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ORIGINAL RESEARCH

RELIABILITY AND VALIDITY OF THE HALO DIGITAL GONIOMETER FOR SHOULDER RANGE OF MOTION IN HEALTHY SUBJECTS

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ABSTRACT

Background: Range of motion (ROM) of the shoulder is an integral component of assessment of musculoskeletal shoulder impairments. ROM is typically measured using a universal goniometer (UG). The UG has demonstrated good intra and inter-rater reliability for measuring shoulder ROM, although limitations exist. In recent years, alternative measurement devices such as smartphone applications and digital goniometers have been introduced, potentially addressing some of the shortcomings of the UG. Limited research is available on the validity and reliability of these alternative devices, including the laser-guided digital goniometer, in measuring shoulder ROM.

Purpose: The purpose of this study was to investigate the intra- and inter-rater reliability and concurrent validity of a laser-guided digital goniometer (HALO) for measuring active shoulder ROM.

Methods: A convenience sample of healthy volunteers was recruited. To be eligible, participants were required to be between 18 and 75 years of age and able to actively move at least one shoulder into 90° of glenohumeral abduction. Self-report of previous significant shoulder injury; previous shoulder surgery; current bilateral shoulder pain; current neck or upper back pain; or referred pain into the upper extremity were exclusion criteria. Active shoulder flexion, abduction, internal rotation, and external rotation were measured for each shoulder. Two evaluators measured each motion twice with each device (HALO and the UG) per shoulder. The intra-class correlation coefficient (ICC) for reliability and validity/agreement between devices was calculated using a two-way mixed model with a 95% confidence interval.

Results: Data were analyzed for 75 shoulders from 41 participants (seven participants had only one shoulder evaluated). Intra-rater reliability ICCs are between 0.82 and 0.91 for the HALO, and 0.83 to 0.95 for the UG. Inter-rater reliability for the HALO was 0.89 to 0.98 and for the UG was 0.90 to 0.98. The ICCs for agreement, comparing the HALO digital goniometer to the UG ranged from 0.79 to 0.99.

Conclusion: This study provides evidence that the HALO digital goniometer can be a reliable and valid tool for measuring shoulder ROM in individuals with healthy shoulders. However, the two devices should not be used interchangeably to evaluate a single individual's change over time for any motion.

Level of Evidence: Diagnostic Study (clinical measurement), Level 2b

Key Words: Clinimetrics, goniometry, reliability, shoulder, validity

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INTRODUCTION

The assessment of joint range of motion (ROM) is an important component of a physical therapy examination.[1-3] These measurements are critical for providing baseline data, determining functional limitations, and monitoring changes in joint mobility in response to treatment. Measurement of ROM may also be used to detect asymmetry and movement restrictions that may increase risk of injury.[4] While the universal goniometer (UG) has been considered the gold standard for clinical assessment of ROM,[5] additional tools used in a clinical setting include inclinometers, digital goniometers, smartphone application-based tools, and laser-guided devices.

Universal goniometry is frequently used by physical therapists to assess ROM due to its ease of use, portability, noninvasive nature, and low cost.[5,6] The UG is reported to have excellent inter-rater and intra-rater reliability for the assessment of upper extremity ROM.[5,7] While studies that evaluate concurrent validity of the UG for assessment of upper extremity ROM are limited, the UG is used frequently in validation studies of alternative ROM measurement devices.[7-10] However, there are limitations associated with its use: the UG requires two hands to manipulate the instrument, can be challenging to accurately position, and requires clear visual estimation for alignment and measurement-reading. These limitations could contribute to measurement error.

Thus, alternative ROM assessment tools, such as smartphone applications are gaining popularity in physical therapy practice settings, due to their low cost, availability, and ease and speed of use. Several studies have evaluated the reliability and validity of smart phone ROM applications.[9-13] Mitchell et al.[13] evaluated the reliability and validity of an iPhone goniometer for the assessment of active shoulder external rotation ROM and found that inter-rater reliability ranged from 0.92 to 0.94 and intra-rater reliability ranged from 0.79 to 0.81. When compared to universal goniometry, concurrent validity was 0.93 to 0.94. Johnson et al.[10] reported that a smartphone magnetometer-based goniometer has equivalent reliability compared to a UG for passive shoulder abduction ROM, however, active shoulder ROM was not reported. However, the reliability of measurements across smartphones for the same application-based tool has not been evaluated. This limitation warrants consideration because individual therapists are likely to use their own smartphone in the clinical setting to evaluate ROM, rather than a clinic-provided tool. Additionally, the absence of guiding mechanisms in identifying bony landmarks during measurement may increase the potential for measurement error.

