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Reliability and Validity of a Clinical Assessment Tool for Measuring Scapular Motion in All 3 Anatomical Planes

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Context: A single clinical assessment device that can be used to objectively measure scapular motion in each anatomical plane is not currently available. The development of a novel electric goniometer would allow scapular motion in all 3 anatomical planes to be quantified.

Objective: To investigate the reliability and validity of an electric goniometer for measuring scapular motion in each anatomical plane during upper extremity elevation.

Design: Cross-sectional study.

Setting: Laboratory.

Patients or Other Participants: Sixty participants (29 women, 31 men; age = 30 ± 14 years, height = 1.73 ± 0.10 m, mass = 75.32 ± 16.90 kg) recruited from the general population.

Intervention(s): An electric goniometer was used to record clinical measurements of scapular position at rest and total arc of motion (excursion) during active upper extremity elevation in 2 testing sessions separated by several days. Measurements were recorded independently by 2 examiners. In 1 session, scapular motion was recorded simultaneously using a 14-camera, 3-dimensional optical motion-capture system.

Main Outcome Measure(s): Reliability analysis included examination of clinical measurements for scapular position at rest and excursion during each condition. Both the intrarater reliability between testing sessions and the interrater reliability recorded in the same session were assessed using intraclass correlation coefficients (ICCs [2,3]). The criterion validity was examined by comparing the mean excursion values of each condition recorded using the electric goniometer and the 3-dimensional optical motion-capture system. Validity was assessed by evaluating the average difference and root mean square error.

Results: The between-sessions intrarater reliability was moderate to good (ICC [2,3] range = 0.628–0.874). The within-session interrater reliability was moderate to excellent (ICC [2,3] range = 0.545–0.912). The average difference between total excursion values recorded using the electric goniometer and the 3-dimensional optical motion-capture system ranged from −7° to 4°, and the root mean square error ranged from 7° to 10°.

Conclusions: The reliability of scapular measurements was best when a standard operating procedure was used. The electric goniometer provided an accurate measurement of scapular excursions in all 3 anatomical planes during upper extremity elevation.

Key Words: psychometric values, upper extremity, shoulder

Key Points

- The electric goniometer provided clinicians and researchers with a simple tool for objectively measuring scapular position and motion in all 3 anatomical planes.
- The electric goniometer demonstrated moderate to excellent intrarater and interrater reliability for measuring scapular position at rest and total excursion within and between testing sessions.
- The device was valid for measuring scapular motion in the transverse plane.

Motion of the shoulder complex consists of a combination of movements from the glenohumeral, acromioclavicular, and sternoclavicular joints, as well as the scapulothoracic articulation.[1,2] The scapula moves in multiple anatomical planes during humeral motion and is integral to optimal function of the upper extremity.[1–3] Alterations in scapular motion have been attributed to pathologic conditions, such as multidirectional instability, impingement, nerve palsies, rotator cuff tears, and biceps tendinopathy.[4–6]

To understand how scapular motion contributes to upper extremity function, clinicians must be able to accurately quantify scapular motion. Currently, the criterion standard for evaluating multiplanar scapular motion includes the use of bone pins, radiography, and magnetic resonance imaging.[2,7–9] Noninvasive reference standards for tracking scapular kinematics, such as video-based 3-dimensional (3D) motion analysis and 3D electromagnetic tracking, have been validated using the criterion standard methods.[8,10] Although they accurately measure scapular motion, these techniques have their drawbacks, such as their lack of availability to clinicians, invasive nature, complex computations required, expense, and restriction to a laboratory setting.

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To overcome these limitations of laboratory-based methods, assessment techniques are needed to measure scapular motion in the clinical setting. Furthermore, reliable and precise objective scapular measurement can guide treatment plans and rehabilitation efforts for upper extremity pathologic conditions. The objective assessment of scapular motion has been examined in previous literature.[11–13] Both observational and palpation-based techniques have been evaluated; however, the observational approach lacks objective measurement values, rendering the method a subjective screening tool.[11] The gravity-referenced digital inclinometer, first investigated by Johnson et al,[12] has demonstrated good to excellent intrarater reliability (intraclass correlation coefficient [ICC] [3,1] range = 0.89–0.96) and moderate to good validity (r range = 0.59–0.73) for measuring the scapular motions of upward and downward rotation in the frontal plane during upper extremity elevation. Subsequently, Scibek and Carcia[13] further investigated the gravity-referenced digital inclinometer for measuring the scapular motions of anterior and posterior tilt in the sagittal plane during upper extremity elevation and reported excellent intrarater reliability (ICC [3,1] range = 0.97–0.99) and moderate to good validity (r range = 0.63–0.86). These findings, supported by subsequent studies,[12–17] demonstrated that gravity-referenced digital inclinometers were reliable and valid for measuring scapular motion in the frontal and sagittal planes.

