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ORIGINAL ARTICLE

Is rasterstereography a valid noninvasive method for the screening of juvenile and adolescent idiopathic scoliosis?

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Abstract

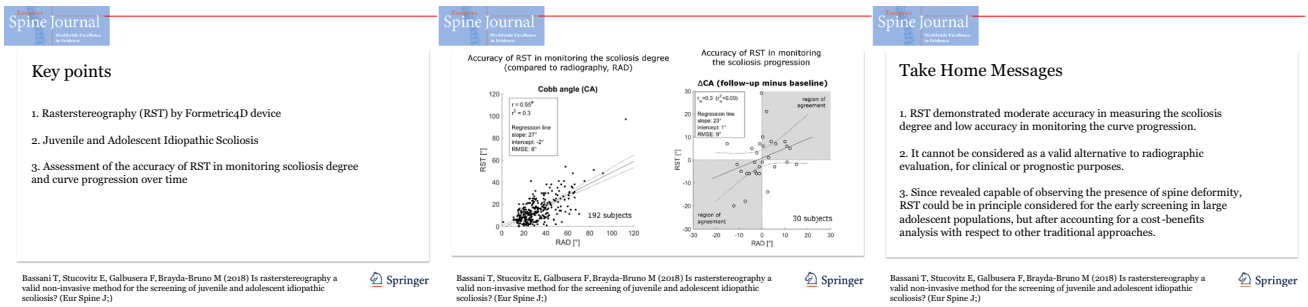
Purpose Aim of the study was to verify the accuracy of rasterstereography (RST), as radiation-free alternative to plain radiography (RAD) in the monitoring of spine deformity and scoliosis progression in juvenile and adolescent subjects with idiopathic scoliosis.

Methods 192 subjects underwent RST (by Formetric 4D device) and low-dose RAD (EOS Imaging, France) in the same session. A sub-group of 30 subjects, selected for conservative treatment with corrective bracing, was assessed at 6-months follow-up. The Cobb angles (CA) obtained by the 3D spine reconstruction from RAD were compared with those provided by RST. Thoracic kyphosis (TK) and lumbar lordosis (LL) were compared as well.

Results RST provided lower CA compared to RAD (15° vs. 33°, mean values). The average difference in measuring CA was 18°, and the correlation coefficient was 0.55. Comparable TK was observed, whereas LL resulted underestimated by RST compared to RAD (34° vs. 43°, average values). The within-subjects correlation, measuring the accuracy of RST in monitoring the scoliosis progression, was 0.3. Accuracy of RST in identifying increased or decreased CA was 67%. Sensitivity and specificity were 64% and 69%.

Conclusions RST demonstrated moderate accuracy in measuring the scoliosis degree and low accuracy in monitoring the curve progression. Accordingly, it cannot be considered as a valid alternative to radiographic evaluation. However, since demonstrated capable of revealing the presence of spine deformity, it could be in principle considered for the early screening in large adolescent populations, but after accounting for a cost-benefit analysis with respect to other traditional approaches.

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



Keywords Scoliosis · Adolescents · Low-dose radiography · Rasterstereography · Formetric 4D

Introduction

Juvenile and adolescent idiopathic scoliosis (JIS and AIS) are a three-dimensional deformity of the spine with prevalence between 1 and 3%, most frequently in females [1–3].

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At present, the diagnosis is based on the clinical evaluation and on confirmation by the radiological examination [4–6]. Monitoring the progression of scoliosis can require frequent radiological assessments, with consequent risks associated with the radiological exposure in pubertal growth [7–10].

Although a lower-dose solution (the EOS Imaging System, EOS Imaging, Paris, France) has been recently developed [11–13], the possibility of exploiting radiation-free methods to monitor scoliosis and its progression would represent an advantage. A number of systems based on back surface topography have been developed as noninvasive alternative to plain radiography [14, 15], e.g., Moirè projection [16, 17], laser scanner [18, 19], electromagnetic topography [20], ultrasound imaging [21, 22], and rasterstereography [8, 23–29]. Being based on the monitoring of the back surface, these systems provide an indirect measurement of spine deformity. Not characterizing the internal spine shape, such techniques cannot in principle allow to diagnose the scoliosis degree. However, they may be potentially exploited as economic and fast methods in the early screening for the presence of spine deformity.

