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ORIGINAL ARTICLE

Radiation-free measurement tools to evaluate sagittal parameters in AIS patients: a reliability and validity study

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Abstract

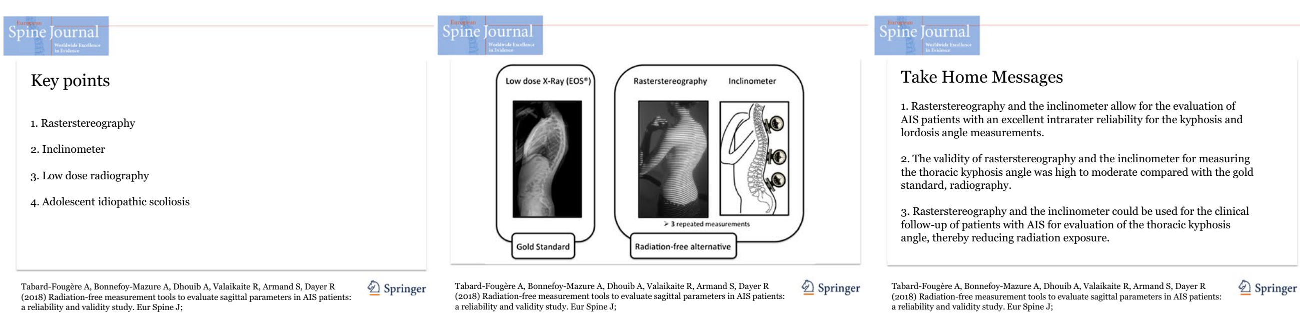
Purpose This study aimed to evaluate the intra-rater reliability and validity in comparison with the two-dimensional radiography (XR) of inclinometer (INCL) and rasterstereography (RAST) for assessing spinal sagittal angles of AIS patients.

Methods Fifty-one AIS patients (13.5 (2.0) years, girls = 32 (63%), Cobb angle = 23.0 (17.4)°) were included in this study. Three repeated measurements of thoracic kyphosis (TK) and lumbar lordosis (LL) were evaluated using the INCL and RAST by the same operator on the same day of the XR examination. Intraclass correlation coefficients (ICC) were used to evaluate the reliability of the INCL and RAST systems. Additionally, Pearson coefficients were computed between the XR and INCL systems and between the XR and RAST systems.

Results Reliability of each radiation-free system was excellent (ICC > 0.75 for INCL and RAST) for both the TK and LL parameters. The Pearson coefficients between each of the radiation-free systems and the XR were high to moderate for the TK (0.50 < RTK < 0.75 for INCL and RAST), high to moderate for the LL as measured with the RAST (0.50 < RLL < 0.75 for RAST) and low for the LL as measured with the INCL (RLL < 0.50 for INCL).

Conclusion This study demonstrated that for the RAST and INCL in AIS patients, there was (1) an excellent reliability for the TK and LL, (2) a high-to-moderate validity for measuring the TK and (3) a moderate and low validity for measuring the LL, respectively. These radiation-free systems could be used for the clinical follow-up of AIS patients for the evaluation of the TK.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.



Keywords Rasterstereography · Inclinometer · Low-dose radiography · Adolescent idiopathic scoliosis

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Introduction

Sagittal imbalance could be a consequence of a spinal deformity. Precise measurement tools are necessary for monitoring the progression of this deformity, including its progression in growing patients with adolescent idiopathic scoliosis (AIS) or Scheuermann kyphosis (SK) [1]. The measurement of sagittal spine parameters, sometimes taken several times during the same year, is essential to have baseline and longitudinal data. These data guide clinicians in their treatment strategies, which are linked to the evolution of these measurements [2].

The gold standard measurement for sagittal spine parameters is the two-dimensional radiography (XR) [3], which exposes patients to radiation. Repeated use of XR in the young patient population has been associated with a long-term increase in mortality from breast cancer [4]. This risk is potentially more important in growing children due to their greater sensitivity to radiation [5]. A recent Danish retrospective study has analyzed the possible association between the radiation dose and the risk of cancer, as well as infertility issues, in 215 AIS patients who were treated 25 years previously [6]. The mean total radiation exposure was 0.8–1.4 mSV per examination and 2.4–5.6 Sv/year, with an average of 16 radiographs performed during the treatment period. The results showed that 4.3% of the AIS patients developed cancer after a follow-up of 25 years. This value was five times higher than that of the normal population, and breast and endometrial cancers were the most frequently observed. This study notes the importance of reducing the radiation dose in the monitoring of AIS patients.

