An analysis of the validity and reliability of a handheld ultrasound device for measuring rectus femoris muscle size.

Willemke Nijholt[a], Astrid Bakker[a], Alicia C. Bennett[b], Morten H. Borgen[c], Anne Ellermann[a], Peter Hogg[b], Patrícia T. Gamboa[d], Martine Thorskog[c], Liesl Vorster[e], Ingrid J. Aandahl[c]

a) Department of Medical Imaging and Radiation Therapy, Hanze University of Applied Sciences, Groningen, the Netherlands.
b) School of Health Sciences, University of Salford, Manchester, United Kingdom.
c) Oslo and Akershus University College of Applied Sciences, Oslo, Norway.
d) Escola Superior de Tecnologia da Saúde de Lisboa, Lisbon, Portugal.
e) Department of Clinical Sciences, Radiography, Central University of Technology, Bloemfontein, South Africa.

Keywords

Rectus Femoris
Reliability
Ultrasound
Validity
Handheld

Abstract

Background: Previous studies show that ultrasound is valid and reliable when measuring muscle size. A Philips handheld ultrasound device was released in April 2015. The aim of this study was to investigate the validity and reliability of the handheld ultrasound device compared to a conventional ultrasound device, when measuring the size of the rectus femoris (RF).

Methods: Two sonographers scanned 39 volunteers (mean age=29.3y, 26 female), once with the Toshiba SSA-660A (regular) ultrasound device and twice with the Philips hand held VISIQ device. The size of the RF (expressed in cross sectional area (CSA) was measured two ways; using the trackball on the Toshiba device and an automatic region of interest on the VISIQ device (method 1), and an ellipse on both devices using the formula π*half width*half length (method 2).

Results: Method 1 resulted in an intraclass correlation coefficient (ICC) of .811 with a 95% (confidence interval) CI of .773-.837 (inter-rater reliability) and .907 with a 95% CI of .822-.951 (validity). The ICCs of method 2 were .787 with a 95% CI of .593-.888 (inter-rater reliability) and .867 with a 95 % CI of .746-.930 (validity).
Conclusion: VISIQ is a valid and reliable device for measuring RF-CSA. In clinical practice VISIQ could be used for measuring RF-CSA, consequently it could be an economical and easily portable technology for use in both clinical and residential settings

Introduction

According to the profile of ageing by the United Nations (UN) the percentage of the worldwide population over the age of 65 in 1980 was 6.0%, and by 2013 had risen to 8.0%. The UN predicts that this percentage will increase to 15.6% by 2050. (1) A condition of ageing is sarcopenia. The term sarcopenia was first used by Rosenberg in 1989 and literally means poverty of flesh.(2) Sarcopenia is now defined as a geriatric syndrome, related to the decline of muscle mass and muscle function.(3) In the study that Cruz-Jentoft (2014) conducted on adults over the age of 50; 1-29% living in community dwelling populations, 14-33% in long term-care populations and 10% in acute hospital care population, developed sarcopenia.(4) Early life developmental influences, poor diet, ageing, sedentary lifestyle, chronic diseases and certain drug treatments are all contributing factors to the development of sarcopenia. An impaired state of health is common amongst people with sarcopenia, the increased risk of falls and fractures, disabilities, loss of independence and mobility disorders all increase the risk of death. Through the measurement of muscle size the risk of falls and injury can be determined early.(4)

Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) are considered to be the "gold standard" for measuring muscle size. However, high costs, long scanning times and restricted accessibility of MRI, as well as the ionizing radiation dose caused by CT, are some drawbacks of these techniques.(3) Ultrasound does not use ionizing radiation, is relatively inexpensive, and allows for a faster diagnosis, in comparison to CT and MRI. Literature shows that ultrasound is another valid and reliable scan method for measuring muscle size. (6) Giles et al. (2015) determined that ultrasound is strongly correlated to MRI when measuring the rectus femoris (RF) thickness.(7) They found that the

intraclass correlation coefficient (ICC) of the mean difference between ultrasound and MRI for measuring the RF is 0.858.