To this regard, rasterstereography (RST) has increasingly become a viable option. Exploiting a structured light, it allows for an approximate 3D image of the spine shape. In particular, the Formetric 4D is a rasterstereographic medical device regularly used in some centers to evaluate the spine deformities in adolescents [30]. Over the last years, Formetric 4D is attempting to gain a widespread approval as radiation-free alternative. Encouraging results have been reported in terms of reliability (the overall consistency of a measure) [31–33] and validity (the extent to which a conclusion corresponds accurately to the reality) [30, 34–37].

However, the works devised to assess validity held some limitations. A small or moderate number of subjects were evaluated in some cases [35, 36]. In another study [34] the ability of the device in recognizing scoliosis was assessed by comparing the scoliosis angle, which is provided automatically and calculated as the maximum angle found between all the vertebral pairs, with the Cobb angle identified by a clinician from radiographic examination. This limitation implies that the compared angles can describe scoliotic curves characterized by different end vertebrae. Moreover, the device provides only one scoliosis angle, but more than one scoliotic curve can be identified from the radiological evaluation. The study which accounted for the largest population (193 subjects recruited in seven different institutes) did not report an exhaustive explanation about which scoliosis angles were compared between Formetric 4D and radiographs [30]. Only one work evaluated the device in monitoring the scoliosis progression over time [37]. However, in this case, the validity of the device was assessed by comparing the lateral vertebral deviation of the reconstructed spine, and not the Cobb angles characterizing the actual scoliotic curves. An accurate evaluation is thus required to verify the use of Formetric 4D as RST alternative to the radiological examination (RAD) and/or as method for the early screening of spine deformity (allowing, for example, to easily monitor large adolescent populations in school context).

The present work is aimed to evaluate the accuracy of RST in monitoring the scoliosis degree (measured by Cobb angle) and the sagittal anatomical parameters (i.e., thoracic kyphosis and lumbar lordosis) in JIS and AIS subjects. Accounting for a large cohort of 200 individuals, the study compares (via correlation and Bland–Altman analyses) Cobb angles and parameters obtained by low-dose RAD (EOS system) with those calculated by RST (Formetric 4D). In particular, analogous Cobb angles, i.e., measured between the same proximal and distal vertebrae, are compared. Furthermore, the scoliosis degree of a sub-group of subjects is evaluated in the follow-up period in order to assess the efficacy of RST in monitoring the progression of the curve over time.

Methods

Experimental protocol

A group of 200 JIS and AIS subjects was evaluated in the period 2014–2016 at a third-level hospital (IRCCS Istituto Ortopedico Galeazzi, Milan, Italy). The sample size was determined to satisfy the statistical requirements (see the corresponding paragraph below) and to be comparable with the largest number of subjects (193 individuals) evaluated in previous studies devised to assess RST [30]. The enrollment was designed on a 3-year basis, by accounting for the number of expected visits performed per year at the institute and a rate of refuse to participate about 20% (based on the experience of previous enrollments with similar populations). The participation in the study was proposed on the occasion of the orthopedic visit for scoliosis or suspected scoliosis, to all subjects planned for radiographic examination and fulfilling the inclusion criteria: age ranging from 8 to 18 years, condition of scoliosis identified if the angle of trunk rotation, measured with scoliometer, exceeded 5°. Both surgical and conservative treatment settings were taken into account. The exclusion criteria were the followings: other concomitant vertebral deformities, secondary scoliosis due to neuropathic and myopathic conditions, congenital or infantile scoliosis, obesity, pregnancy. Subject assent and parental permission to participate in the study and use anonymized data were given by signing an informed consent. The study was approved by the local Ethical Committee.

Each subject underwent, in the same session, low-dose biplanar RAD and RST.