Whereas a digital inclinometer is a noninvasive, portable clinical assessment tool for objectively measuring scapular motion in the frontal and sagittal planes, it is not capable of measuring the scapular motions of internal and external rotation in the transverse plane because of its reliance on gravity-referenced sensors. However, new advances in the development of a novel electric goniometer, equipped with an inertial measurement unit (IMU), allow clinical measurements of scapular motion in the transverse plane. Like the angular rotation recorded by the accelerometer in the gravity-referenced inclinometer, the IMU captures angular rotations relative to a reference position created and stored using a triaxial gyroscope and magnetometer. The 2 additional sensors enable the system to calculate angular rotations relative to any defined calibration position, which does not have to be in the line of gravity, thereby overcoming the limitations of gravity-referenced inclinometers.

Currently, easily and accurately quantifying scapular motion in all 3 anatomical planes using a single clinical device is not possible. Although a new electric goniometer equipped with an IMU can overcome this limitation, we do not know if this novel device is reliable or valid for measuring scapular motion in each anatomical plane. Therefore, the purpose of our study was to investigate the reliability and validity of an IMU-based electric goniometer for measuring scapular motion during upper extremity elevation. To determine the intrarater and interrater reliability, we examined the reliability characteristics of measurements across days and between examiners. We also sought to establish criterion validity by comparing the measurements recorded using the electric goniometer and a validated reference standard of 3D optical motion capture. We hypothesized that the measurements recorded using the electric goniometer would not exceed 10° of error compared with those recorded using the 3D optical motion-capture system, and we proposed that the intrarater reliability of each examiner between the 2 test days would exceed an ICC value of 0.80, whereas the interrater reliability between the examiners on a single day of testing would exceed an ICC value of 0.70. Establishing the reliability and validity characteristics of the electric goniometer will provide critical evidence regarding the utility of these IMU-based devices for measuring scapular motion. If reliable and valid, these types of devices will enable clinicians to objectively measure scapular motion in the clinical setting.

METHODS

Participants

A convenience sample generated a total of 67 inquiries from the general population in Lexington, Kentucky. All volunteers were screened for eligibility based on the following inclusion criteria: age between 18 and 99 years, willingness to attend 2 testing sessions separated by at least 24 hours, the ability to lift the right upper extremity to at least 120° in the scapular plane, and no self-reported medical restrictions relating to the upper extremity or spine at the time of the study. An a priori power analysis conducted using nQuery software (version 8.1; Statistical Solutions Ltd) indicated a sample size of 60 participants would have 90% power to detect a difference in means of 3° in scapular motion and minimize the chance of type II error.

We identified and enrolled 60 participants (29 women, 31 men; age = 30 ± 14 years, height = 1.73 ± 0.10 m, mass = 75.32 ± 16.90 kg) who met the inclusion criteria. All participants completed 2 testing sessions, with an average time between sessions of 9 days. All participants provided written informed consent, and the study protocol was approved by the University of Kentucky Institutional Review Board (No. 43537).

Instrumentation

The EasyAngle electric goniometer (Meloq AB) was used to perform clinical measurements of scapular motion (Figure 1). Before data collection, an upright polyvinyl chloride (PVC) pole was placed at 30° anterior to the frontal plane relative to the participant's sitting location, marking the scapular plane. Participants were instructed to actively raise the upper extremity with the wrist touching the PVC pole until they reached 120°, as confirmed using a standard goniometer. When the individual reached 120° of upper extremity elevation, a quick-grip mini bar clamp (Irwin Tools) was used to mark and physically limit 120° of upper extremity elevation on the PVC pole (Figure 2). An I-beam square bubble level (model 7724; Johnson Level & Tool Manufacturing Co, Inc) was used to calibrate the electric goniometer for measurements taken in the sagittal plane as described.

