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Design, reliability, and validity of a portable electronic device based on ergonomics for early screening of adolescent scoliosis



Chunxu Li^{a,1}, Bojun Zhang^{b,1}, Liang Liu^c, You Li^c, Yong Xu^d, Li Wang^c, Cai Yun^{d,**}, Yu Zhao^{a,*}

^a Department of Orthopaedics, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Beijing, 100730, China

^b Department of Mechanical Engineering, Xi'an Jiaotong University, Xi'an, Shanxi, 710049, China

^c National Key Laboratory of Human Factors Engineering, China Astronaut Research and Training Center, Beijing, 100094, China

^d Shijingshan Teaching Hospital of Capital Medical University, Beijing Shijingshan Hospital, Beijing, 100043, China

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ABSTRACT

Background/objective: The reported incidence of scoliosis among adolescents in China differs according to screening method owing to the lack of uniformity and limitations of certain techniques. We aimed to design, develop, and validate a non-invasive, accurate, portable, fast, and automated tool that would enable the measurement and storage of data during scoliosis screening.

Methods: We designed a new portable electronic scoliosis screening device (PESSD)—for the identification of adolescent scoliosis based on ergonomics theory. The device measured the axial deflection angle of the trunk of the human body using a built-in angle sensor. Data obtained using the PESSD, a traditional scoliometer manual ruler, and X-ray measurement of the Cobb angle were compared.

Results: The PESSD exhibited more sensitive detection of small-angle scoliosis and improved repeatability compared with the scoliometer. The data obtained using the PESSD showed good correlation with Cobb angle data measured from X-ray images. All patients who were indicated to be positive for scoliosis using the PESSD were found to have clinically identifiable scoliosis from X-ray examination.

Conclusions: The PESSD may be able to achieve early detection of scoliosis in adolescents. It is non-invasive, highly precise, portable, easy to use, and offers automated data storage and traceability. This study is a pilot or preliminary validation study. With further, more in depth studies, the PESSD has excellent potential for transformation into an effective tool for use in large-scale screening programs for adolescent scoliosis in schools and communities.

The translational potential of this article: This article is about designing a new portable electronic scoliosis screening device based on ergonomics theory. Because there are currently no uniform screening methods and standards, the results in this article could facilitate the adoption of a uniform screening tool into large-scale screening programs for adolescent scoliosis in schools and communities, preliminary examination in hospitals, and self-testing at home after parent training.

Introduction

The International Scoliosis Research Society (SRS) defines scoliosis as a curvature of the spine greater than 10°, as measured by the Cobb angle on spinal orthostatic X-ray images taken in a standing position [1]. The

presence of scoliosis in patients between the ages of 10 and 18 is referred to as adolescent scoliosis, which is currently the fifth most common disease among adolescents and can seriously affect patients' physical and mental health [2]. In clinical practice, most adolescent patients seek treatment late, which complicates treatment and leads to increasing

* Corresponding author. Department of Orthopaedics, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Dong Cheng District Shuai Fu Yuan No.1, Beijing, 100730, China.

** Corresponding author. Shijingshan teaching hospital of Capital Medical University, Beijing Shijingshan Hospital, Shijingshan District Shijingshan Road No.24, Beijing, 100043, China.

E-mail addresses: lichunxupumch@163.com (C. Li), zbj178016760@stu.xjtu.edu.cn (B. Zhang), 13718992331@163.com (L. Liu), liyoun@nudt.edu.cn (Y. Li), jxuyong@126.com (Y. Xu), wanglihumanfactor@163.com (L. Wang), 13331026109@189.cn (C. Yun), zhaoyupumch@126.com (Y. Zhao).

¹ These authors contributed equally to this work.