RAD Digitized radiographic images of the thoracolumbar spine and pelvis were simultaneously acquired in the coronal and sagittal planes (Fig. 1a, b) with the EOS system. The subjects were evaluated in orthostatic position with arms flexed and fingertips on cheekbones. The images pair was processed by an experienced orthopedist through sterEOS software (EOS Imaging, Paris, France), allowing to identify the scoliotic curves (characterized by Cobb angles > 10°) and providing the 3D spine reconstruction (Fig. 1c, d). The following parameters were extracted for each subject: (1) number of scoliotic curves and related Cobb angle (CA); (2) thoracic kyphosis T1–T12 (TK); (3) lumbar lordosis L1–L5 (LL).

RST Surface topography was performed with Formetric 4D device (DIERS Biomedical Solutions, Schlangenbad, Germany). The subjects were evaluated in orthostatic position with arms relaxed (Fig. 2a). After the acquisition, TK (named as 'Thoracic kyphosis angle VP-T12' in the outputs) and LL (named as 'Lumbar lordosis angle T12-DM') were automatically provided by the system (software DiCAM v. 5.2.10). VP and DM landmarks indicate the vertebra prominens and the middle point between the sacral dimples, respectively (Fig. 2d). Differently from RAD, the identification of the end vertebrae of the scoliotic curves and of the related CA was not allowed. Only the output named as 'Scoliosis angle,' calculated as the maximum angle found between all the vertebral pairs, is automatically provided. However, the device allows to obtain any CA by user intervention, by manually selecting the appropriate end vertebrae in the reconstructed spine model (Fig. 2b), replicating the scoliotic curves previously identified by RAD (Fig. 1c). Since Formetric 4D reconstructs the spine model from C7 to L4 neglecting L5 (Fig. 2b), the curves identified by RAD as lower limited at L5 were then processed in RST by restricting them to L4.

Follow-up evaluation

A sub-group of 30 subjects, identified by RAD as 'scoliotic' (one or two curves, with CA < 40°) and selected for conservative treatment with corrective bracing, was assessed 6 months after the first examination session, in concomitance with the planned clinical and radiological evaluation of the scoliosis progression. During this second session, RAD and RST were consecutively performed. The CA of the scoliotic curve which had been identified in the first session (the primary one in case of two curves) was measured anew, i.e., the end vertebrae of the curve were the same as in the first session.

Study endpoints

The accuracy of RST in identifying the scoliosis degree was evaluated by assessing the correlation coefficient, r,