Three-dimensional motion capture was recorded using a Nexus (Vicon Motion Systems Ltd) 14-camera, high-speed, infrared, video-based, optical, motion-capture system. Raw marker trajectory data were stored and reconstructed using Nexus software (version 2.9; Vicon Motion Systems Ltd). Reconstructed kinematic data were exported and analyzed using Visual3D (version 9 Professional; C-Motion, Inc).

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Figure 1. A, Identification of one-third of the distance between the root of the scapular spine and the posterior acromial angle. Orientation of the electric goniometer (EasyAngle; Meloq AB) for measuring scapular motion in the B, frontal plane; C, transverse plane; and D, sagittal plane, with inset illustrating calibration in the sagittal plane.

Procedures

The clinical measurements using the electric goniometer were recorded independently by each examiner during upper extremity elevation in the frontal, transverse, and sagittal planes. To facilitate consistency of the clinical measurements between examiners and to accommodate the placement of the retroreflective markers used for 3D optical motion capture, a standard operating procedure was implemented. For each anatomical plane, the calibration

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Figure 2. Measurement of scapular motion in the frontal plane during upper extremity elevation to 120° in the scapular plane.



Figure 3. Standardized marker setup for 3-dimensional optical motion capture. The scapular and thorax joint coordinate system is shown with positive motion in the direction of the arrows.

technique and specific location for the electric goniometer based on several scapular landmarks followed a standard procedure. To measure scapular motion in the frontal plane, we calibrated the electric goniometer to the floor directly beneath participants to represent 0°. The electric goniometer was placed on the scapular spine at one-third of the distance between the root of the scapular spine and the posterior acromial angle, as measured and marked using a cloth tape measure (Figure 1A), and oriented posteriorly (Figure 1B). To measure scapular motion in the transverse plane, the electric goniometer was calibrated using a perpendicular edge of a floor tile beneath participants to represent 0°. The electric goniometer was placed at the same location on the scapular spine as described for frontal-plane motion but oriented superiorly (Figure 1C). To record scapular motion in the sagittal plane, we calibrated the electric goniometer to the vertical I-beam square level to represent 0°, placed on the most prominent portion of the medial scapular border and oriented laterally (Figure 1D).

All participants began each trial seated in an upright position on a 35-cm-tall stool with their feet flat on the floor. The motion of upper extremity elevation was explained and demonstrated. They were able to practice the motion several times and ask questions before data collection. To begin each trial, the examiner applied the electric goniometer to the specified scapular landmark and instructed the participant to assume an upright and relaxed sitting posture. The scapular rest position was recorded, and then the participant was prompted to perform the desired condition. After completing active movement, the individual held the final position for several seconds while the examiner measured the end scapular position. Total excursion values were calculated by subtracting the initial scapular position (rest) from the final scapular position (end) after motion was completed. Three trials of active upper extremity elevation were recorded for each scapular condition, totaling 9 trials for data collection. Constant pressure and contact were maintained with the scapular landmark during each movement. The order of anatomical planes was randomized before testing, and the same order was used on both test days. Clinical measurements of scapular motion were interpreted following the guidelines of the International Society of Biomechanics[18]: positive scapular motion in the frontal, transverse, and sagittal planes is identified as downward rotation, internal rotation, and posterior tilt, respectively.

On 1 day of testing, 3D optical motion capture was recorded simultaneously with the clinical measurements. Surface reflective markers were attached to the participant using 2-sided tape following the procedures outlined by Chu et al[8] in a validation study of the marker-based motion-capture model of scapular motion (Figure 3). A scapular acromial marker cluster (AMC) was created using a rigid triangular body and was applied to the posterior acromial process and medial to the posterior acromial calibration marker (Figure 1B). Recording of scapular motion using an AMC has shown excellent within-session reliability (ICC range = 0.90–0.98) and a standard error of measurement (SEM) of 2.25° for active upper extremity elevation, protraction, and retraction and has been validated against criterion standard techniques, such as dynamic radiography.[8,19] The raw kinematic camera data were collected at 200 Hz and smoothed using a low-pass Butterworth filter with a cutoff frequency of 6 Hz. Joint coordinate systems and segment parameters for the trunk, pelvis, and scapula were oriented with the x axis pointed anteriorly, the y axis

