Validation of a Scoliometer Smartphone App to Assess Scoliosis

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Background: Surgeons and software developers recognize that apps can improve patient care by replicating the function of existing medical devices. However, the incorporation of new tools requires that the clinical data being recorded is accurate and valid. This study attempts to validate a new iPhone app to measure scoliotic rotation. The objective of this study was to validate the scoliogauge iPhone application by comparing the results to simultaneous readings from a standard Scoliometer.

Methods: Four orthopaedic medical providers (attending surgeon, fellow, resident, and nurse practitioner) each read a standard scoliometer at 60 randomly selected angular measurements between −30 and 30 degrees, whereas a blinded observer simultaneously recorded the angular measurement derived from the scoligauge app. The correlation between the 2 measurements were calculated using a Pearson correlation coefficient with a *P*-value set to <0.05 for significance.

Results: The Pearson correlation values ranged from 0.9994 to 0.9996 for all providers and all *P*-values <0.001. There was no increase in time associated with using the app compared with the standard device.

Conclusions: The scoligauge app is a convenient novel tool that replicates the function of a standard clinical scoliometer but with a potentially decreased financial cost and greater convenience for providers.

Clinical Relevance: Validation of this new device demonstrates the potential to increase the distribution of cost-effective scoliosis screening tools to a broad population of medical providers.

Key Words: smartphone, app, scoliometer, scoligauge, scoliosis, iPhone, mobile, technology

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The increasing use of smartphone devices among the general population, as well as their high prevalence among medical providers, has resulted in the rapid expansion of clinical apps for physicians.[1–3] The internal hardware and software capabilities of these devices, including large touch screens, wireless access, internal accelerometers, and cameras, has resulted in a variety of innovative uses for smartphones in the medical setting. However, although many providers are aware of the multitude of useful apps and their potential convenience in a clinical setting, the use of apps in practice may be limited by a provider's confidence in the app developer and their mobile device hardware and software.

One app that may be useful to pediatric orthopaedic surgeons and other pediatric medical providers is scoligauge,[4] an app that utilizes the internal iPhone (Apple, Cupertino, CA) accelerometer to mimic a standard Scoliometer (Orthopedic Systems Inc., Hayward, CA; Fig. 1). The scoliometer was developed in 1989[5] as a tool for measuring trunk rotation in patients with idiopathic scoliosis. The intention was to develop a clinical tool that was faster and easier to use than the current gold standard for the diagnosis of scoliosis: Cobb angle as measured on anteroposterior radiography of the spine.[6] The device has since been widely used with multiple validation studies reporting good to excellent interrater and intrarater reliability and validity.[6–11] By developing a custom-designed plastic accessory for the iPhone (Fig. 2), replacing a scoliometer with a low-cost app that already exists on one's iPhone has the potential for cost savings and improved clinical efficiency and convenience. However, for an app to gain widespread use and acceptance, validity and reliability should be demonstrated.

The purpose of this brief study was to validate measurements obtained from the scoligauge app in comparison with those read by various medical providers using a standard scoliometer.

METHODS

This study was designed to validate measurements obtained using a standardized mobile device to a standard scoliometer read by various medical providers. The purpose was to demonstrate equivalence between the 2 devices and among providers. Because the study design followed a biomechanical validation testing protocol without the use of patients or medical information, no institutional review board approval was required. The

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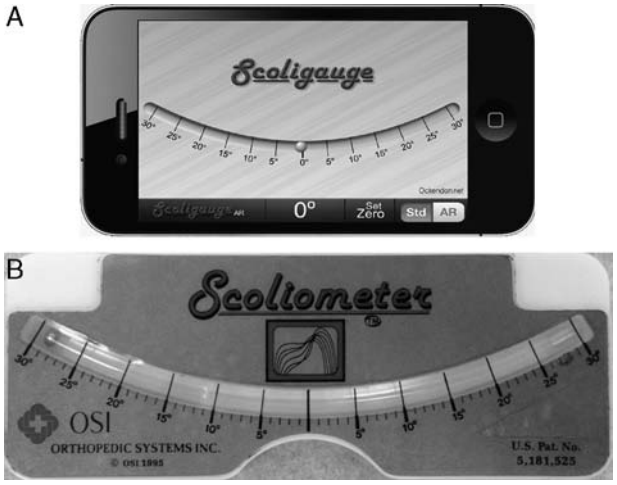

FIGURE 1. Images of the scoligauge iPhone app (A) and scoliometer (B) used for the validation study. During actual testing, the iPhone was turned to face the reverse direction so that the 2 investigators could read the results simultaneously and blinded.