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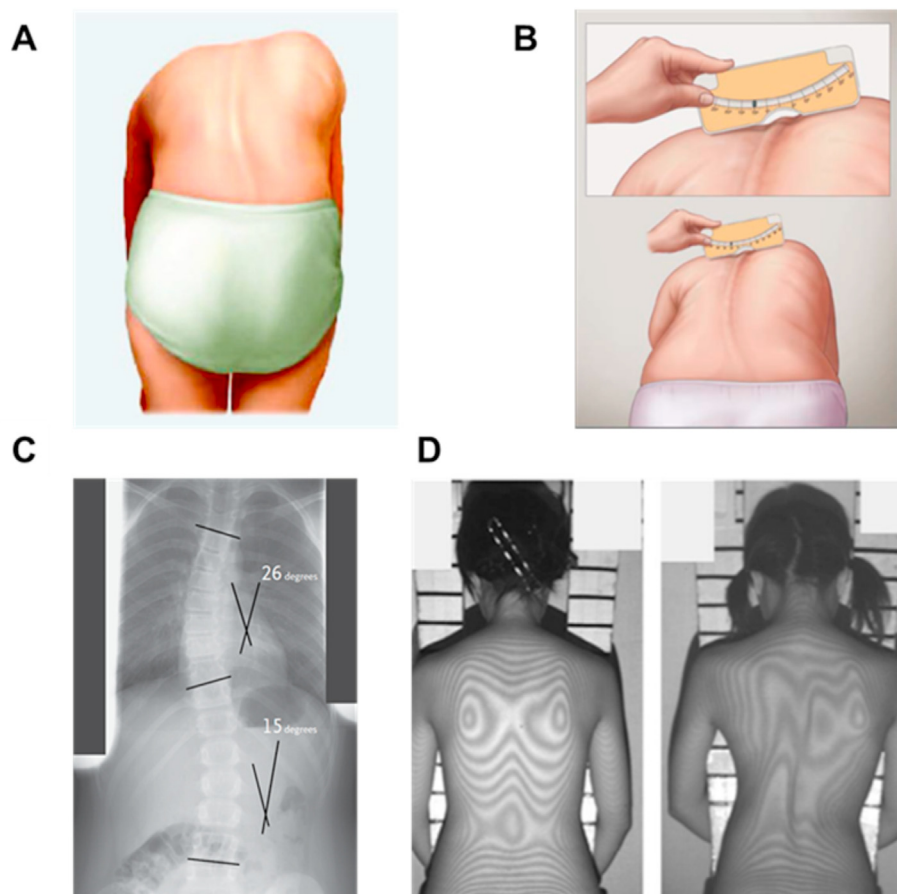


Figure 1. Schematic diagram of screening methods for adolescent scoliosis. Diagrams show schematics of (A) the Adams forward-bend test (the patient is bent forward with the knees in extension and the arms reaching toward the feet with the palms together) (B) scoliometer measurement (C) Cobb angle measurement on an orthostatic whole-spine X-ray image, and (D) the Moire measurement method (left: normal; right: scoliosis). Image A was reproduced from Ref. [5] with permission from BMJ Publishing Group Ltd, B, C were reproduced from Ref. [6] with permission from the American Academy of Family Physicians, and D was reproduced from Ref. [7] with permission from Elsevier.

healthcare costs and worse outcomes [3]. Early detection of this potentially progressive deformity is considered key to successful intervention. Therefore, School Scoliosis Screening (SSS) should be actively promoted and individuals determined to have scoliosis must be frequently observed to determine whether the curvature increases during growth [4].

The most commonly used screening methods for adolescent scoliosis include the Adams forward-bend test [5], scoliometer measurement [6], Cobb angle measurement [6], and Moire measurement [7] (Fig. 1). The Adams forward-bend test is a recognised primary examination method that is simple to perform, non-invasive, and inexpensive but has obvious shortcomings; namely, the technology leads to a high rate of false positive and false negative results with consequent misdiagnoses and unnecessary referrals. A recent meta-analysis indicated that SSS using the Adams forward-bend test as the only evaluation tool is too subjective to enable reliable and accurate diagnosis, so the authors recommended that additional tests should be included in screening programs [8]. One of the most basic evaluations is the use of a spine-measuring scale combined with the Adams forward-bend test [9]. Launched by Bunnell in 1984, the scoliometer is a simple tool that is widely used to measure surface trunk rotation (STR) as part of idiopathic scoliosis tests [10]. The repeatability and reliability of STR measurement using a scoliometer is reportedly high [11], and scoliometer measurement is more sensitive than visual examination. However, the rate of early detection of scoliosis by scoliometer is low, and the throughput of the device is limited, so the screening capability is also low. Furthermore, inter-operator differences and the inconvenience of recording and storing data can greatly impact subsequent screening efforts. Although screening by Moire measurement reduces the requirement for X-ray examinations and therefore the number of films, the rate of missed diagnosis is high and the procedures are complicated and expensive. However, screening that involves X-ray examinations exposes children to unnecessary radiation and will not be

accepted by schools or parents [12].