A new mobile ultrasound device (VISIQ Philips medical) was released by Philips in April 2015. The VISIQ Ultrasound device is mobile, meaning the ultrasound device can be used in general health care, for example, at nursing homes and in Intensive Care Units. The VISIQ is more practical and convenient to use than the conventional Toshiba SSA-660A Xario ultrasound device because of its level of mobility. Due to the often limited mobility of the elderly, visits to health centres for imaging such as MRI and CT can be difficult. The mobility of the VISIQ means that examinations can be carried out in the homes of elderly patients. The VISIQ is more affordable when compared to the Toshiba SSA-660A. Despite the high expectations of the VISIQ, information about the validity and reliability of VISIQ in measuring muscle size is lacking.

The aim of this study, therefore, is to investigate the validity and reliability of VISIQ ultrasound device compared to the Toshiba SSA-660A Xario ultrasound device, when measuring the size of the Rectus Femoris (RF) in healthy adults.

Methodology

Study population

In this quasi-experimental study, healthy adults who took part in OPTIMAX 2015 were invited to volunteer in the study. Volunteers were selected if they met the inclusion criteria; they had to be over the age of 18 and in good general health. The volunteers were fully informed about the study procedures, the aim of the study and gave written informed consent before participation. This study was carried out over 3 weeks, at the Hanze University of Applied Sciences, Groningen, Netherlands. Before ultrasonography measurements were taken, age, height and weight were collected of all participants, and the BMI calculated. Ethical approval for the study was granted by The Medical Ethical Committee, of The University Medical Centre, Groningen (reference number: METc 2015/305).

Ultrasonography measurement

Measurements of the RF were obtained using a Toshiba SSA-660A Xario ultrasound device (Toshiba Medical Systems Corporation, Tochigi-Ken, Japan) and a Philips VISIQ ultrasound device (Philips Healthcare, Bothell, United States).(8)assessing its concordance with dual energy X-ray densitometry (DEXA The transducers used were a curved array transducer, type C5-2 on the VISIQ and a curved array transducer, type PVT375BT on the Toshiba SSA-660A. A fixed scanning protocol was used on both devices; frequency 11Hz, gain 64 dB and a depth of 8 cm.

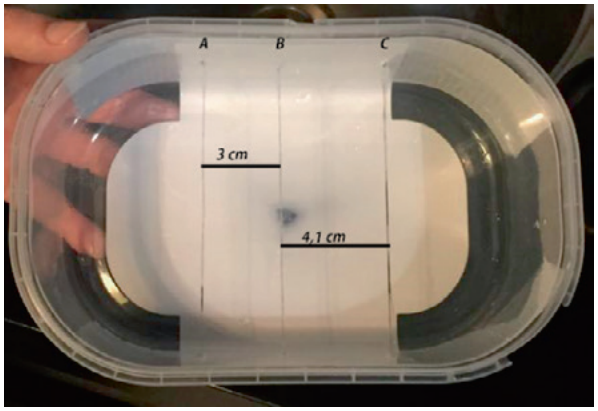

Fig 1. Phantom measurements

Measurements were acquired individually by two trained sonographers, blinded to each other's measurements. In order to investigate the inter-rater reliability and the validity, both sonographers scanned each volunteer three times, once with the Toshiba SSA-660A and twice with the VISIQ.

Operator Measurement Accuracy test

Before any study data was collected, a phantom was used to determine the accuracy of both sonographers in taking measurements from the screen data. Test scans were carried out twice, on two different days, using the Toshiba SSA-660A. The phantom contained three lines of fishing wire, placed at varying distances within gel.(9) The distance from line A to B was 3 cm, and the distance from line B to C was 4.1 cm *(fig.1)*. Both sonographers were unaware of the distances during the tests. Individually, the sonographers were tasked with measuring the distances between the lines using the Toshiba SSA-660A. While carrying out the tests, the previous measurements on the ultrasound screen were covered, making it impossible for the sonographers to see the results until all of the tests had been completed.