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Table 1. Intrarater Reliability Results of a Single Rater Between 2 Testing Sessions

Scapular Measure	Anatomical Plane	Day, ° (Mean ± SD)		Intraclass Correlation Coefficient (2,3)	Standard Error of Measure, °	Minimal Detectable Change at 90% CI, °
		1	2			
Rest position	Frontal[a]	−3 ± 6	−2 ± 5	0.692	3	7
	Transverse[b]	30 ± 7	30 ± 7	0.805	3	7
	Sagittal[c]	−26 ± 7	−28 ± 7	0.874	3	6
Total excursion	Frontal[a]	−19 ± 7	−19 ± 6	0.701	4	9
	Transverse[b]	−5 ± 4	−5 ± 3	0.628	2	5
	Sagittal[c]	18 ± 6	20 ± 6	0.790	3	7

[a] Positive values indicated downward rotation.
[b] Positive values indicated internal rotation.
[c] Positive values indicated posterior tilt.

oriented superiorly, and the z axis oriented laterally (Figure 3).[18] A Euler rotation sequence for scapular motion in the frontal and transverse planes was resolved as Y, X, Z and calculated relative to the thorax per the guidelines of the International Society of Biomechanics.[18]

Statistical Analysis

We applied a test-retest design to examine the intrarater reliability of each examiner between testing sessions and the interrater reliability of both examiners in the same testing session for clinical measurements recorded using the electric goniometer. Both the intrarater and interrater reliability of scapular measurements recorded during rest and excursion for each anatomical plane were assessed via ICC (2,3) using the average of 3 trials of motion. We interpreted the ICCs as *poor* (<0.5), *moderate* (0.5–0.75), *good* (0.76–0.90), or *excellent* (>0.90) reliability.[20] Measurement precision was determined by calculating the SEM and the minimal detectable change score at the 90% CI.[21]

The criterion validity of the electric goniometer versus the reference standard of the 3D optical motion-capture system for measuring total scapular excursion in each anatomical plane was determined using several approaches. First, a paired *t* test was used to compare the average excursion of 3 trials of motion between the electric goniometer and the 3D optical motion-capture system. We set the α level a priori at $\leq$.05, although a Bonferroni correction was applied to account for the 3 comparisons of each condition in each plane. This correction reduced the α level to $\leq$.017. Second, the root mean square error (RMSE) was calculated to determine the error associated with the electric goniometer versus the 3D optical motion-capture system for each condition. Third, we created Bland-Altman plots to examine the average difference and limits of agreement (LOAs) between the electric goniometer and 3D optical motion-capture system. The LOAs were calculated by multiplying the SD of the average difference by 1.96 to observe the 95% CIs.[22] Validity was determined by observing the RMSE values: <5° indicated *strong*, 5° to 10° indicated *moderate*, and >10° indicated *poor* validity.[8,23] Analysis of the Bland-Altman plots revealed a systematic average difference of −7° between scapular excursions recorded using the electric goniometer and the 3D optical motion-capture system for scapular motion measured in the frontal plane. Therefore, a correction factor of +7° was applied to the clinical data for mean scapular excursion in the frontal plane.

RESULTS

Reliability

We observed moderate to good intrarater reliability for determining the scapular rest position and scapular excursion between testing sessions (Table 1). Interrater reliability was good to excellent for measuring the scapular rest position and moderate for measuring the scapular excursion during a testing session (Table 2).

Validity

The validity results are presented in Table 3. Bland-Altman plots are provided in Supplemental Figures 1 through 3. We found differences between the mean scapular excursions recorded using the electric goniometer and 3D optical motion-capture system for the frontal ($P <$ .001), transverse ($P = .015$), and sagittal ($P <$ .001) planes. The RMSE ranged from 7° to 10°, and the average difference ranged from −7° to 4°.

DISCUSSION

We investigated the reliability and validity of a novel electric goniometer for measuring scapular motion in each anatomical plane during upper extremity elevation. The intrarater and interrater reliability of the clinical scapular measurements was investigated across days and between examiners and addressed the criterion validity of measurements recorded using the clinical assessment device compared with the reference standard of 3D optical motion capture. Our results indicated that the electric goniometer was a reliable device for measuring the scapular rest position and total excursion in each anatomical plane when a standard operating procedure was used. Furthermore, the electric goniometer had moderate validity for measuring scapular excursions in all 3 anatomical planes in a clinical setting.