In China, the Adams forward-bend test is currently the most important screening method for scoliosis. This test relies on visual and physical examinations to obtain data, and therefore the personal experience and professional skill of the screening doctors have a significant influence on the results. Considerable systematic errors may occur owing to differences in personal standards in large-scale screening programs. Because of the lack of appropriate professional skills in the field, the number of doctors capable of carrying out scoliosis screening in medical institutions is insufficient at all levels, making large-scale nationwide screening programs difficult. Recent results of epidemiological surveys of adolescent scoliosis in China have shown the prevalence of the condition to be 0.11%–12.05% [13–17]. The main reason for this variation is that domestic screening methods and standards are not uniform, making comparison and evaluation of the methods difficult. Furthermore, owing to the lack of ergonomic design, the use of screening tools results in the introduction of some human error. Establishing a unified and scientific screening system based on ergonomic design is essential if these problems are to be solved.

Ergonomics (human factors) is the scientific discipline concerned with understanding the interactions between humans and other elements of a system and the application of theory, principles, data, and methods to design for optimising human well-being and overall system performance [18]. The ergonomic design of equipment and environments is primarily based on the characteristics of the operation/user group and the optimisation of equipment and environment for operation and use by such groups to minimise human error and improve work efficiency, safety, and comfort [19]. At present, ergonomics has been applied in many fields including complex modern machinery such as high-speed jet aircraft [20], computers [21], radars [22], nuclear submarines [23], and space vehicles [24] as well as simple equipment such as road signs [25],

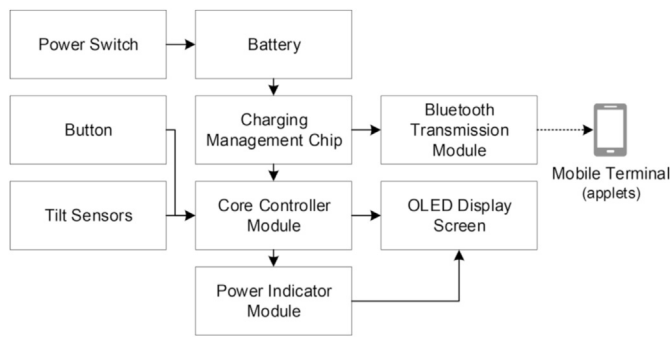


Figure 2. Internal logic block diagram. Abbreviations: OLED, organic light-emitting diode.

telephones [26], hand tools [27], and kitchen appliances [28]. Many studies have demonstrated that the application of ergonomics in clinical practice can effectively reduce medical errors and ensure patient safety [29–32]. The present study aims to develop a new portable electronic scoliosis screening device (PESSD) based on ergonomics theory with the goal of improving the efficiency and sensitivity of screening, increasing the satisfaction of screened individuals, and reducing the rate of errors. We expect this to become a preferred measurement tool for SSS and other scoliosis screening. The design and development of this PESSD may contribute to the standardisation and promotion of scoliosis screening as it achieves early detection of adolescent scoliosis, prevention of continuous deterioration, and contributes to the outcomes of conservative therapy. The risk of secondary injury caused by surgical treatment can be reduced through ergonomic design, decreasing the economic burden on families and society. The PESSD is a non-invasive, effective, reliable, and portable device with a large data storage capacity, making it highly suitable for screenings such as SSS and community screening.

Materials and methods

Principle and structure of the PESSD

The PESSD was intended to fit into a briefcase; therefore, we determined that the dimensions of 210 × 130 × 30 mm and a weight of <250 g would be suitable. The device must incorporate a high-precision sensor with error of <0.05° and a power supply enabling it to run continuously for 8 h and recharge within 2 h. The storage must be equivalent to 2 GB of cloud space, with which we predicted the capability to store screening data for 1.8 million cases. Dedicated personnel regularly maintain and expand the data in the cloud space, so there is no upper limit to the screening data that the device could actually store and track.

Considering different operating environments, the equipment could be normally used within the temperature range of –20–60 °C. The equipment did not produce harmful radiation and the materials used were not toxic.

To meet the design requirements, the basic design of the PESSD involved the use of miniature angle sensors to collect the STR of screened individuals. Fig. 2 presents the internal logic for the PESSD.