Table 1a and 1b show the accuracy test results from both sonographers. The results gained from the phantom show that the accuracy of both the sonographers was high as their measurements were close to the actual distances of the phantom. These results show that both sonographers had a 3% error when measuring distance A-B, and sonographer 1 had a 1% error when measuring distance B-C, whereas sonographer 2 had a 2% error. The level of error was low for both sonographers indicating their high level of accuracy.

Table 1a. Results accuracy test A-B

	Actual distance = 3 cm	
	Sonographer 1	Sonographer 2
T_0 *Measured*	3.10	3.17
T_1 *Measured*	3.09	3.10

Measured= measured distance between A-B in cm

Table 1b. Results accuracy test B-C

	Actual distance= 4.1 cm	
	Sonographer 1	Sonographer 2
T_0 *Measured*	4.23	4.21
T_1 *Measured*	4.12	4.20

Measured= measured distance between B-C in cm

Measurements of RF muscle

Imaging was conducted with the volunteer lying supine with a rested extended leg. The cross sectional area (CSA) of the RF was measured in order to determine muscle size. To establish the location of the CSA of the RF muscle, a mark between the superior patella border and the Anterior Superior Iliac Spine (ASIS) was made on the right upper leg. This point represents the maximum size of the RF muscle.

Three measurement methods were considered when measuring the CSA during this research; manual trackball, automatic ROI and ellipse equation. (8,10) assessing its concordance with dual energy X-ray densitometry (DEXA To assess RF CSA on the Toshiba SSA-660A, the manual trackball was used. As a manual trackball is not available on the VISIQ, an automatic ROI was used to determine RF CSA on the VISIQ. The last measurement was the CSA of the RF using an ellipse equation. Half of the depth (a; representing the minor ellipse axis) and half of the width (b; representing the major ellipse axes) were calculated using the equation, πab, to give the area of the ellipse. For all the three measurement methods, RF-CSA was expressed in cm^2.

Method of analysis

Data was analysed using IBM SPSS Statistics 20, for windows. Two outcomes were calculated; inter-rater reliability and validity. The inter-rater reliability was assessed by comparing the first VISIQ scan from sonographer 1, with the first VISIQ scan from sonographer 2. The validity was assessed by comparing the first VISIQ scan carried

out by sonographer 1, with the Toshiba SSA-660A scan carried out by sonographer 1. An Intra-class Correlation Coefficient (ICC) test was carried out to assess the level of agreement between both sonographers. A Bland Altman plot was constructed to visualize the spread of the data.

Results

Subjects

Thirty nine volunteers were used for this study, of which 26 were females and 13 males. The age of the volunteers ranged between 18 and 62 years. The mean diameter of the RF at its thickest point, measured by the Toshiba SSA-660A, was 2.07 cm for females and 2.31 cm for the males. The mean CSA of the RF measured using the trackball function on the Toshiba SSA-660A, was 9.40 cm^2 for the females and 12.96 cm^2 for the males. More participant characteristics are listed in Table 2.

Validity

Table 3 shows the results of the validity assessment of the different measurement methods. The comparison of the CSA of the manual trackball and the automatic ROI yielded an ICC score of .907. The manual trackball compared to the ellipse equation yielded an ICC of .802. Comparing the ellipse equations between both devices resulted in an ICC of .867.

Two outliers were identified (Fig 2a). These outliers were re-measured and the ICC tests were repeated (Fig 2b). The results of the CSA range improved from .802 - .907 to .826 - .968.

Table 2 Participant characteristics

	Mean	Min	Max	SD
Age (years)	29.3	18	62	11.92
Weight (kg)	72.49	58.10	103.60	13.32
Height (m)	1.74	1.60	1.99	.089
BMI (kg/m2)	23.9	17.80	31.90	3.87
Upper leg(cm)	44.4	41.0	51.0	2.77
RF- Diameter (cm)	2.15	1.63	3.29	.33
CSA(cm2)	10.43	2.13	19.29	2.93

Min= minimum, Max= maximum, SD= standard deviation
Upper leg = distance between Anterior Superior Iliac Spine (ASIS) and Patella, RF-Diameter= Rectus femoris diameter measured with Toshiba SSA-660,CSA = Cross-sectional area