Indeed, various alternative methods could be used to evaluate the thoracic kyphosis and lumbar lordosis angles. A recent systematic review highlighted a total of 15 methods/instruments for the measurement of noninvasive thoracic kyphosis [7]. These methods include the flexicurve index, flexicurve angle, spinal mouse, manual inclinometer, 3-D ultrasound, rasterstereography and electrogoniometer. For all of the studies, the reliability of the data was high (ICC > 0.8), while the validity of these instruments compared to the XR was not tested. Among all of these methods, the inclinometer is a simple, quick and low-cost system that received widespread attention by many authors and clinicians for the measurement and following of spinal posture progression in patients. The inclinometer has an excellent reliability (ICC > 0.90) [8, 9], but no studies have measured the intra- and inter-reliability and validity in adolescent idiopathic scoliosis (AIS) patients.

Conversely, the rasterstereography system is based on surface topography and allows for the measurement of spinal deformity. The intra-rater and inter-rater reliability are excellent in asymptomatic subjects [10] and for the AIS pediatric population [11] in the measurement of the deformity of the frontal plane. In 2016, Knott et al. [2] analyzed the reliability and reproducibility of a rasterstereography system (Diers International GmbH; Schlangenbad, Germany) across multiple users in 193 AIS patients (mean age 13.2 years; age range 8–18 years) and compared these measurements with conventional radiographic Cobb angles. The results showed a strong reproducibility for the rasterstereography system, with an ICC range of 0.86–0.94 as well as a moderate correlation with XR for the lumbar curve ($r = 0.5$), and a strong correlation for the thoracic kyphosis ($r = 0.8$). In addition, the differences between the scoliosis angle and Cobb angle were between 5 and 10°. However, none of the studies compared the spinal sagittal angle measured using inclinometers and rasterstereography system with radiography, which is considered the gold standard, in AIS patients.

The aim of this study was to evaluate the intra-rater reliability of the inclinometer and rasterstereography systems and then to evaluate the validity of these two systems with the gold standard (XR) to assess the spinal sagittal angles in patients with AIS.

Methods

Participants

Adolescents with AIS were recruited among patients who were scheduled for a biplanar radiography examination EOS system (Biospace Med, Paris, France) for suspected scoliosis or for monitoring of scoliosis that was previously diagnosed. The local ethics committee approved this study (CER No. 13-255), and informed consent was obtained from all of the participants and their respective legal guardians.

The inclusion criteria included an age between 10 and 18 years and a diagnosis of idiopathic adolescent scoliosis with a Cobb angle > 10° as measured on the radiography by the routine clinician (RD). The exclusion criteria included being unable to stand upright and walk > 100 m, the presence of tattoos or scarring on the back and a body mass index (BMI) ≥ 29 [12].

Data assessment

Each patient who was recruited had three evaluations on the same day and in the following order: biplanar radiography, rasterstereographic evaluation and inclinometer examination.

First, patients underwent posteroanterior biplanar radiography, which was performed with the EOS® system, as part of their clinical visit. Patients were in a standing position, allowing the spine to be examined under normal weight-bearing conditions. The feet of the patients were on the same alignment in the frontal plane, with 20–25 cm between the two feet. To decrease the artifacts due to the projection of the humerus on the spine in the lateral view without modifying the spine shape, the upper arm fingers were tipped onto the clavicles (Fig. 1).

Second, and immediately after radiographic evaluation, the rasterstereographic Formetric 4-D System with DICAM