The angle sensors collected the spatial angle of the device relative to the earth-fixed coordinate system using a nine-axis gyroscope and transferred the data into the core controller module. The core controller module performed the following calculation:

$$R = R_z(\varphi)R_y(\theta)R_x(\psi) = \begin{bmatrix} \cos \theta \cos \varphi & \sin \psi \sin \theta \cos \varphi - \cos \psi \sin \varphi & \cos \psi \sin \theta \cos \varphi + \sin \psi \sin \varphi \\ \cos \theta \sin \varphi & \sin \psi \sin \theta \sin \varphi + \cos \psi \cos \varphi & \cos \psi \sin \theta \sin \varphi - \sin \psi \cos \varphi \\ -\sin \theta & \sin \psi \cos \theta & \cos \psi \cos \theta \end{bmatrix},$$

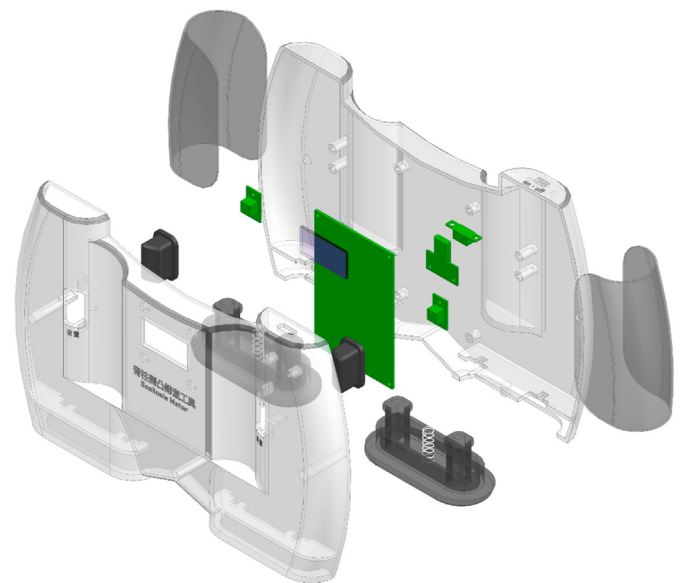


Figure 3. Structural design of the portable scoliosis screening electronic device.

to obtain the angle between the lower edge of the device and the horizontal plane (regarded as the object’s STR), which was then output to the display screen and sent to the mobile terminal. The section of the spine being evaluated could be selected and switched by pressing a button on the connected mobile phone.

A 600-mA 3.7-V lithium ion battery with a Type-C interface to the charging management chip was selected for power storage and supply (Fig. 3).

Use process of the PESSD

The operating mode of the PESSD was determined according to the interaction between the doctor and the screening device. The procedure for PESSD operation that was most suitable for scoliosis screening was as follows: Similar to the generally accepted practice for applying a conventional scoliometer, the device was held with both hands and swept along the back with equal contact force at the paraspinal regions. Then, the device was swept down the spine from the neck and the angle was recorded at three positions: the upper thoracic vertebra (T3–T4), main thoracic vertebra (T5–T12), and thoracolumbar spine (T12–L1 or L2–L3) [33]. The angles of these three segments represented the main data for screening. The angle of STR was presented on the light-emitting-diode display screen; to meet the requirements of multiple scenarios, an applet was also designed for use with the device.

Reliability verification of PESSD

Our PESSD and a scoliometer were used simultaneously for screening at the Primary and Secondary School Health Care Centre in Shijingshan District, Beijing. The screening program involved 1486 high school students with a mean age of 15 years from 17 schools in Shijingshan.

Validity verification of the PESSD

One study showed that 0° – 3° was the normal range, so 2° was chosen to include more participants for determining the screening threshold for the PESSD [34]. All patients determined to have an STR angle of $>2^{\circ}$ were invited to the Peking Union Medical College Hospital for further examination. The Cobb angle and PESSD data were compared to evaluate the screening effect of PESSD. The STR of the thoracic segment, thoracic lumbar segment, and lumbar segment— α_1 , α_2 , and α_3 , respectively—were obtained and the maximum value of the three was defined as α_{\max} for use as a screening diagnostic parameter in comparisons with X-ray Cobb angle data.

Statistical analysis

In the screening process, participants are always randomly assigned to observers. Researchers and observers are not repeated, and observers are trained and standardised. The most intuitive indication of the accuracy of a screening device is whether it can screen all positive patients. In addition, data from multiple screenings of the same patient are also a reference for the repeatability of the device, which means that when the multiple screening data of the same patient are closer, the repeatability of the screening device is higher. In contrast, X-ray diagnosis is currently the most accurate diagnosis of scoliosis, so if the diagnosis result of the device is closer to the result of the X-ray, this indicates the diagnosis effect of the device is better.