	Initial measurement		Re-measurement	
	ICC	95% CI	ICC	95 % CI
CSA Manual trackball vs. Automatic ROI*	.907*	.822 - .951	.968*	.932 - .984
CSA Manual trackball vs. Ellipse equation*	.802*	.508- .909	.826*	.327- .934
Ellipse equations	.867*	.746- .930	.911*	.795- .957

Table 3 Validity measurements between the Toshiba and VISIQ devices of the different measurements methods

*ICC= intraclass correlation, 95%CI = 95% Confidence Interval, CSA = Cross-sectional area, ROI= Region of Interest, Ellipse= ellipse equation, * p-value <.001*

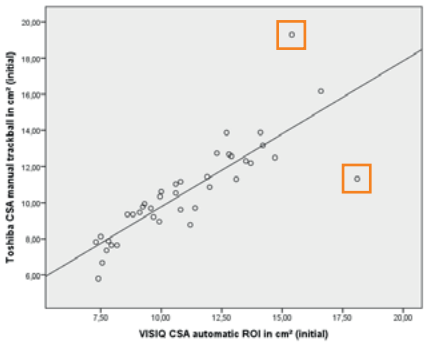

Fig 2a Scatter plot of initial measurements of the Cross-sectional area (CSA) using the trackball function on the Toshiba SSA-660A compared to the automatic Region of interest (ROI) function on the VISIQ device.

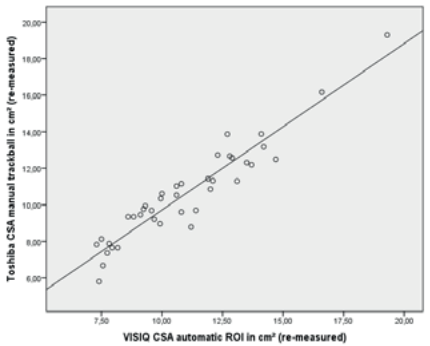

Fig 2b Scatter plot of re-measurements of the Cross-sectional area (CSA) using the trackball function on the Toshiba SSA-660A compared to the automatic Region of interest (ROI) function on the VISIQ device.

Reliability

The ICC of the CSA measured by the automatic ROI (.881) and the ellipse equations (.787) carried out by the two sonographers (Table 4), show a strong positive correlation. The correlation increased to .905 and .842 respectively after re-measurement. A Bland Altman plot illustrates the spread of the differences of the measurements between the two devices, with a systematic error of -.29 and limits of agreement between -3.10 and 2.52 (Fig 3).

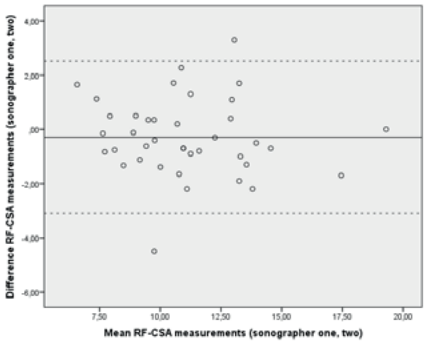

Fig3 Bland Altman plot between sonographer one and sonographer two measurements of RF-CSA with the automatic ROI after re-measurement. A positive value indicates that the measured value of the RF-CSA of sonographer one is higher than the measurement of sonographer two.

	Initial measurement		Re-measurement	
	ICC	95% CI	ICC	95 % CI
CSA-ROI	.881*	.773-.837	.905*	.820-.950
CSA- Ellipse	.787*	.593-.888	.842*	.701-.917

ICC= intraclass correlation, 95%CI = 95% Confidence Interval,
*CSA = Cross-sectional area, ROI= Region of Interest, Ellipse= ellipse equation, * p-value <.00*

Table 4 Inter- rater Reliability

Discussion

The aim of this research was to investigate the validity and reliability of the VISIQ compared to the Toshiba SSA-660A for measuring the CSA of the RF. Results show that the level of agreement between the sonographers (ICC between .787 to .881) and the validity of the VISIQ compared to the Toshiba SSA-660A (ICC between .802 to .907) are both excellent.