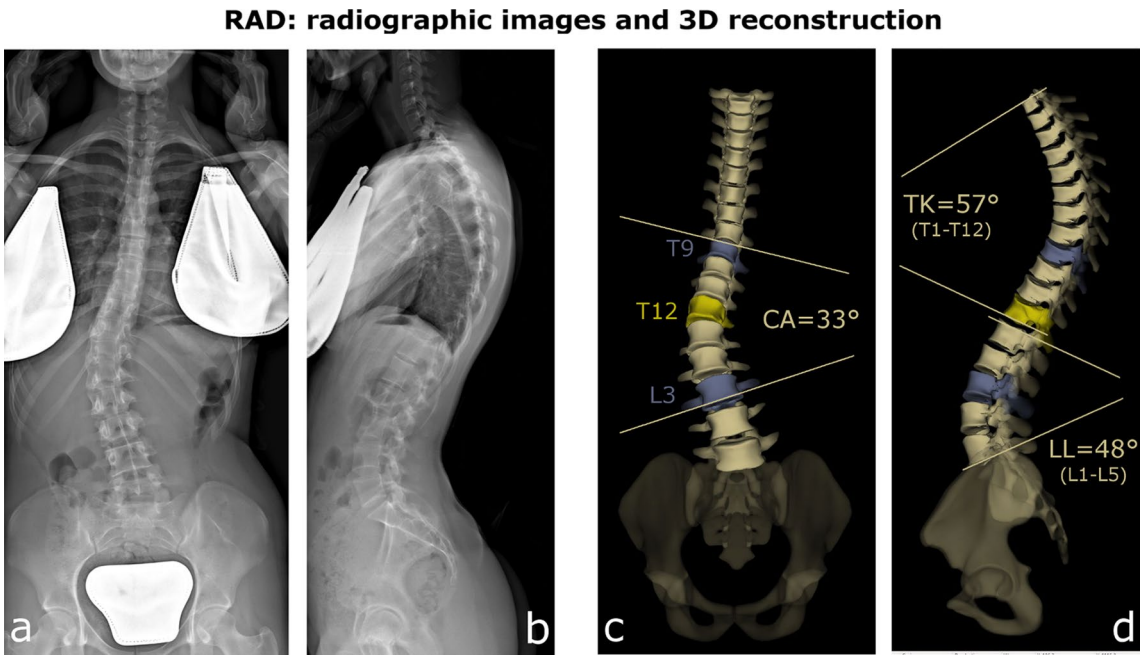

Fig. 1 Spine model reconstruction performed through RAD for a 13-year-old female subject. **a**, **b** Pictures depict the frontal and lateral radiographic images simultaneously acquired with the EOS system. **c**, **d** Pictures depict the corresponding 3D spine model. The blue and the yellow vertebrae interpret the limits and the apex of the scoliotic curve, respectively. The Cobb angle (CA = 33°), in (**c**), and the anatomical parameters (TK and LL), in (**d**), are reported as well