Based on the above considerations, the number of effective positive patients with different screening devices and the repeat error of each patient using different screening device were obtained, and the average value of the repeat error using the PESSD and using the scoliometer were calculated separately. A linear regression analysis of the Cobb angle data under the X-ray and the screening angle data of the PESSD was made to verify the effectiveness of the PESSD. The level of significance was set at $p < 0.05$.

Results

Appearance design and function of the PESSD

The appearance and interaction of the device were designed based on ergonomic theory, doctors' operating habits during screening, and the characteristics of the adolescent spine. The design of the grip was based on reported anthropometric data relating to the shape and size of the hand [35] and grip strength [36,37] of adults in mainland China. This was intended to ensure that the operating force and feedback of the PESSD would be comfortable and efficient. The body of the PESSD was designed to be flat and light for portability with a textured holding area to increase friction and reduce slip for stability during operation of the device (Fig. 4B). Because the PESSD needs to be moved from the top to the bottom of the spine maintaining close contact, the device must fit



Figure 5. Applet interface design.

across the width of the spine and be comfortable against the skin. To achieve this, several clinical patients were measured, and a gap was included in the design to ensure unimpeded movement along the spine. The part in contact with the skin was made from smooth and slightly elastic plastic. It was also shaped with rounded corners to prevent accidental injury (Fig. 4C). In terms of the accuracy and stability of measurement, the PESSD was significantly better than the accelerometer-based application (app), ScolioGauge (Fig. 4A) [38]. It also had obvious advantages in terms of data processing.

The applet display was designed to be simple, intuitive, and easy to operate. A colour scheme with reasonable brightness and contrast was used to ensure visibility under different light conditions (Fig. 5). During screening, the device transmitted the data to a mobile phone via a Bluetooth transmission module to display real-time STR data, which was then uploaded to cloud storage. Personal information and other remarks could be inputted to facilitate follow-up management as well as the retrieval and tracing of individual records.

Reliability analysis of the PESSD

Data obtained using the PESSD and scoliometer are shown in Table 1. According to Huang, Shier-Chieg's research in 1997 [39], a 5° STR was



Figure 4. (A) Measurement of STR with the ScolioGauge iPhone app, reproduced from Ref. [38] with permission from Wolters Kluwer Health, Inc (B) Appearance of the portable scoliosis screening electronic device (C) Measurement of STR with the PESSD with the patient in the forward bending position.

Table 1
Comparison of data obtained using the PESSD and scoliometer.

Screening Indicators	PESSD			Scoliometer		
	Male	Female	Total	Male	Female	Total
Number of people screened	703	680	1383	703	680	1383
Number of suspected cases	37	66	103	33	57	90
Suspected incidence	5.00%	8.85%	6.93%	4.69%	8.38%	6.51%
Mean iteration error	0.7°	0.9°	0.8°	1.5°	1.4°	1.4°

Abbreviations: PESSD, portable scoliosis screening electronic device.

adopted as the criterion for suspected scoliosis and subsequent referral. The PESSD identified 113 suspected cases of scoliosis whereas the scoliometer detected 90. The suspected cases that were identified by the PESSD but not the scoliometer all had an STR of 3°–4°. Therefore, the PESSD was less likely to miss cases of small-angle scoliosis than the scoliometer. The average difference between two measurements of the same individual was 0.8° for the PESSD and 1.4° for the scoliometer. Therefore, the accuracy of the PESSD was 1.8 times that of the scoliometer, and data collection using the PESSD was more stable.

Validity analysis of PESSD

The PESSD data identified 30 participants with suspected scoliosis (24 females and 6 males) with a mean age of 13.7 years (standard deviation [SD] = 2.2, range = 10–18 years). The diagnosis of scoliosis was confirmed by X-ray in 28 (considered “positive” cases; Fig. 6). The mean Cobb angle of the positive cases was 31.3° (SD = 12.4, range = 16°–49°), whereas that of negative cases was 2.5° (SD = 0.7, range = 2°–3°). The mean α_{max} of positive and negative samples according to the PESSD was

9.1° (SD = 5.0, range = 3.4°–27.7°) and 2.6° (SD = 0.4, range = 2.3°–2.8°), respectively.

