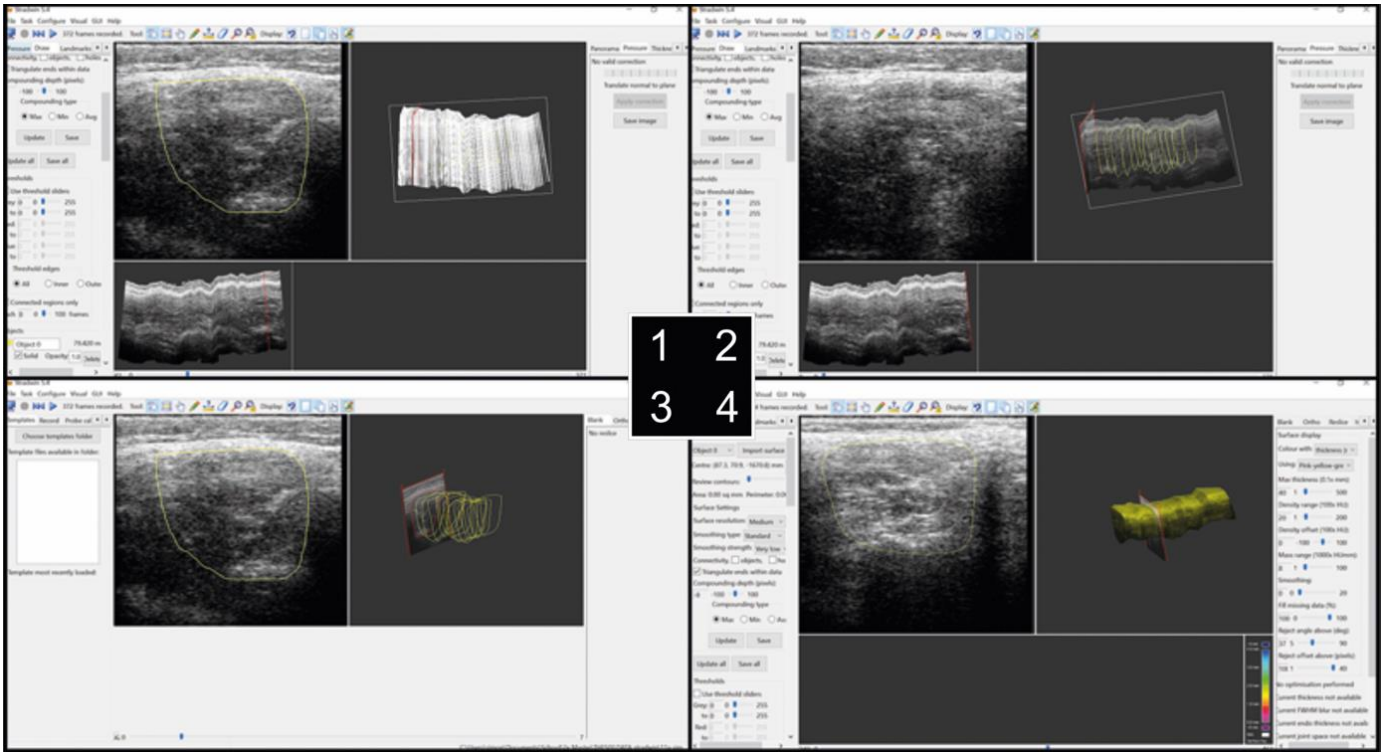


FIGURE 3

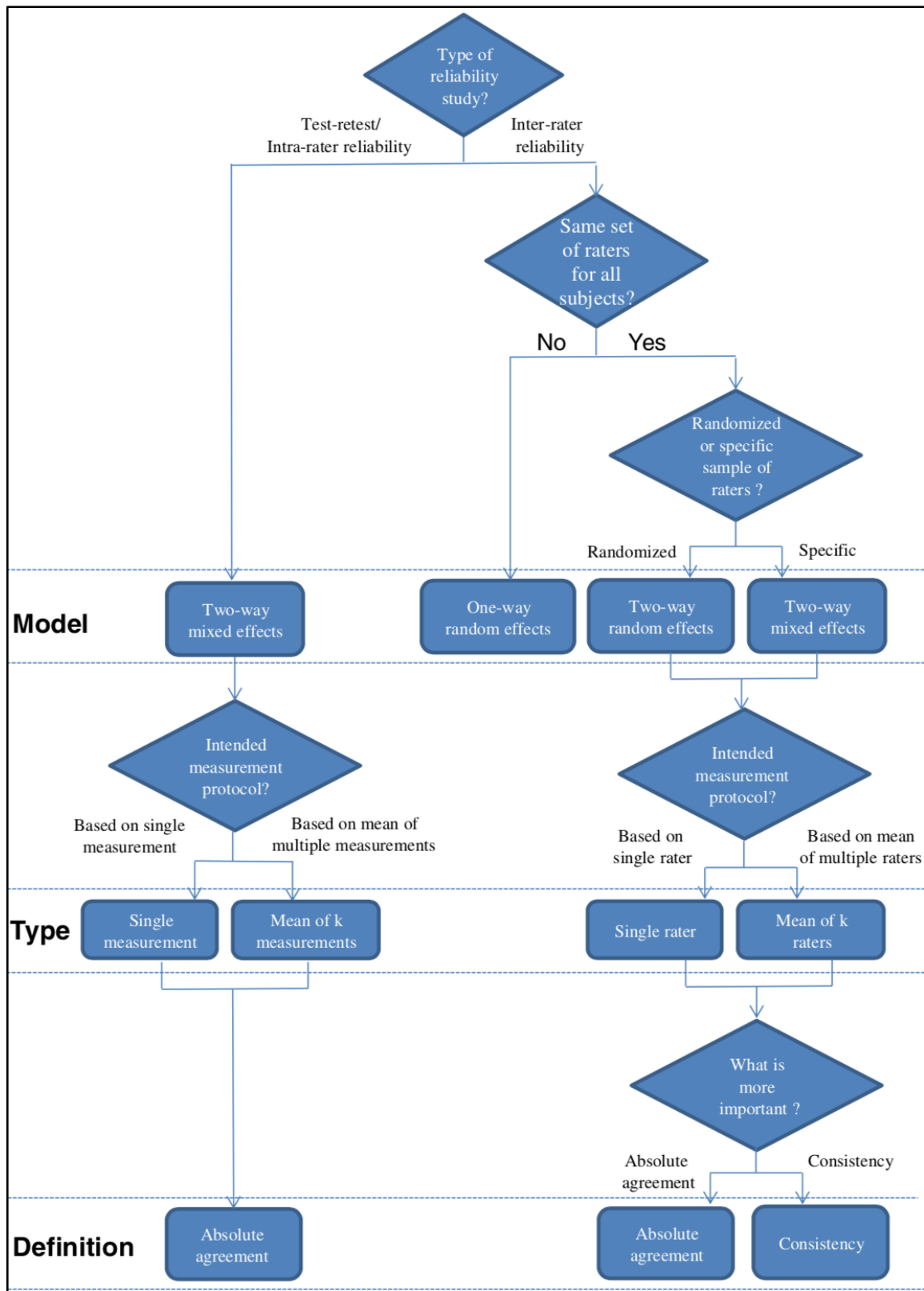


FIGURE 4

KOO & LI, 2016