In contrast to smartphone application-based goniometers and the UG, the laser-guided digital goniometer utilizes lasers that intersect with anatomical landmarks, distal and proximal to the joint being measured. This feature reduces the need for the visual estimation required by smart phone applications and the relatively short arms of the UG. There is currently one device commercially available that uses lasers, as well as a magnetic system and accelerometers, to guide alignment with anatomical landmarks (HALO, model HG1, HALO Medical Devices, Australia). A single methodological study assessed reliability and validity of the HALO for active shoulder internal rotation (IR) and external rotation (ER) in 15 healthy participants (30 shoulders).[14] Intra-rater reliability was excellent ($ICC_{3,1}$ = 0.97–0.98). Concurrent validity, comparing the HALO to the inclinometer was also excellent ($ICC_{3,1}$ = 0.97–0.98). These findings support use of the HALO for measuring active shoulder IR and ER ROM. However, there is a need for further research to confirm these findings, evaluate additional movements, and assess inter-rater reliability. Additionally, assessment of the agreement between the HALO laser-guided digital goniometer and the UG is warranted.

Therefore, the purpose of this study was to investigate the intra- and inter-rater reliability and concurrent validity of a laser-guided digital goniometer (HALO) for measuring active shoulder ROM. Active shoulder flexion, abduction, IR, and ER were examined in healthy adults. The results of this study will inform future research to compare reliability and validity among smartphone application-based goniometric tools, the HALO laser guided digital goniometer, and the UG. Rigorous methodological research is needed to ensure that joint range of motion measurements obtained with these new devices are consistent and accurate, in both research and clinical settings.

METHODS

Participants: A convenience sample of healthy volunteers was recruited from faculty, staff, and students of the University of California San Francisco/San Francisco State University Graduate Program in Physical Therapy, from October 2016 through January 2017. To be included in this cross sectional methodological study, participants had to be adults between 18 and 75 years of age; able to easily move between supine and standing positions; and able to actively move at least one shoulder into 90° of glenohumeral abduction. Exclusion criteria were self-report of previous significant shoulder injury; previous shoulder surgery; current bilateral shoulder pain; current neck or upper back pain; or referred pain into the upper extremity (i.e. cervical radiculopathy). Approval was received from the University of California, San Francisco Institutional Review Board prior to participant recruitment. All participants gave written informed consent. Participants completed a demographic questionnaire including information on age, income, ethnicity, activity status, occupation, health, and participant-reported height and weight.

Devices: Shoulder active range of motion (AROM) was assessed with the universal goniometer (UG) and the laser guided digital goniometer. *UG:* The universal mechanical goniometer (Baseline® Plastic Goniometer - HiRes™ 360 Degree Head - 12 inch arms) is a high-resolution plastic goniometer that permits observation of the axis of motion and ROM of the joint being measured. *Laser-guided Digital Goniometer:* The laser-guided digital goniometer (Halo, Halo Medical Devices, Subiaco, Western Australia) is a hand-held, pocket-sized (88mm x 88mm x 17mm), digital goniometer using low-level Class 1 laser technology to measure joint angles.

Assessors: Two third-year Physical Therapy doctoral students served as the assessors and another served as the recorder. The assessors received specific training in the use of the HALO device and the UG to measure shoulder AROM. Four third year doctoral physical therapy students independently reviewed the HALO instruction manual, online videos provided by the manufacturer's website, and current literature to develop study procedures. Training was provided by two full time faculty members with 15 and 30 years of clinical experience and who teach clinical examination skills (including goniometry) to physical therapy doctoral students.The student researchers and faculty members practiced the technique in group sessions for shoulder range of motion in the development of procedures through multiple sessions from April-June 2016, with instruction and training provided by the faculty members.