Three measurement methods were considered for measuring CSA during this research; manual trackball, automatic ROI and ellipse equation. In accordance with previous studies, e.g. Reeves et al.(2004), our study considered the manual trackball CSA measurement as the gold standard.(11)disuse and ageing. The considered 'gold standard' for cross-sectional area measurements of muscle size is magnetic resonance imaging (MRI Our study is the first to use an automatic ROI to determine the RF CSA. A disadvantage of this method is that it is impossible to delineate the edge of the muscle because the ROI has fixed borders. Despite this

limitation the correlation between the trackball and the automatic ROI is high (ICC .907) (table 3). An automatic ROI and an ellipse equation were also used to determine CSA. ICC values of .802 for the ellipse equation and .867 for the automatic ROI suggest there is a strong correlation between the trackball and the ellipse measurements. Awadh et al. (2006) suggested that an ellipse measurement can be used to measure the CSA of the heart as a valid and reliable measurement.(10)

On initial analysis, two outliers were identified (Fig2a). After the outliers were investigated and subsequently re-measured (Fig2b), the ICC RF CSA (Toshiba) versus the automatic ROI measurement (VISIQ) improved from .907 to .948. Prior to analysis, we recommend that the ROI and ellipse positions should be reviewed to ensure placement accuracy. Another explanation for the outliers may be due to the difficulty of measuring the CSA on the VISIQ. The VISIQ has fixed borders which restrict measurement parameters of the muscle.

Strengths

Confidence in the results are strengthened by a number of factors. In this study a curved-array transducer was used on both devices. Hammond et al(2014) showed that this transducer is valid and reliable when measuring muscle size.(13) This study population is comparable to studies such as Thomaes et al (2012) (25 participants) and Seymour et al. (26 participants).(12,14) An additional strength of our method is that a blinded phantom test has been performed to minimise measurement biases between the two sonographers. The outcome of this study was that both sonographers performed similarly and consistently accurately.

Limitations

During the research some limitations of the method came to light. First; the different methods of measurements used on both devices were a limitation of the study. The VISIQ did not have a manual trackball function meaning the CSA could not be assessed in the same way as the Toshiba SSA-660A. In order to assess the CSA on the VISIQ an ellipse equation (πab) was used. An advantage of using the equation to assess the CSA of the RF is that the calculation can be applied to the scans from both the VISIQ and the Toshiba SSA-660A. The fact that this kind of calculation can be done on both devices allows the results to be truly comparable. A previous study used this equation to measure CSA.(10) Second; the CSA was measured using the trackball on the Toshiba, and the automatic ROI on the VISIQ. The automatic ROI function (ICC .907) and the ellipse equation (ICC .802) of the VISIQ were compared to the CSA measured by the manual trackball function of the Toshiba device. Even though the correlation between the ellipse equation (VISIQ) and the manual

measurement of the CSA (Toshiba) is the lowest of all, it still indicates a strong positive correlation ($p<0.001$) (Initial ICC .802, Re-measurement ICC .826).

In further research a more precise comparison can be made if the data from both devices is exported into a suitable graphics package so that ROI can be used to accurately define the edge of RF, which could potentially improve the accuracy of RF area estimation.

This study was conducted on healthy adults and may not necessarily apply to the elderly population as both functional and structural changes in muscles are common with aging. Therefore, further research in the use of the VISIQ to measure muscle size of the elderly may give more information. Similarly, to assess the use of the VISIQ for diagnosing sarcopenia in elderly, more research is needed.

Conclusion

VISIQ is a valid and reliable device for measuring RF CSA. In clinical practice VISIQ could be used for measuring RF CSA. Consequently it could be an economical and easily portable technology for use in both clinical and residential settings.

Acknowledgements

We would like to thank the Hanze University of Applied Sciences, Groningen, The Netherlands, for allowing us to carry out the research within the university and also for the use of the VISIQ ultrasound device. We are also grateful to volunteers from the OPTIMAX summer school, who participated in this study. A special thanks to Eva Gorter for her help during the data collection.