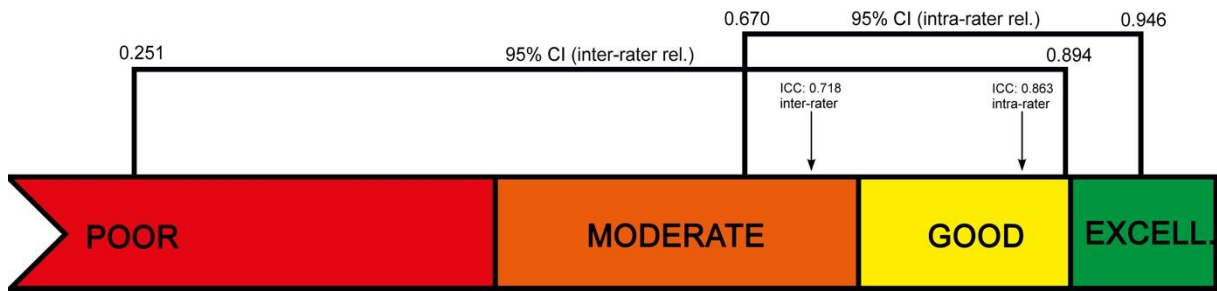


FIGURE 5

Notes: CI = confidence interval; ICC = intraclass correlation; rel. = reliability; EXCELL. = excellent