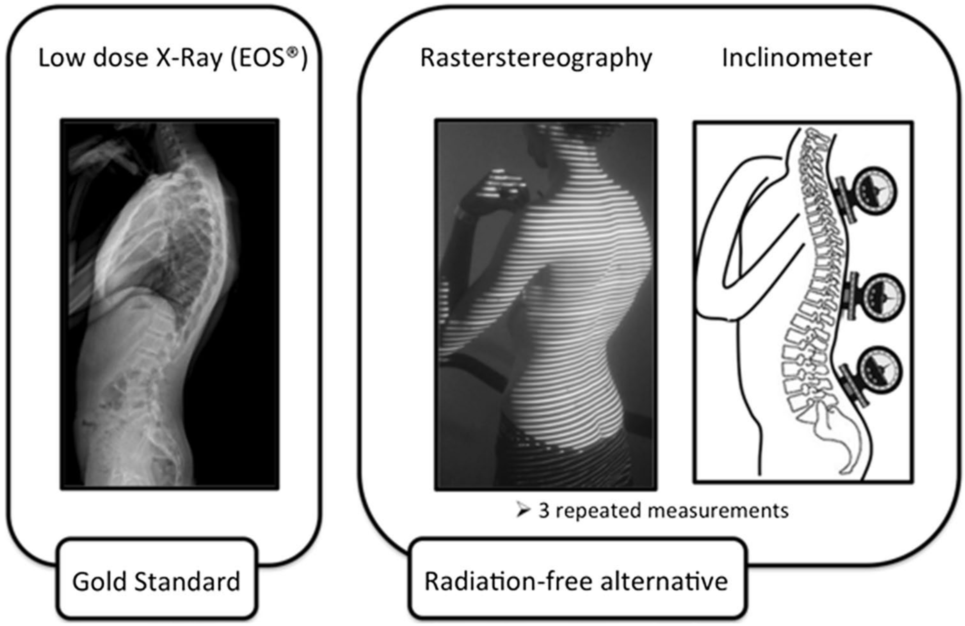

Fig. 1 Illustration of the protocol using radiography, rasterstereography and inclinometer to measure thoracic kyphosis and lumbar lordosis angles

software (Diers International GmbH, Schlangenbad, Germany) was used to assess the spinal sagittal angles. The patient's upper body was undressed with their pants pulled down under the buttocks, and the hair of the patient was tied up to the hairline to make the neck visible. Reflective markers were manually placed at the level of the vertebra prominent (VP), right and left lumbar dimples (DR and DL) and apical vertebra for patients with obvious scoliosis. The modality that was evaluated was 3-D static, which allows measurements to be made based on a one-second capture. To enable the comparison with XR measurements, the patients were examined in a standing position in XR with their fists on their clavicles, elbow flexed and head looking forward [13].

Third, spinal sagittal angles were evaluated using two gravity-dependent inclinometers (bi-level inclinometer, Isomed, Inc, Portland, Oregon, USA). The same operator made the rasterstereography measurements. The base of the inclinometers was placed over two targeted spinous processes directly on the surface of the back, and angle that was calculated was the difference between the two values that were read [14]. The bases of both inclinometers were 2.5 cm apart, and this remained constant for all subjects.

Parameters

The parameters selected for the analysis were the thoracic kyphosis angle (TK) and lumbar lordosis angle (LL), which were provided by the posteroanterior biplanar radiography, rasterstereography and the inclinometer (Fig. 1).

For the XR (gold standard), the TK was measured as the angle between the line tangent to the cranial endplate of fourth thoracic vertebra (T4) and caudal endplate of 12th thoracic vertebra (T12), and the LL angle was measured using two different methods: (1) between tangents at the cranial L1 and sacral endplates (S1), which is called L1–S1 and (2) between T12 or L1 and S1, depending on which gave the maximum value, which is called LLmax.

For rasterstereography, the automatic algorithm computed TK as the maximal thoracic angle between the line tangent to the cranial endplate of the vertebra prominent (VP) and the caudal endplate of T12. In the same way, the LL angle was computed as the maximal lumbar angle between the line tangent to the cranial endplate of T12 and the midpoint between the lumbar dimples (DM).

For the inclinometer, the TK angle was measured by placing the feet of the inclinometer systems over the spinous processes of T1/T2 and T12/L1 located by manual palpation. The LL angle was measured by placing the feet of the system over T12/L1 and L5/S1. Three repeated measurements were performed by the same operator, and the average of these measurements was used for future analysis.

Statistical analysis

Descriptive data were calculated as the mean (standard deviation) for continuous variables and as n (%) for dichotomous variables. The normality of the data distribution was evaluated using the Shapiro–Wilk test.

To evaluate the intra-rater reliability of inclinometer and rasterstereography systems, an intraclass correlation coefficient (ICC) was calculated using the equation ICC (1, 1) between three repeated measures that were made on same day and by the same operator. The ICC was considered excellent if higher than 0.75, acceptable if between 0.74 and 0.40 and poor if lower than 0.39 [15]. In addition, Pearson correlations were also calculated between the two radiation-free systems to evaluate the link between these two techniques.