References

1. United Nations Department of Economic and Social Affairs Population Devision. Profiles of Ageing 2013 [Internet]. December 2013. 2013. Available from: http://www.un.org/en/development/desa/population/publications/dataset/urban/profilesOfAgeing2013.shtml
2. Rosenberg I. Summary comments: epidemiological and methodological problems in determining nutritional status of older persons. Am J Clin Nutr. 1987;50:1231–2133.
3. Mijnarends DM, Meijers JMM, Halfens RJG, Ter Borg S, Luiking YC, Verlaan S, et al. Validity and Reliability of Tools to Measure Muscle Mass, Strength, and Physical Performance in Community-Dwelling Older People: A Systematic Review. J Am Med Dir Assoc. Elsevier Ltd; 2013;14(3):170–8.
4. Cruz-Jentoft AJ, Baeyens JP, Bauer JM, Boirie Y, Cederholm T, Landi F, et al. Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People. Age Ageing [Internet]. 2010 Jul [cited 2014 Jul 9];39(4):412–23. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2886201&tool=pmcentrez&rendertype=abstract
5. Malafarina V, Uriz-Otano F, Iniesta R, Gil-Guerrero L. Sarcopenia in the elderly: diagnosis, physiopathology and treatment. Maturitas [Internet]. Elsevier Ireland Ltd; 2012 Feb [cited 2015 Aug 27];71(2):109–14. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22153348
6. English C, Fisher L, Thoirs K. Reliability of real-time ultrasound for measuring skeletal muscle size in human limbs in vivo: a systematic review. Clin Rehabil [Internet]. 2012 Oct [cited 2015 Aug 18];26(10):934–44. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22324054
7. Giles LS, Webster KE, McClelland J a, Cook J. Can ultrasound measurements of muscle thickness be used to measure the size of individual quadriceps muscles in people with patellofemoral pain? Phys Ther Sport [Internet]. Elsevier Ltd; 2015 Feb [cited 2015 Aug 18];16(1):45–52. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24894764
8. Berger J, Bunout D, Barrera G, de la Maza MP, Henriquez S, Leiva L, et al. Rectus femoris (RF) ultrasound for the assessment of muscle mass in older people. Arch Gerontol Geriatr [Internet]. 2015 [cited 2015 Aug 18];61(1):33–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25890633
9. Szczepura K. personal communication [12-08-2015]. 2015.
10. Awadh a M a, Prefumo F, Bland JM, Carvalho JS. Assessment of the intraobserver variability in the measurement of fetal cardiothoracic ratio using ellipse and diameter methods. Ultrasound Obstet Gynecol [Internet]. 2006 Jul [cited 2015 Aug 21];28(1):53–6. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16758439
11. Reeves ND, Maganaris CN, Narici M V. Ultrasonographic assessment of human skeletal muscle size. Eur J Appl Physiol [Internet]. 2004 Jan [cited 2015 Aug 27];91(1):116–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14639480
12. Seymour JM, Ward K, Sidhu PS, Puthucheary Z, Steier J, Jolley CJ, et al. Ultrasound measurement of rectus femoris cross-sectional area and the relationship with quadriceps strength in COPD. Thorax [Internet]. 2009 May [cited 2015 Aug 27];64(5):418–23. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19158125
13. Hammond K, Mampilly J, Laghi F a, Goyal A, Collins EG, McBurney C, et al. Validity and reliability of rectus femoris ultrasound measurements: Comparison of curved-array and linear-array transducers. J Rehabil Res Dev [Internet]. 2014 Jan;51(7):1155–64. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25437305
14. Thomaes T, Thomis M, Onkelinx S, Coudyzer W, Cornelissen V, Vanhees L. Reliability and validity of the ultrasound technique to measure the rectus femoris muscle diameter in older CAD-patients. BMC Med Imaging [Internet]. BioMed Central Ltd; 2012 Jan [cited 2015 Jul 14];12(1):7. Available from: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3342139&tool=pmcentrez&rendertype=abstract