Before data collection, we hypothesized that the measurements recorded using the electric goniometer would not exceed 10° of error compared with those recorded using the 3D optical motion-capture system. Although the resultant *P* values demonstrated differences among mean values for scapular excursion in each anatomical plane, the comparison of means alone was not sufficient for a complete validity analysis.[24] Therefore, we used a multistep approach to assess validity using statistics, such as RMSE, average difference, and LOA.[22] The threshold of RMSE was rooted in the notion that 10° of

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Table 2. Interrater Reliability Between 2 Raters in a Single Testing Session

Scapular Measure	Anatomical Plane	Rater, ° (Mean ± SD)		Intraclass Correlation Coefficient (2,3)	Standard Error of Measure, °	Minimal Detectable Change at 90% CI, °
		1	2			
Rest position	Frontal[a]	−1 ± 5	−2 ± 5	0.833	3	8
	Transverse[b]	30 ± 7	30 ± 7	0.912	4	9
	Sagittal[c]	−24 ± 6	−28 ± 7	0.841	3	7
Total excursion	Frontal[a]	−22 ± 7	−19 ± 6	0.724	4	9
	Transverse[b]	−6 ± 4	−5 ± 3	0.545	4	8
	Sagittal[c]	19 ± 6	20 ± 6	0.703	5	11

[a] Positive values indicated downward rotation.
[b] Positive values indicated internal rotation.
[c] Positive values indicated posterior tilt.

error would exceed both the SEM and minimal detectable change score at 90% CI, such that error >10° would indicate an invalid measurement of scapular motion. Additionally, previous researchers[8,25,26] found that RMSE values >10° indicated inaccurate measures of true scapular motion. In our study, the RMSE values were ≤10° for all planes of motion. Furthermore, the average difference between the electric goniometer and the 3D motion-capture system ranged from −7° to 4° across the 3 anatomical planes. Taken together, these results suggest that the electric goniometer was capable of measuring scapular motion in each anatomical plane during upper extremity elevation with a moderate degree of accuracy.

The RMSE associated with upper extremity elevation in the frontal plane highlights a limitation of using a 3D optical motion-capture system with an AMC to capture scapular motion. The AMC represents the scapula, and its motion was recorded using the 14-camera 3D optical motion-capture system to represent scapular movement. Placement of the AMC on the posterior acromion was difficult and restricted access to the scapular spine. As shown in Figures 1B and 1C, placement of the electric goniometer was limited to the medial aspect of the scapular spine due to the AMC's position on the acromion. Therefore, the correction factor was applied to frontal-plane data, the plane of motion most affected by the AMC. The correction reduced the RMSE value from 10° to 7° and increased the associated *P* value to .96, illustrating no difference between the electric goniometer and the 3D optical motion-capture system when measuring scapular motion in the frontal plane during upper extremity elevation.

We observed a similar error between the measurement methods during motion in the sagittal plane. Given the difference between methods despite an RMSE of 9° and an average difference of 4°, we suspect that accessory motion from spinal flexion and extension contributed to the overall differences in scapular measurement. Although participants were orally instructed to not move their spines during each trial and were closely observed during testing, it was not possible to eliminate the inherent motion of the spine. This concept highlights a limitation of calibrating the electric goniometer to a standalone vertical surface (I-beam square level). To overcome this limitation in the future, we suggest calibrating the electric goniometer to the participant's spine before measuring sagittal-plane motion. This adjustment in calibration will ideally capture the inherent trunk position of the participant and account for any initial spinal offset in the sagittal plane.

Although each measurement recorded by the electric goniometer introduced a specific limitation, the comparison between mean excursion values recorded by the device and those from previous research is encouraging. Specifically, the average scapular external rotation in our study in the transverse plane (–8°) was identical to the average scapular external rotation that Chu et al[8] recorded using the AMC (–8°) and similar to the value noted by McClure et al[3] using bone pins (–6°). In addition, the average total excursion of scapular posterior tilt recorded using the electric goniometer (18°) agreed with the average excursion that Ludewig et al[2] identified using intracortical measurement techniques (18°). These comparisons with earlier findings using criterion standard measurement techniques demonstrate promising capabilities for scapular measurement in each anatomical plane during upper extremity elevation.