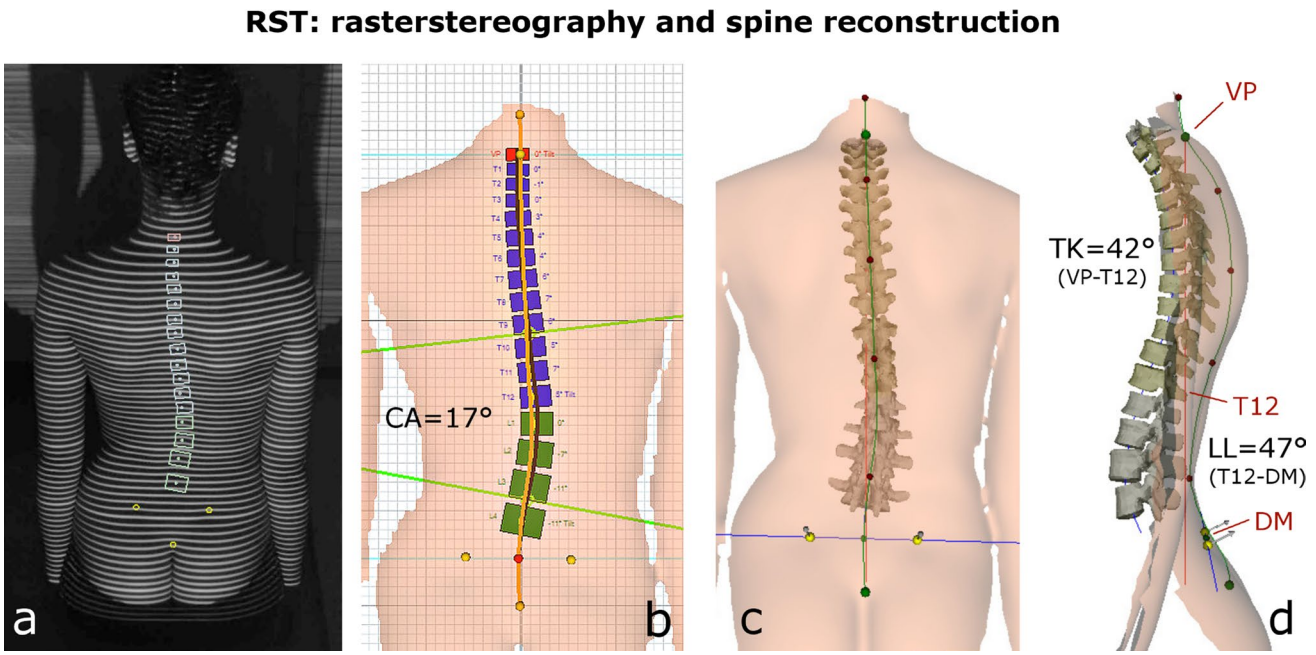

Fig. 2 Spine model reconstruction performed through RST (Formetric 4D) for the 13-year-old female subject presented in Fig. 1. **a** Picture shows the image of the back surface acquired with RST, with the spine model overlaid. **b** Picture reports the spine model and the Cobb angle (CA = 17°) obtained in correspondence of the scoliotic curve previously identified through RAD (see Fig. 1 for comparison). **c**, **d** Pictures depict the corresponding 3D spine model. The VP and DM landmarks, in (**d**), indicate, respectively, the vertebra prominens and the middle point between the sacral dimples, used to compute TK and LL

between the CA obtained, respectively, by RAD and RST. The accuracy of RST in measuring the sagittal parameters was checked by assessing the correlation about TK and LL. The differences were evaluated considering all subjects and differentiating between those subjects identified by RAD as 'scoliotic' (one or two curves) and 'not scoliotic' (zero curves). The Bland–Altman plots were evaluated as well.

In the follow-up evaluation, the accuracy of RST in measuring the progression of scoliosis in comparison with RAD was assessed by the within-subjects correlation coefficient, r_w, of the CA parameter. Accounting for the repeated observations factor, r_w allows verifying the agreement between RST and RAD in measuring the difference in the CA values obtained in the first acquisition session (baseline) and at the follow-up. More specifically, r_w quantifies whether an increase (or decrease) in the CA measured by RST within the individual is associated with an increase (or decrease) in that measured by RAD [38].

Statistical analysis

The r coefficient was computed according to Pearson correlation, or Spearman rank correlation in case that a normal distribution was not achieved. Both coefficients range from −1 to 1, where 0 indicates null linear correlation and −1 and 1 indicate full negative and positive linear correlations, respectively. Statistical significance of the coefficients was tested according to two-tailed *t* test or permutation distribution test assessing Pearson and Spearman coefficients, respectively. The computation of r_w (ranging likewise *r*) and the testing of the statistical significance were performed as described by Bland and Altman [38]. The total sample size (200 subjects) and that accounted for in the follow-up evaluation (30 subjects) were verified to guarantee identifying as significantly different from zero, a correlation value larger than 0.5 (i.e., moderate correlation), by *t* test at 0.05 level alpha and power 90% (G * Power software, Universitat Dusseldorf, Germany).

The difference in the mean values between female and male groups was assessed according to two-sample *t* test or Wilkoxon rank sum test. The difference in the proportion of the number of subjects in the gender groups was tested via chi-square or Fisher exact test where necessary. All the tests assumed 0.05 as significance level. The analyses were performed in MATLAB software (MathWorks Inc., Natick, MA).

Results

Eight subjects in 200 were excluded from the analyses because considered as dropout (i.e., in five cases, the femoral heads were inadvertently neglected in the radiographic scan, thus not allowing the 3D spine reconstruction, two

Table 1 Values describing population and distribution of scoliotic curves within the subjects (measured by RAD), considering all subjects and distinguishing between females (F) and males (M)

	All	F	M
Population			
Number of subjects	192	160 (83%)	32 (17%)
Age (years)	13 ± 2	13 ± 2	14 ± 3
Distribution of scoliotic curves within the subjects			
Number of scoliotic curves			
0	38 (20%)	28 (18%)	10 (31%)
1	26 (14%)	20 (13%)	6 (19%)
2	128 (67%)	112 (70%)	16 (50%)*
Subjects with severe scoliosis (CA > 40°)	47 (24%)	44 (28%)	3 (9%)*

Values expressed as mean ± SD or number of subjects (and percentage with respect to total)

*Significant difference between the F and M groups

Table 2 Cobb angle (CA), thoracic kyphosis (TK), and lumbar lordosis (LL) measured with RAD and RST, and difference between them, expressed as mean ± SD