Assessors were blinded to the results of laser-guided digital goniometer for both the repeated tests (reliability) and the concurrent tests (validity). To prevent measurement bias, an index card was placed on the face of the HALO digital goniometer after the device was zeroed, and the measurement scribed by the study recorder. Excellent reliability of the standard goniometer has been established in previous studies,[5,7] and evaluation of reliability, of the UG, while reported, was not the goal of this study. Therefore, the assessors were not blinded to the repeated measurements obtained with the UG.

Procedures: Step-by-step procedures for the range of motion assessment are outlined in Appendix 1. To reduce the risk of a mobilization effect from repeated shoulder movements, the first assessor personally demonstrated the desired movement (beginning with shoulder flexion), and then the participant performed a single return demonstration for that movement as a warm-up. The warm-up motion served two purposes: first, as a teaching tool for the participant to practice the ROM movement demonstrated by the assessor; and second, as an initial stretch through that ROM to minimize an increase in range obtained by repeated motions. After the warm-up, the participant performed the desired movement and maintained the end position for assessment by both assessors. Each device was used twice, once by each assessor. The HALO was used first, followed by the UG. Assessor order was randomly assigned. A third research assistant recorded all the measurements.

The assessors then instructed the participant to return to the starting position and the procedure was repeated for each of the remaining AROM shoulder motions: abduction, IR, and ER. The four active shoulder ROM movements were assessed with the participant in supine following the procedures outlined by

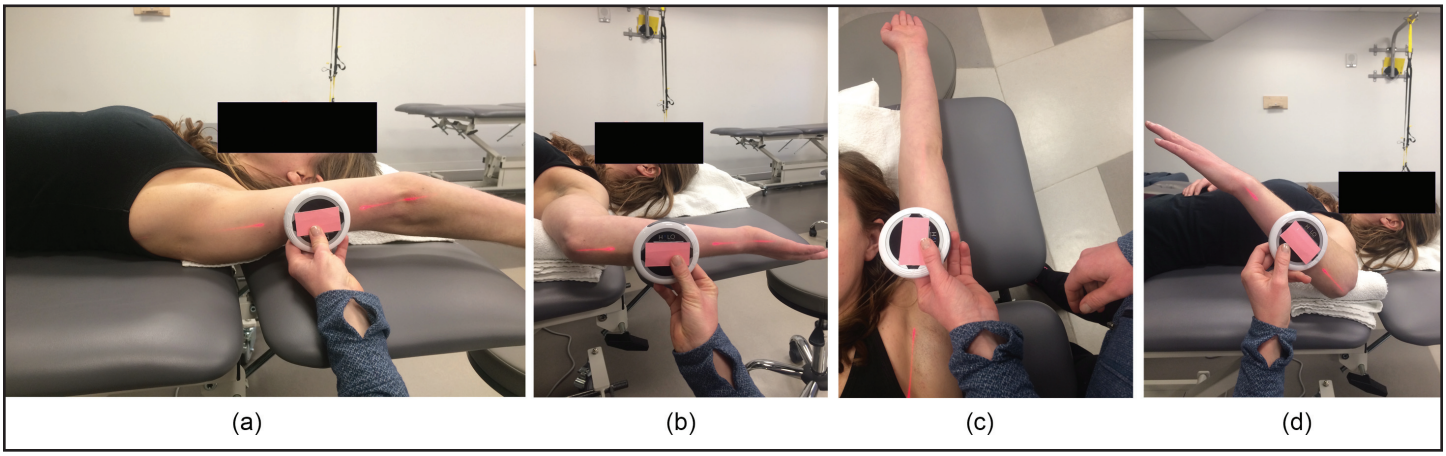

Figure 1. *Positions for measurement of active shoulder range of motion. (a) flexion; (b) abduction; (c) external rotation; (d) internal rotation. The Halo device is pictured. Note the alignment of the lasers and the blinding of the digital display..*

Norkin and White,[1] specifying anatomic landmarks and accounting for thoracic extension during shoulder flexion in supine (Figures 1a-d). When eligible for bilateral assessment (i.e. no shoulder pathology), this procedure was repeated for the contralateral shoulder as well. All measurements were repeated for each shoulder, with verbal instruction and demonstration without the warm-up step, for a second trial. The warm-up step was not repeated between trial 1 and 2 as this would further increase the number of repeated motions, potentially increasing the change in ROM between trials. Additionally, the participants were already familiarized with the desired active motions by practice through the initial warm up and first trial.