To evaluate the validity between the inclinometers and rasterstereography against the gold standard (XR), Pearson correlation coefficients were calculated.

Finally, the average differences between the respective inclinometers and rasterstereography with the XR were also evaluated for the TK and LL, and the proportion of participants with a difference greater than 5° was reported. Moreover, in order to remove the systematic bias, the corrected mean difference was calculated as the difference between the average difference minus the mean difference for all of the patients. The proportion of participants with a corrected difference greater than 5° was also reported. The statistical analysis was done using the R v.3.1.3 software [16] with the RStudio interface [17].

Table 1 Patient demographic characteristics

Variables	Values ($n=51$)
Female, *n* (%)	32 (63%)
Age, years, mean (sd)	13.5 (2.0)
BMI, kg m^{-2}, mean (sd)	18.9 (2.8)
Weight, kg, mean (sd)	51.0 (11.2)
Height, m, mean (sd)	163.5 (11.2)
Cobb angle, degrees, mean (sd)	22.9 (17.4)

SD standard deviation, *kg* kilograms, *m* meters, *n* number of participants

Results

Participants

Fifty-one patients were included according to the inclusion and exclusion criteria. The demographic and radiological characteristics of the patients [age: 13.5 ± 2.0 years; BMI: 18.9 ± 2.8 kg m^{-2}; girls: 32 (63%)] are summarized in Table 1.

Repeatability and correlation of radiation-free measurement tools

As summarized in Table 2, the correlation coefficients (ICC (1, 1), $n=51$) were excellent for all of the variables (ICC > 0.85). Between inclinometers and by rasterstereography, the Pearson correlation was strong for the TK ($r=0.805$, $p<0.001$) and moderate for the LL measured between the L1–S1($r=0.684$, $p<0.001$).

Validation of the radiation-free measurement tools with the gold standard

As summarized in Table 3 and Fig. 2, TK measured with the XR was strongly correlated with the inclinometers ($r=0.738$) and rasterstereography ($r=0.737$). LL measured with the XR between tangents at the cranial L1 and sacral endplates (S1) the LLmax with the XR was poorly correlated with the inclinometer ($r=0.309$) and moderately with the rasterstereography ($r=0.605$) (Fig. 3). Similarly, LL measured between the L1–S1 with the XR was poorly correlated with the inclinometer ($r=0.320$) and moderately with the rasterstereography ($r=0.625$) (Fig. 3).

For the TK (Table 3), the mean difference between inclinometer and rasterstereography with gold standard was 7.2 ± 6.0° (with 29 (57%) patients who had more than 5° of

Table 2 Mean values with standard deviations of the thoracic kyphosis and lumbar lordosis angles in degrees measured with inclinometer and rasterstereography. Intraclass correlation coefficient (ICC) was calculated between the three repeated measurements made by the same operator the same day

	Mean (SD)	ICC	*P* value	95% CI
Thoracic kyphosis				
Inclinometer (°)	39.7 (10.3)	0.982	< 0.001	0.971 < ICC < 0.989
Rasterstereography (°)	36.9 (11. 5)	0.937	< 0.001	0.902 < ICC < 0.961
Lumbar lordosis				
Inclinometer (°)	38.2 (7.3)	0.964	< 0.001	0.943 < ICC < 0.978
Rasterstereography (°)	36.5 (9.9)	0.965	< 0.001	0.946 < ICC < 0.979

CI confidence interval, *SD* standard deviation, *ICC* intraclass correlation coefficient

Table 3 Validity of inclinometer and rasterstereography in comparison with the gold standard (radiography)