Table 3. Comparison Between Total Excursion Values Recorded Using the EasyAngle[a] Electric Goniometer and the 3-Dimensional Optical Motion-Capture System

Anatomical Plane	° (Mean ± SD)		Average Difference, °	Root Mean Square Error, °	*P* Value
	EasyAngle	3-Dimensional System			
Frontal[b]	−23 ± 6	−30 ± 7	−7	10	<.001[f]
Corrected frontal[b,c]	−30 ± 6	−30 ± 7	0	7	.96
Transverse[d]	−8 ± 5	−6 ± 7	2	7	.015[f]
Sagittal[e]	18 ± 7	22 ± 7	4	9	<.001[f]

[a] Meloq AB.
[b] Positive values indicated downward rotation.
[c] Corrected frontal indicates a correction of −7° added to the mean scapular excursion recorded by the EasyAngle in the frontal plane.
[d] Positive values indicated internal rotation.
[e] Positive values indicated posterior tilt.
[f] Indicates difference, accounting for Bonferroni correction ($\alpha \leq .017$).

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A strength of our study was the examination of both the intrarater and interrater reliability. Previous investigations of the reliability of clinical measurement of scapular motion are limited. Reliability values have been described[23,27] for measurements recorded by a single examiner between 2 testing sessions on the same day, whereas in other works,[12,28] the authors did not provide the time between testing sessions. We examined both the intrarater reliability of the electric goniometer across 2 testing sessions and the interrater reliability within a single testing session. The average rest position and average excursion values from the 3 trials of motion were analyzed for reliability. To minimize the risk of error between measurement techniques, we used standardized placement procedures. Our results are consistent with those of previous research[29] on digital goniometer measurement in finding a higher intrarater than interrater reliability, even when a standard procedure was used.

The electric goniometer was reliable for determining both scapular rest position (ICC [2,3] range = 0.692–0.874) and total excursion (ICC [2,3] range = 0.628–0.790) across an average of 9 days. The associated error was less when we measured rest position (SEM = 3°) than scapular excursions (SEM range = 2°–4°). The decrease in ICC values and increase in SEM between the rest and excursion measurements could be linked to variations in individuals' movement patterns across days. Furthermore, our same-day interrater reliability of scapular rest position (ICC [2,3] range = 0.833–0.912) across all 3 anatomical planes was higher than that reported by Watson et al[27] (ICC range = 0.21–0.52). Reliability for total scapular excursion was also higher in our study (ICC [2,3] range = 0.545–0.724) than in the study of Watson et al[27] (ICC = 0.23) during upper extremity elevation. These results demonstrating increased interrater reliability support the concept that the electric goniometer is reliable when used by multiple raters in a single testing session.

This study had limitations. The electric goniometer offers a surface-based assessment, which is affected by soft tissue obstruction and movement. As reported in the literature,[17,19,30] scapular clinical assessment is limited by the presence of soft tissue and skin movement artifact. This limitation was apparent during the measurement of frontal-plane scapular motion during upper extremity elevation; a correction factor was necessary to account for an average difference of −7°. In addition, measurement of the scapula during sagittal-plane motion may be inhibited by the posterior bunching of soft tissues during active movement. Conversely, measuring scapular motion in the sagittal plane is challenging because of difficulty palpating the scapula as it wraps around the thorax, making the prominent bony aspects on the scapula difficult to discern. As a result, we believe that either teaching videos or hands-on training using the device before implementation in practice or research may be necessary. Another limitation was the sample population. Our participants were asymptomatic and did not have any pathologic shoulder conditions at the time of the study. This highlights a constraint to the clinical application of the electric goniometer as a screening tool versus a diagnostic device based on our work. Future researchers should include patients with pathologic shoulder conditions to determine if scapular motion measured using the electric goniometer can discriminate between healthy and pathologic states.

CONCLUSIONS

Ultimately, the results of this investigation demonstrated that the IMU-equipped electric goniometer was a reliable and moderately valid device to measure scapular motion in each anatomical plane during upper extremity elevation in a healthy population. The degree of error associated with the device when measuring scapular-motion excursions depended on soft tissue and palpation restrictions. We recommend using a clear and defined standard operating procedure when scapular measurements are taken by more than 1 examiner. These findings provide evidence of a clinically portable and consistent device for objectively measuring scapular motion in the clinical setting.

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