Statistical Analysis

A sample size of 42 was estimated using the method described by Walter et al.[15] Statistical analyses were performed using IBM SPSS Version 23 (Armonk, NY: IBM Corp.) Means and standard deviations for continuous data as well as frequencies and percents for categorical variables were calculated for baseline demographic characteristics. Intraclass correlation coefficient and 95% confidence intervals were calculated for inter- and intra-rater reliability and agreement, using a two-way mixed model, with fixed raters, and evaluated absolute agreement. $ICC_{3,1}$ was used to calculate intra-rater reliability between measure one and measure two for each rater. Inter-rater reliability was calculated using the average of the two measures from Rater A and the average of the two measures from Rater B ($ICC_{3,2}$). In order to quantify variability and measurement error, standard error of measurement (SEM) and smallest real difference (SRD) were calculated. SEM was calculated using the item variance from the ICC analysis of variance output. The square root of the item variance is the SD, and was then used in the formula for calculating the SEM: $SEM = SD * \sqrt{(1\text{-}ICC)}$.[16] The SRD was calculated from the SEM: $1.96 (SEM * \sqrt{2})$.[17] The SRD is also known as the minimally detectable change (MDC).

RESULTS

Data were analyzed for 75 shoulders (39 right, 36 left) from 41 participants. Seven participants had only one shoulder evaluated due to past or current shoulder dysfunction or pain. Participants included 30 females and 11 males with an age range of 18 to 70. All but one of the participants were right-handed (Table 1).

Intra-rater reliability ICC, SEM, and SRD values are presented in Table 2. Intra-rater reliability ICCs for the HALO ranged from 0.82 to 0.91, and for the UG 0.83 to 0.95. All ICC values were within the good (>0.75) to excellent (>0.90) reliability ranges for both devices.[18] SEM and SRD values were similar between devices and raters for flexion ROM, as was the case for internal and external rotation. However, the SEM and SRD values for the HALO were higher compared to the UG in all positions, with the exception of flexion for Rater B, which revealed

Table 1. *Demographics (n = 41 participants*).*

Characteristic	Mean (SD)
Age (years)	32.30 (2.12)
BMI (kg/m^2)	22.63 (2.29)
	Frequency (%)
Dominant upper limb Right Left	 40 (97.6%) 1 (2.4%)
Sex Males Females	 11 (26.8%) 30 (73.2%)
Sides evaluated (n=75 shoulders) Right Left	 39 (52%) 36 (48%)

BMI: Body mass index (kilograms per meter squared), SD: Standard Deviation
*of 41 participants 34 had bilateral shoulder assessments

a higher value for the UG compared to the HALO device. SEM and SRD values were highest for abduction ROM measured with the HALO, particularly for Rater A. The intrarater SRD for the HALO was 6.9 to 21.1 degrees, and 6.8 to 15.1 degrees for the UG, depending on the motion.

Inter-rater reliability ICC, SEM and SRD values calculated are presented in Table 3. Inter-rater reliability ICCs for the HALO ranged 0.89 to 0.98, which is considered good to excellent. For the UG inter-rater reliability for ICCs ranged from 0.90 to 0.98, all of which are considered excellent. The SEM and SRD values for the HALO revealed higher numbers compared to the UG for flexion and abduction but were essentially the same for IR and ER. The inter-rater SRD for the HALO was 4.9 to 13 degrees, and 4.6 to 7.4 degrees for the UG, depending on the motion.

To determine the accuracy of the digital goniometer, the ICCs for agreement, comparing the HALO digital goniometer to the UG, are presented in Table 4. ICCs ranged from 0.79 to 0.99. The highest ICC values were calculated for IR and ER, followed by abduction, then the lowest values for flexion. However, all ICC values for validity between the instruments were considered good for flexion and excellent for the other three motions.