	Thoracic kyphosis (°)	Lumbar lordosis (°)	
Gold standard (radiography)	T4–T12	Max (L1/T12)–S1	L1–S1
Mean (SD)	34.4 (11.2)	60.4 (10.7)	59.3 (10.1)
Inclinometer			
Mean (SD)	39.7 (10.3)	38.2 (7.3)	38.2 (7.3)
Mean of differences	7.2 (6.0)	22.6 (9.9)	21.5 (9.6)
N (%) patients with difference > 5°	29 (57%)	49 (96%)	47 (92%)
N (%) patients with corrected*difference > 5	9 (18%)	17 (33%)	18 (35%)
Correlation (*r*)	0.738	0.320	0.309
95% CI	0.581–0.842	0.049–0.548	0.037–0.539
Rasterstereography			
Mean (SD)	36.9 (11.5)	36.5 (9.9)	36.5 (9.9)
Mean of differences	6.9 (5.1)	23.9 (8.9)	22.9 (8.5)
N (%) patients with difference > 5°	28 (55%)	49 (96%)	49 (96%)
N (%) patients with corrected*difference > 5	12 (24%)	13 (25%)	15 (29%)
Correlation (*r*)	0.737	0.625	0.604
95% CI	0.579–0.841	0.423–0.770	0.395–0.754

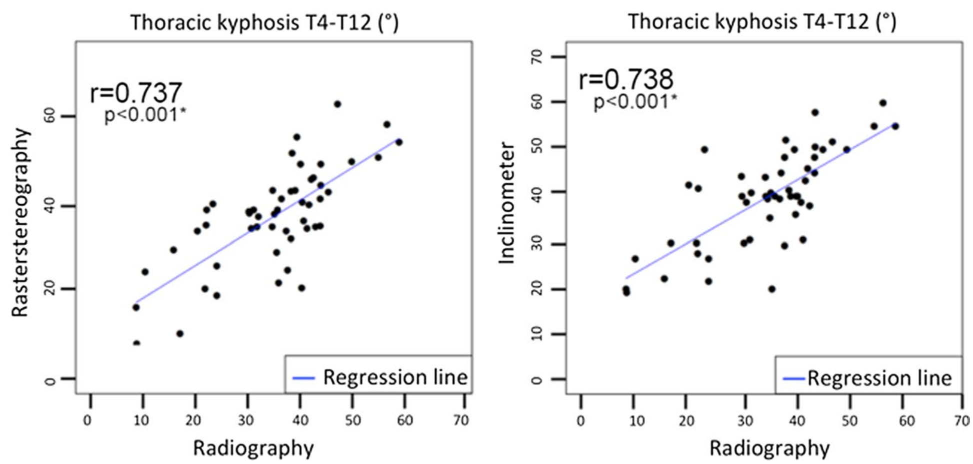

Fig. 2 Correlation between radiation-free measurements tools (rasterstereography and inclinometer) and radiography for the thoracic kyphosis angle

a difference) and 6.9 ± 5.1° (with 28 (55%) patients who had more than 5° of difference), respectively.

Regarding the corrected mean difference, 18% of the patients had more than 5° of a difference between the inclinometer and XR and 24% of the patients had more than 5° of a difference between rasterstereography and XR.

For the LLmax, the values of the mean differences between the inclinometer and rasterstereography with the gold standard were, respectively, 22.6 ± 9.9° (with 49 (96%) patients who had more than a 5° difference) and 23.9 ± 8.9° (with 49 (96%) patients who had more than a 5° difference).

After correction of the mean differences, 33% of the patients had more than 5° of a difference between the inclinometer and XR and 25% of the patients had more than 5° of a difference between rasterstereography and the XR.

For L1–S1, the mean differences were, respectively, 21.5 ± 9.6° (with 47 (92%) patients who had more than a 5° difference) and 22.9 ± 8.5° (with 49 (96%) patients who had more than a 5° difference).

After correction of the mean differences, 35% of the patients had more than 5° of a difference between the inclinometer and XR and 29% of the patients had more than 5° of a difference between rasterstereography and the XR.

Discussion

This study evaluated intra-rater reliability of two radiation-free systems, the inclinometer and rasterstereography. The study also compared the validity of these two radiation-free systems with the gold standard of the sagittal spinal angles in AIS patients.