In te vullen door de promotor(en) en eventuele copromotor aan het einde van MP2:

Naam Student(e): Max van der Velde en
Suzanne Geesels Datum: 24/5/19

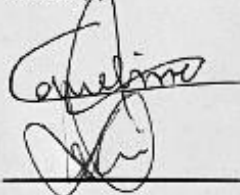
Titel Masterproef: An evaluation of the inter-rater and intra-rater
reliability in volume measurements with a 3D-ultrasound apparatus
of the masticular musculature in healthy subjects

- 1) Geef aan in hoeverre de student(e) onderstaande competenties zelfstandig uitvoerde:
- NVT: De student(e) leverde hierin geen bijdrage, aangezien hij/zij in een reeds lopende studie meewerkte.
 - 1: De student(e) was niet zelfstandig en sterk afhankelijk van medestudent(e) of promotor en teamleden bij de uitwerking en uitvoering.
 - 2: De student(e) had veel hulp en ondersteuning nodig bij de uitwerking en uitvoering.
 - 3: De student(e) was redelijk zelfstandig bij de uitwerking en uitvoering
 - 4: De student(e) had weinig tot geringe hulp nodig bij de uitwerking en uitvoering.
 - 5: De student(e) werkte zeer zelfstandig en had slechts zeer sporadisch hulp en bijsturing nodig van de promotor of zijn team bij de uitwerking en uitvoering.

Competenties	NVT	1	2	3	4	5
Opstelling onderzoeksvraag	0	0	0	0	X	0
Methodologische uitwerking	0	0	0	0	X	0
Data acquisitie	0	0	0	0	0	X
Data management	0	0	0	0	0	X
Dataverwerking/Statistiek	0	0	0	0	0	X
Rapportage	0	0	0	0	0	X

- 2) Niet-bindend advies: Student(e) krijgt toelating/ geen toelating (schrappen wat niet past) om bovenvermelde Wetenschappelijke stage/masterproef deel 2 te verdedigen in bovenvermelde periode. Deze eventuele toelating houdt geen garantie in dat de student geslaagd is voor dit opleidingsonderdeel.
- 3) Deze wetenschappelijke stage/masterproef deel 2 mag wel/niet (schrappen wat niet past) openbaar verdedigd worden.
- 4) Deze wetenschappelijke stage/masterproef deel 2 mag wel/niet (schrappen wat niet past) opgenomen worden in de bibliotheek en docserver van de U Hasselt.

Datum en handtekening
Student(en)

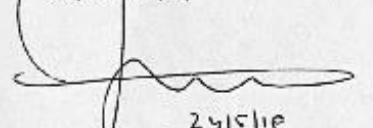


Datum en handtekening
promotor(en)

24/5/19

A. Agten

Datum en handtekening
Co-promotor(en)


24/5/19
F. Van der Beeke

INVENTARISATIEFORMULIER WETENSCHAPPELIJKE STAGE DEEL 2

DATUM	INHOUD OVERLEG	HANDEKENINGEN
nov okt.	besp. bespreking aanvraag CTE	Promotor: [handtekening] Copromotor/Begeleider: [handtekening] Student(e): [handtekening] Student(e): [handtekening]
nov	verdediging CTE aanvraag	Promotor: [handtekening] Copromotor/Begeleider: [handtekening] Student(e): [handtekening] Student(e): [handtekening]
nov-mei	contact via mail voor opvolging masterproef.	Promotor: [handtekening] Copromotor/Begeleider: [handtekening] Student(e): [handtekening] Student(e): [handtekening]
		Promotor: Copromotor/Begeleider: Student(e): Student(e):
		Promotor: Copromotor/Begeleider: Student(e): Student(e):
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		Promotor: Copromotor/Begeleider: Student(e): Student(e):
		Promotor: Copromotor/Begeleider: Student(e): Student(e):