gold standard used for this study was a scoliometer manufactured by Orthopedic Systems Inc. (Fig. 1). The comparison tool was the scoligauge app created for iPhone and running on an iPhone 4S device with iOS 5 installed. The app mimics the use of a scoliometer without any additional training or instructions, and the authors of this study have no relationship, financial or otherwise, with the developer of the software application. Before initiating the study, the iPhone was placed on a level surface to calibrate the internal goniometer to 0, however, the scoligauge app read 0 degrees before calibration, suggesting this step was not required. The study was performed in the following manner: first, the flat surface of the iPhone was aligned and held firmly against the flat top surface of the scoliometer, but with the iPhone screen facing 180 degrees from the scoliometer's analog gauge. This permitted 2 different individuals to read the scoligauge app and the scoliometer devices simultaneously, independently, and blindly with respect to the other device. An independent examiner was responsible for holding the 2 devices firmly together and rotating them through a series of randomly selected angular measurements between −30 and 30 degrees. The devices were held at each location for approximately 2 seconds, allowing both the devices to reflect a stable and unchanging reading, whereas 2 independent observers, each facing either the scoliometer gauge or the iPhone screen, reported the result. The responses were then recorded. For each of the 4 different observers, 60 individual measurements at randomly selected positions were independently tested. Because the scoliogauge app provides an analog measurement that does not require interpretation by the user, the number shown by the app was read by a single observer (O.I.F.). The 4 observers selected to read the scoliometer device included a fellowship-trained pediatric orthopaedic spine surgeon (P.O.N.), an orthopaedic fellow (C.B.), an orthopaedic resident, and an orthopaedic nurse practitioner. A total of 240 angular measurements were recorded for each device. The data were plotted as a scatter histogram and analyzed for each observer as well as combined for all observers. The Pearson correlation coefficient was calculated and reported for each provider as well as for the complete data set P set at <0.05 significance. All statistical analyses were performed using SPSS v19 (IBM, Armonk, NY).

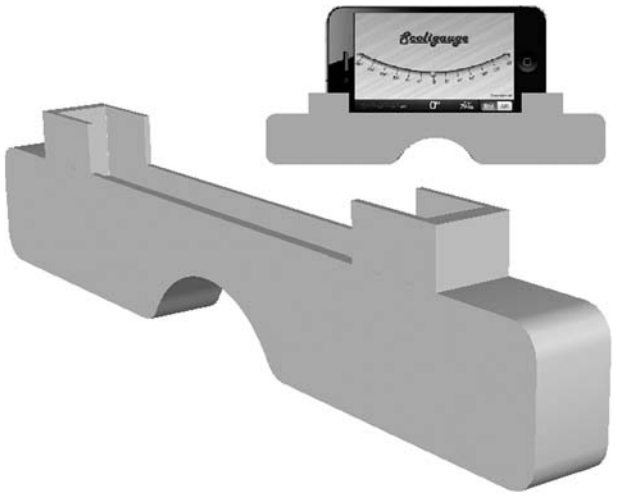

FIGURE 2. Custom-designed accessory to replicate the dimensions of a standard scoliometer when using an iPhone 4.

RESULTS

None of the providers had difficulty reading either the scoliometer or the scoligauge app, and each measurement was performed in approximately 3 to 5 seconds. There were no complications with using either device among the 240 data points collected and no recalibrations were performed during the testing period. The correlations for each provider are shown in Fig. 3. All Pearson correlation values were >0.99 with P-values <0.001, as listed in Table 1.

DISCUSSION

This brief report demonstrates the validity and reliability of the scoligauge iPhone app by comparing it to the gold standard device for clinically assessed deformity in scoliosis. The correlation between these 2 devices was 0.999 with a P-value of <0.001, suggesting a near-perfect correlation without any additional training, learning curve, or time to data acquisition. The implications of this report suggest that if used appropriately, the scoligauge app is an alternative to standard measurement techniques.

The scoliometer was first introduced in 1984 as a valid and reliable method for scoliosis screening.[12] It has since been shown to demonstrate very good to excellent intrarater and interrater reliability by 1 study in the upper, medium, and lower thorax and lumbar segments with