Our results showed that the reliability of these two radiation-free systems was excellent (ICC > 0.85) for the TK

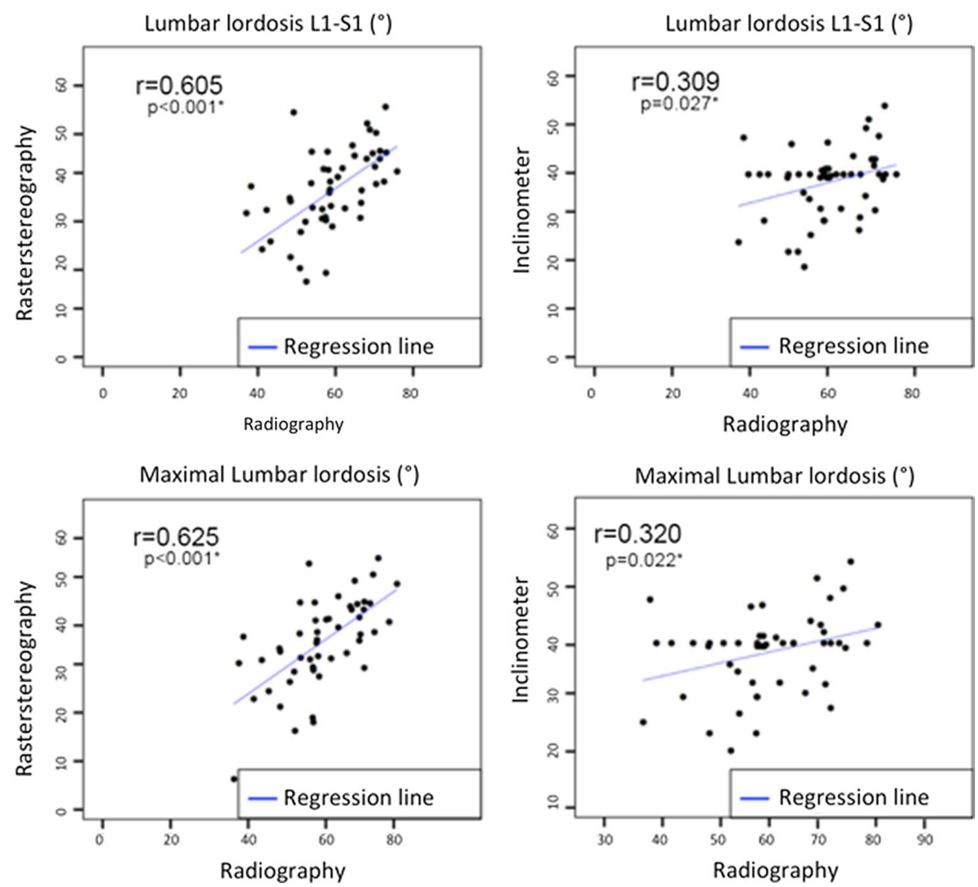

Fig. 3 Correlation between radiation-free measurements tools (rasterstereography and inclinometer) and radiography for the lumbar lordosis angles (L1–S1 and lumbar lordosis maximal)

and LL. In the systematic review written by Barrett et al. [7], these two systems were also found to be very reliable for healthy participants as in the reliability study written by Zaina et al. [18] in patients with spinal deformities (AIS and hyperkyphosis). Thus, our results confirmed that for the kyphosis and lordosis angles, these two systems are reliable for AIS patients. Regarding the correlations between these two systems to evaluate the TK and LL angles, a strong correlation for the TK and a moderate correlation for the LL were observed. This is probably not surprising because these systems evaluate the same value of the angle using the shape of the curve of the back. Concerning the correlation of these two systems with the gold standard (XR), our results showed a good correlation ($r > 0.7$) of the inclinometers and rasterstereography for the TK angle. In the available literature, contrasting results were published for the comparison of topographic data compared to the XR. Fortin et al. [19] found a moderate correlation for TK ($r = 0.35$), while Knott et al. [2] found as strong as a correlation for TK ($r = 0.87$) as Frerich et al. ($r = 0.79$) did in young patients with idiopathic scoliosis [20]. However, there have been no results published concerning the validity of the inclinometers compared to the XR. For the TK angle, it appears that the inclinometers and rasterstereography have a good reliability and validity, which shows that these two systems could be used in the clinical setting as a complement to radiography.