DISCUSSION

This is the first study to compare the HALO device to the UG for assessment of shoulder AROM. The results of this study provide clinically relevant information regarding the use of the HALO digital goniometer by physical therapists to measure complex shoulder AROM. The initial aim was to determine reliability of the HALO and validity of the HALO compared to the UG. An ICC for reliability of >0.75 is considered good and >0.90 is considered excellent.[15] All intra-rater reliability ICCs are between 0.82 and 0.91 for the HALO, and 0.83 to 0.95 for the

Table 2. *Intra-rater reliability for shoulder range of motion.*

Movement (Rater)	Halo $ICC_{3,1}$ (95% CI)	Halo SEM	Halo SRD	Goniometer $ICC_{3,1}$ (95% CI)	Goniometer SEM	Goniometer SRD
Flexion (Rater A)	.86 (.77-.91)	2.7	7.5	.83 (.71-.90)	2.5	6.8
Flexion (Rater B)	.88 (.79-.92)	2.5	6.9	.84 (.75-.90)	2.8	7.7
Abduction (Rater A)	.86 (.77-.91)	7.6	21.1	.94 (.90-.96)	3.9	10.8
Abduction (Rater B)	.91 (.85-.94)	5.1	14.1	.95 (.92-.97)	3.5	9.8
IR (Rater A)	.82 (.71-.89)	5.7	15.9	.83 (.73-.89)	5.5	15.1
IR (Rater B)	.85 (.75-.90)	5.7	15.9	.87 (.78-.92)	5.2	14.3
ER (Rater A)	.90 (.84-.94)	4.2	11.7	.90 (.85-.94)	4.0	11.1
ER (Rater B)	.89 (.82-.93)	4.3	11.9	.88 (.81-.92)	4.2	11.7

CI: Confidence interval; ER: External Rotation; ICC: Intraclass correlation coefficient; IR: Internal Rotation; SEM: Standard Error of the Measurement; SRD: Smallest Real Difference

Table 3. *Inter-rater reliability for shoulder range of motion: comparing Rater A to Rater B.*

Movement	Halo $ICC_{3,2}$ (95% CI)	Halo SEM	Halo SRD	Goniometer $ICC_{3,2}$ (95% CI)	Goniometer SEM	Goniometer SRD
Flexion	.89 (.82-.93)	2.3	6.4	.90 (.80-.94)	1.9	5.3
Abduction	.93 (.88-.95)	4.7	13.0	.97 (.91-.99)	2.7	7.4
IR	.96 (.90-.98)	2.5	6.9	.96 (.92-.98)	2.6	7.1
ER	.98 (.96-.99)	1.8	4.9	.98 (.96-.99)	1.7	4.6

CI: Confidence interval; ER: External Rotation; ICC: Intraclass correlation coefficient; IR: Internal Rotation; SEM: Standard Error of the Measurement; SRD: Smallest Real Difference

Table 4. *Accuracy (Validity): Comparison of HALO to Universal Goniometer (n = 75 shoulders).*

Movement	Rater A $ICC_{3,2}$ (95% CI)	Rater B $ICC_{3,2}$ (95% CI)
Flexion	.82 (.07-.94)	.79 (.01-.92)
Abduction	.91 (.47-.97)	.96 (.86-.98)
IR	.98 (.92-.99)	.98 (.95-.99)
ER	.94 (.96-.99)	.99 (.98-.99)

CI: Confidence interval; ER: External Rotation; ICC: Intraclass correlation coefficient; IR: Internal Rotation

UG. Thus, both are considered good to excellent for all AROM measurements performed in this study, providing evidence for the use of either the HALO device or the UG for measurement of shoulder AROM. These findings are consistent with previous studies that evaluated standard goniometry[5,7,8] and the HALO.[14] Similarly, the inter-rater reliability for the HALO was considered good to excellent (0.89 to 0.98) and for the UG considered excellent (0.90 to 0.98). The two raters in this study demonstrated consistent, reproducible measurements between their individual measurements, and between one another for both the HALO and for the UG for all shoulder motions.

Overall, the ICCs for intra-rater reliability for both the HALO and the UG tended to be slightly lower than those for inter-rater reliability. This finding may be due to the fact that subjects went through the motion a second time for the second measurement, and it is possible that the subjects gained motion with the third movement despite performing an initial, pre-measurement, warm-up motion. Additionally, subjects held the motion at end range for a period of time for two raters to measure with each instrument, which may have resulted in a true change in ROM.