There was a good linear correlation between α_{max} measured using the PESSD and the Cobb angle measured from X-ray images ($r^2 = 0.5117$, $P < 0.0001$, Fig. 7). However, α_{max} was greater than 3° in all positive cases and <3° in negative cases. Therefore, we believe that 3° STR was an appropriate cut-off value for scoliosis screening using the PESSD.

Discussion

We have developed a new digital device for scoliosis screening based on ergonomic design. Our study preliminarily verified that the PESSD was non-invasive, effective, reliable and portable, potentially making screening possible in schools. Comparison of our device with a traditional scoliometer for scoliosis screening in primary and secondary school

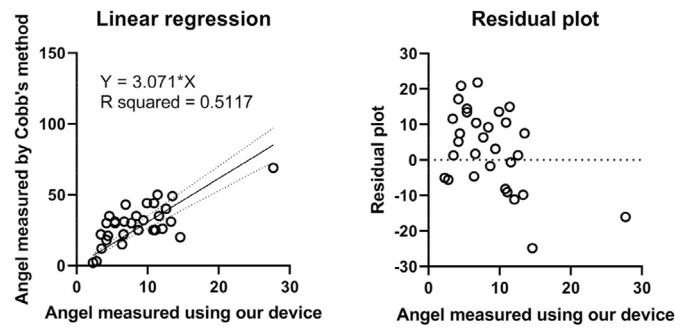


Figure 7. Graphs illustrating the correlation of α_{max} measured using the portable scoliosis screening electronic device with the Cobb angle measured from X-ray images.

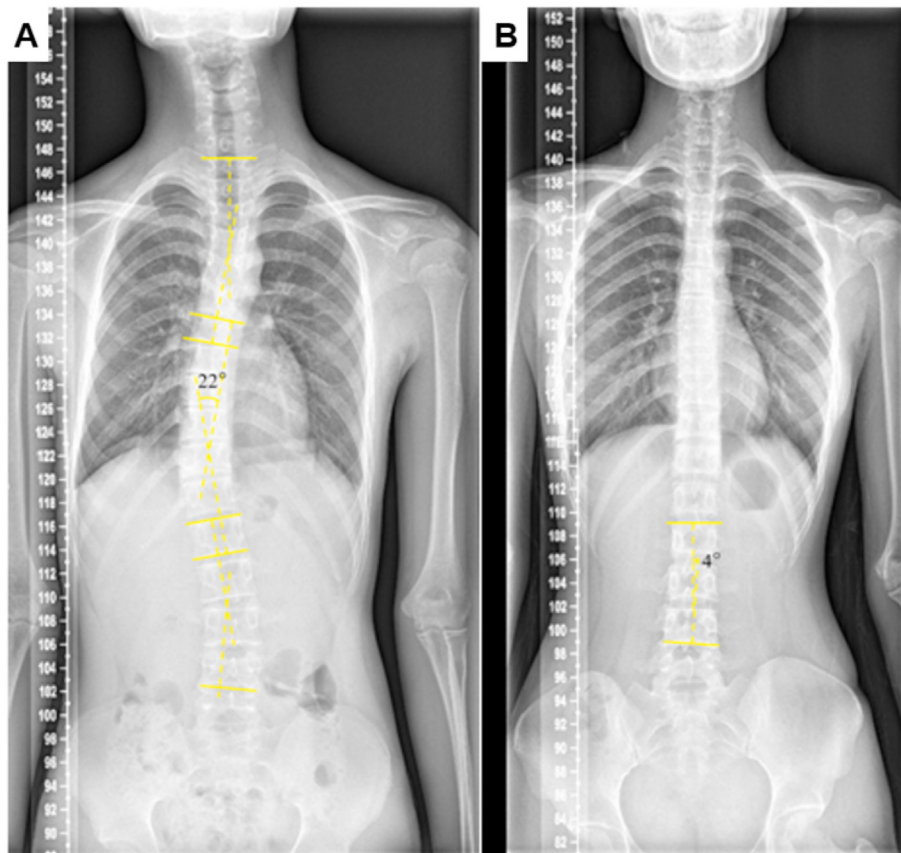


Figure 6. Representative X-ray images illustrating the measurement of the Cobb angle in participants with suspected scoliosis from screening (A) A Cobb angle of >10° was diagnosed as scoliosis (B) A Cobb angle of <10° measured on X-ray film was considered negative for scoliosis.