Concerning the LL angle, the correlation obtained in this study showed a poor correlation between the inclinometers and the XR but a moderate correlation between rasterstereography and the XR, with a higher correlation for the LLmax. Fortin et al. [19] also observed a poor correlation for the LL angle compared to XR ($r = 0.3$), but Knott et al., as well as Frerich et al., observed a high correlation ($r = 0.81$) [2, 20]. The low and moderate correlations found in this study can be also explained by the important variability to measure the lumbar dimples. Indeed, localization of these specific anatomical points has a direct impact on the lumbar angle calculation done by the rasterstereography system which used these landmarks to the back shape reconstruction algorithm [21]. Thus, depending on the patients' anatomy, changes in soft tissue contour could influence these landmark positions that are not necessarily link to the underlying structure of the pelvis. Finally, the lumber dimples are often manually repositioned or adjusted by the operator with a possible influence on the angle calculations [22]. Thus, low-to-moderate validity of the two radiation-free systems was determined in the present cohort.

In addition, we observed a mean average difference between the XR and topography measurement that was higher than those found by Knott et al. [2], who studied 62 adolescents with idiopathic scoliosis and observed a value of 9.7°, compared to 21.5° for LLmax in the present cohort and 22.9° for L1–S1. These differences could be explained by the fact that several factors can affect the lumbar curvature, including the strain on ligaments and muscles, muscle balance between back and hip muscles, abdominal muscles and pelvis inclination in a standing position [23, 24]. Moreover, the differences observed between the present study and the study of Frerich et al. [20] and Knott et al. [2] concerning the comparison of rasterstereography with XR could also be explained by the position of the patient during the XR measurement. In the present study, the patients were positioned with their fists on their clavicles, elbow flexed and head looking forward, whereas in the two others studies, the patients had their arms along their bodies. Zaina et al. [18] reported that the influence of arm positioning in sagittal plane spine is strongly in favor of a surface measurement. The arm positioning is very relevant, and usually problematic in XR, while inclinometers and rasterstereography allow for a natural position.

Furthermore, Knott et al. [2] matched the rasterstereography value to the maximum TK and LL that were evaluated on the XR. This implies that T12 and L1 were sometimes used as the endpoints, depending on which one gave their maximum value. Their measurements are thus different than those that are traditionally done on XR, and this could explain some of the differences observed between the present results and their findings. In addition, the lower reliability in the lumbar spine observed in the present results could be related to the absence of ribs that can influence topographic measurement. Moreover, it appears that the breathing should be also considered as a component of variability in the reported results [20].

Concerning the mean differences obtained after the correction for TK, LLmax and L1–S1, we observed better results compared to the XR, with a number of patients who had values that were greater than 5° diminish when compared to the results obtained without the correction. Thus, taking into account the biases in the measurement technique, the two radiation-free systems have pretty good results, especially for the TK angles.

The main limitation of this study is the influence of the postural variation in not only the measures with the radiation-free systems but also in those with the XR. The XR quantifies the underlying skeleton deformities of the spine, and the radiation-free systems quantify the shape of the spine curvature with potential inaccuracies in the palpations of anatomical landmarks. Additionally, the type of scoliosis curve in the present cohort could also be a limitation due to the heterogeneity of the Cobb angle severity and in the shape of the curve.

In perspective, it would be interesting for further studies to perform an independent validation of the methodology in a larger cohort of patients with a multicenter study.

Finally, as a radiation-free alternative, ultrasound imaging method can identify curve progression in AIS patients [25, 26], even if it seems to underestimate scoliosis angle [27]. These results in AIS patients support the need of radiation-free alternative tools to monitor the spine curve evolution and highlighted interest for further studies to evaluate the ability of rasterstereography to identify scoliosis curve progression in AIS patients [28]. These radiation-free and accessible systems could help to reduce radiation exposure in growing population.

Conclusion

The clinical implications of this study are that both the inclinometer and rasterstereography systems are reliable and consistent for quantifying the TK angle in AIS patients and that they have the advantage of being free of radiation, simple, fast and economical compared to XR. Moreover, concerning the LL angle, it appears that the anatomical structure of the lumber dimples and their detections have a large impact on the angle values. Thus, in a clinical context and follow-up, it is important to have an experimented operator to realize the records with these kinds of systems. Indeed, the clinical accuracy of the LL angle but also of the TK angle are largely influenced by the patient position and also by the capacity to find and to replace manually the specific anatomical landmarks of the back shape that are used in the future calculations. It could help clinicians not only in their monitoring of patient diagnosis but also in their educational feedback to their patients with a direct impact on the diminution of the number of XR over the time. In last, these radiation-free systems could also be potentially relevant for the follow-up of patients with SK.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest related to this work.

Ethical approval This work was approved by the local ethics committee (CER No. 13-255).

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