The ICCs for accuracy, comparing the HALO digital goniometer to the UG, all fell in the good to excellent range (0.79 to 0.99). The lowest ICC was found for flexion (0.82 and 0.79 for Rater A and Rater B, respectively), which may be due to difficulty visualizing the mid-axillary line and the joint axis during movement. Because ICCs are considered excellent for abduction, internal rotation, and external rotation, the HALO digital goniometer appears to be a valid tool for measuring these shoulder motions, compared to the reference standard of the UG; however, because agreement was lower in flexion,

additional evaluation of its accuracy, with emphasis on using standardized protocols and device placement, is warranted, particularly for this movement. Also, the two devices should not be used interchangeably to evaluate a single individual's change over time for any motion.

The SRD, the smallest real difference, also known as the minimal detectable change, represents the amount of change in a patient's ROM beyond measurement error. The intrarater SRD for the HALO was 6.9 to 21.1 degrees, and 6.8 to 15.1 degrees for the UG, depending on the motion. SRD was highest for abduction measured with the HALO (14.1 degrees for Rater B and 21.1 degrees for Rater A). Higher intra-rater SRD values were seen for Rater A for flexion and abduction compared to Rater B, and for both raters SRDs were greatest for abduction, followed by IR. The variability associated with these measurements could be explained by difficulty in consistently identifying bony landmarks for reference or variability in maintaining the plane of motion. That the SRD is greatest for the HALO when measuring abduction suggests that more training may be required to reduce variability and error when using this device.

Despite the strengths of this study, there are limitations that warrant consideration. A particular challenge during this study was the need to repeat abduction measurements due to device "error", as the display would produce error whenever the user tilted the device out of the horizontal plane. After consulting with the manufacturer to review technique and to identify the issue, it was determined that when the device is moved out of the horizontal plane, the altered position of the accelerometer intermittently created marked measurement errors, necessitating repeated measurement. These obvious instrument errors were well over 90 degrees and obviously not related to rater measurement error. Thus, these measurements were repeated and the erroneous data were excluded from data analyses. The HALO device is sensitive to changes out of the plane of movement and greater skill and more practice may be needed for greatest accuracy, relative to the UG. Additionally, participant safety should be carefully considered during shoulder abduction measurements due to the direction of the laser pointing toward the participant's eyes. This risk was minimized by instructing the participant to close their eyes during measurement. Fortunately, the type of laser used in the HALO device is low level and does not cause harm with limited exposure (per manufacturer report).

Third year physical therapy students measured AROM on a convenience sample of participants with healthy shoulders only, therefore, study findings cannot be generalized to the clinical setting of therapists with significantly more years of experience, nor to patients with shoulder impairment, nor to other joints. Additionally, while the results of this study provide support for the reliability and validity of this tool, the time required (as a proxy for efficiency) for ROM measurement was not tracked in this study. It was decided to not to evaluate time required in the context of this study due to the need for blinding and repeated measurement. The time necessary to train therapists how to properly use the HALO may be a significant consideration. Finally, the experience of the investigators in this study suggests that this device is challenging to use for assessment of horizontal motions (i.e. for assessment of abduction in the anatomic coronal plane, but measured in supine). This issue is not an issue for the UG because it is not sensitive to tilt out of any cardinal plane. The manufacturer provides alternative methods for measurement of joint angles that may improve ease of use but these must also be assessed for reliability and accuracy. Additional diagnostic studies are needed to determine the most reliable and accurate landmarks and procedures for use of the HALO, so that standardized protocols can be developed for research and for clinical practice.

CONCLUSIONS

The results of this study suggest that the HALO laser guided digital goniometer may be a viable alternative goniometric device for healthcare practitioners to measure active shoulder range of motion. The UG demonstrated lower SRDs for all measurements except for shoulder flexion intra-rater reliability, which suggests that the use of the less expensive UG may provide less measurement error than the HALO device for measurement of AROM of the shoulder. However, the HALO may provide advantages over

the UG for some clinicians: 1) the ability to use only one hand during measurements, which could be helpful for clinicians with disabilities of the upper extremity, and 2) an easy-to-read digital display with memory features, which may be of benefit for therapists with visual impairments. Further research must be done to investigate the reliability and validity of this device in patients with shoulder impairments, as well as its accuracy in measuring ROM of other joints.

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