students revealed that, because of the increased accuracy of electronic readings, the PESSD could identify more potential cases of scoliosis. In the past, the use of devices with insufficient accuracy led to measurement errors, which could also be caused by the operation method based on the experience of the user. These errors can seriously affect the outcomes of scoliosis screening. However, human factors such as operators' habits and ease of operation have not been considered in the design of previous instruments. We introduced the concept of ergonomics to our design to eliminate human error, meaning that systematic errors caused by differences in height, operating posture, and reading angle were reduced and the screening sensitivity was increased compared with the Adams forward-bend test. Our device uploads data to cloud storage in real time, which is convenient and enables large amounts of data to be stored, which is beneficial for subsequent screening. We expect that our device will enable a unified database for domestic adolescent scoliosis screening to be established. Patias et al. compared the measurement parameters of various scoliosis screening methods such as the Adams experimental optical measurement technique and found the correlation between surface and Cobb angle measurements to be very small [33]. Moreover, the sensitivity, specificity, and observation error differed among the methods. These differences can be attributed to the complicated positioning of patients and unclear anatomical markers. Our device overcomes these problems using a three-point measurement technique and electronic data recording. We preliminarily verified the possible correlation between angles measured using the PESSD and the Cobb angle measured from X-ray images (the gold standard for the diagnosis of scoliosis in hospitals) and found that 3° might be an appropriate threshold for identifying suspected scoliosis.

There are few screening programs for adolescent scoliosis in China, so it is difficult to compare and evaluate the different methods. The PESSD used in the present study aims to unify other screening methods by providing data support for regular screening methods and future epidemiological investigations. Our new instrument meets the needs of the SSS program and makes it possible to screen adolescents in school environments as well as physical examination centres. Furthermore, it eliminates the need for radiation exposure and offers a non-polluting method that requires minimal technical skill. Although this is a preliminary pilot work, we can foresee that the implementation of the PESSD in scoliosis screening could reduce the workload of doctors by automating the recording, processing, and analysis of data. Further, it could increase the reliability and validity of such data. Therefore, after simple and specific training, school and community doctors who do not have professional knowledge of the spine would be able to use the PESSD for scoliosis screening. It could even help adolescents who have undergone orthopaedic treatment with braces at home to monitor the progression of their condition in real time. This will increase the potential reach of scoliosis screening among schools and communities and enable a normalised screening system to be established and relevant strategies to be developed.

According to clinical feedback, one limitation of the PESSD is that it cannot distinguish whether asymmetry of the back is caused by asymmetry of the muscle tissue, which may lead to false positives. In subsequent experiments, when selecting participants for screening, the clinician will first conduct a physical examination to exclude participants with muscle asymmetry. Despite the possible correlation between the Cobb angle and axial deflection angles of the trunk surface, the latter does not directly represent the Cobb angle. Thus, secondary examination by X-ray is still necessary after screening with the PESSD to confirm the diagnosis of scoliosis. In addition, when the PESSD is used to measure STR, it is necessary to press the button to perform the measurement at the next position, and only a small number of intermittent measurement data are collected. In future, we will consider improving the device so it can perform dynamic measurement and collect multiple STR data. Finally, validation of the PESSD requires further studies involving large numbers of clinical samples. We intend to continue to add clinical samples from various hospitals to further validate the application of the PESSD in

scoliosis screening.

Conclusions

The PESSD may be able to achieve early detection of scoliosis in adolescents. The data we collected revealed that the PESSD offered high accuracy, excellent sensitivity, excellent specificity, and high diagnostic value. Our data also suggested that an angle of 3° was a suitable threshold for the identification of scoliosis, which could eliminate human error caused by different doctors' judgment based on their own experience. This study is a pilot or preliminary validation study. With further, more in depth studies, the PESSD has the potential to realise intelligent and automatic scoliosis screening with increased efficiency and reduced labour cost. The design and development of the PESSD are novel because it incorporates ergonomics to develop medical technology and aims to address unsolved social problems through the integration of the medical and industrial fields. In future, we will attempt to improve other medical devices and equipment using this approach with ergonomics, which is widely utilised to solve medical problems.

Ethical approval

This study and all its protocols were approved (JS-1946) by the Ethics Committee and Institutional Review Board of Peking Union Medical College Hospital. Informed consent was obtained from all participants and their parents prior to enrolment in the study.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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