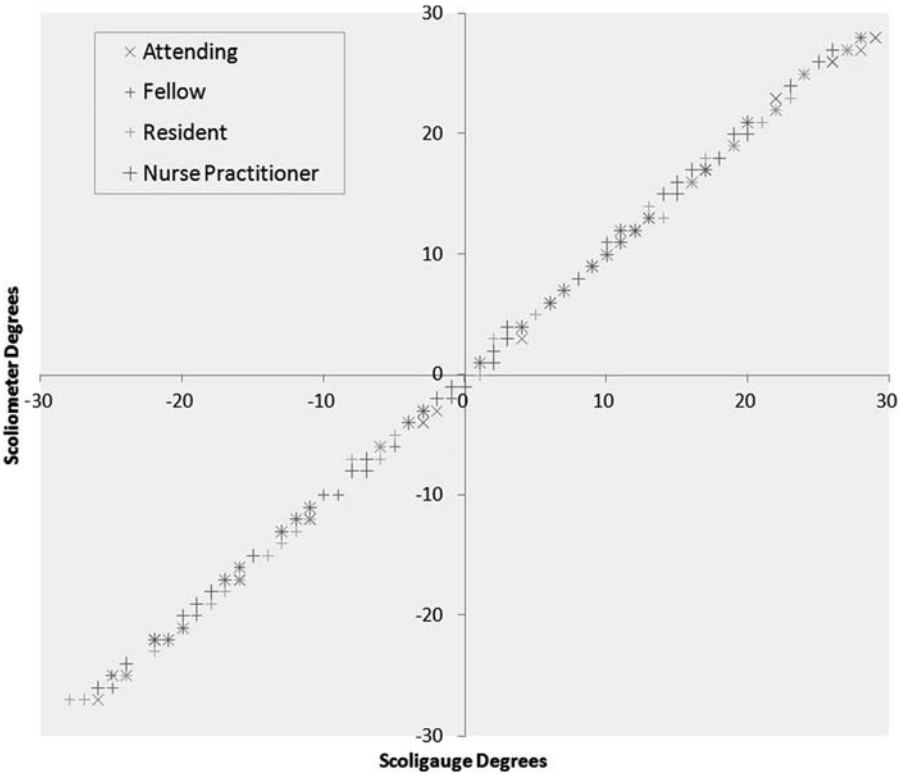

FIGURE 3. Scatter plot for all 240 data points among the 4 orthopaedic providers.

intraclass correlation coefficients ranging from 0.74 to 0.95 at various regions of the spine.[8] A separate study reported similar intrarater and interrater reliability Pearson coefficients ranging from 0.86 to 0.97, and a third study reports correlation coefficient ρ-values of 0.998 and 0.995.[7,10] Combined, these studies provide strong evidence that use of a scoliometer device is a reliable clinical tool. Thus, with a near-perfect correlation between the scoligauge app and the previously validated scoliometer, a smartphone-based app may be more convenient for screening and evaluating scoliosis in a clinical setting.

Scoligauge has the potential to provide cost and time savings to many providers, including orthopaedic surgeons as well as nurses, physician assistants, primary care physicians, and other providers who screen adolescents for scoliosis. The app is available through the iTunes App Store and runs on an iPhone device, which is currently used by 55% of orthopaedic surgeons and trainees, and 48% of physicians and trainees among all medical specialties.[2,13] In addition, a proof of concept for this technique was developed by these authors with a custom acrylic accessory that was manufactured using computer-assisted design software. The purpose of this additional adapter was to hold the iPhone stable and ensure that the adapter footprint matched in dimension to the footprint of the standard scoliometer device (patent pending, Fig. 3). The device was developed subsequent to the validation results described above, and thus was not used during testing. The cost of the app ($0.99) and manufacturing the custom part were < $25, and when purchased in bulk would cost < $5/unit. This is in contrast to a standard scoliometer that ranges in cost from $45 to $90 among medical device retailers and requires the provider to carry an additional tool that measures about 16.5 × 6.4 × 1 cm. Of note, the iPhone 4S measures approximately 11.4 × 6.1 × 0.8 cm, making it smaller than the scoliometer. Currently, the device is not widely available for purchase, but may be produced and distributed in the future.

The recent interest in developing smartphone apps for medical providers is likely the result of increased convenience, efficiency, and cost, as demonstrated above. Although a plethora of useful apps are currently being developed, released, and marketed to orthopaedic patients and providers (http://www.TopOrthoApps.com), the validity of these devices should be demonstrated before their incorporation into practice.

TABLE 1. Correlation Coefficients are Reported for Each of the Four Tested Providers Revealing >0.999 Correlation With a Standard Goniometer in All Cases

Providers	Pearson Correlation Coefficient (ρ)	*P*
Attending	0.9996	< 0.001
Fellow	0.9996	< 0.001
Resident	0.9994	< 0.001
Nurse practitioner	0.9995	< 0.001
All providers	0.9995	< 0.001

There are limitations to this study. First, the validity of the app demonstrated here depends on the proper function of the iPhone's internal accelerometer, which may not be easy to assess. It is worth noting that the iPhone is currently not approved by the Food and Drug Administration as a medical device, and thus the standards for safety may not be equivalent to other medical products. In addition, a standard scoliometer has a 16.5 cm base with a cut-out for the spinous process, which likely increases the reproducibility of measurements on a scoliotic spine. In the cast of an unmodified iPhone, this may be more challenging because of its shorter length. However, this limitation can be easily overcome with an iPhone accessory built to the same dimensions of the scoliometer and designed to hold the iPhone during angular testing.

In conclusion, the scoligauge app is a creative and novel tool that replicates the function of a standard clinical scoliometer but with a decreased financial cost and potential greater convenience for providers.

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