	CA	TK	LL
RAD	33° ± 15°	36° ± 15°	43° ± 12°
RST	15° ± 11°*	37° ± 11°	34° ± 10°*
RAD minus RST	18° ± 11°	−1° ± 11°	10° ± 11°
Correlation RAD-RST			
All subjects	–	0.70#	0.51#
Scoliotic	0.55#	0.56#	0.51#
Not scoliotic	–	0.71#	0.51#

In the lower section: the correlation coefficients computed between RAD and RST, considering all the subjects and differentiating between scoliotic (one or two curves identified by RAD) and not scoliotic (zero curves)

*Significant difference between RAD and RST for the considered parameter

#Correlation value statistically different from zero

subjects resulted out of age range at the scanning time, and one subject exhibited congenital scoliosis). Accordingly, 192 subjects (160 females and 32 males) were analyzed. Female and male groups showed comparable mean age (13 and 14 years, respectively, Table 1). Scoliosis was found generally more severe in females. Indeed, the percentages of female subjects with two curves (70%) and CA > 40° (28%) were found statistically larger ($p = 0.05$ in both cases) than that of males (50% and 9%, respectively, Table 1).

Regarding the accuracy of RST in measuring the scoliosis degree, RST provided significant ($p < 0.001$) lower CA values (15° ± 11° as mean ± SD, Table 2) in comparison with RAD (33° ± 15°). The average difference in measuring CA was 18° ± 11°. The correlation between RAD and RST in measuring CA was found equal to 0.55 (Table 2), statistically different from zero ($p < 0.001$). Concerning the accuracy in measuring the sagittal parameters, comparable TK values were determined by RAD and RST (36° ± 15° and 37° ± 11°, respectively), whereas significant differences were found about LL (43° ± 12° and 34° ± 10°, $p < 0.001$). The r coefficient was equal to 0.70 ($p < 0.001$) for TK when considering all subjects, while lower values were found for LL (0.51, $p < 0.001$). It is important to note that the arms were kept flexed (placing fingertips on cheekbones) when performing RAD scan (Fig. 1a), whereas they were relaxed during RST (Fig. 2a). Such difference could in principle affect the correlation in the parameters. However, since this potential limitation had been observed during the execution of the study, two consecutive RST scans (one with arms flexed and one relaxed) were accordingly performed in the same session in the last 103 enrolled subjects. The correlation between RST and RAD revealed comparable values in the two cases: 0.48 and 0.55 for CA, 0.69 and 0.70 for TK, 0.53 and 0.51 for LL. This result confirms that arms position does not affect the measurements provided by RST.

When distinguishing between 'scoliotic' and 'not scoliotic' subjects, the r of TK diminished in 'scoliotic' group (0.56, $p < 0.001$) compared to 'not scoliotic' (0.71, $p < 0.001$). Similar values were exhibited by LL. When evaluating the linear regression between RST and RAD accounting for all the subjects, the line slope and the root-mean-square error (RMSE) resulted, respectively, 27° and 8° for CA (Fig. 3a), 26° and 8° for TK (Fig. 3b), 22° and 8° for LL (Fig. 3c). The Bland–Altman analysis revealed a mean difference of 18° when measuring CA (significantly different from zero, $p < 0.001$), −0.85° TK, and 10° ($p < 0.001$) LL (Fig. 3d–f).

Concerning the accuracy of RST in monitoring the scoliosis progression, 30 subjects (27 females and 3 males) were evaluated at baseline and 6-month follow-up. The average age was 14 ± 2 years, overall. The mean values of the difference between CA at follow-up and that at baseline (ΔCA) were small and not significantly different for RST and RAD (0° ± 7° and 1° ± 9°, respectively, Table 3). The within-subjects correlation r_w (Fig. 4a) and the mean difference in measuring ΔCA (Fig. 4b) were found equal to 0.30 and −0.89°, respectively, and both not statistically different from zero. Agreement between RST and RAD in identifying increased or decreased CA was found in the 67% of the evaluated subjects (Table 3).

Discussion

Concerning the accuracy of RST in identifying CA, the results pointed out barely moderate correlation between RST and RAD ($r = 0.55$), with a tendency of RST toward

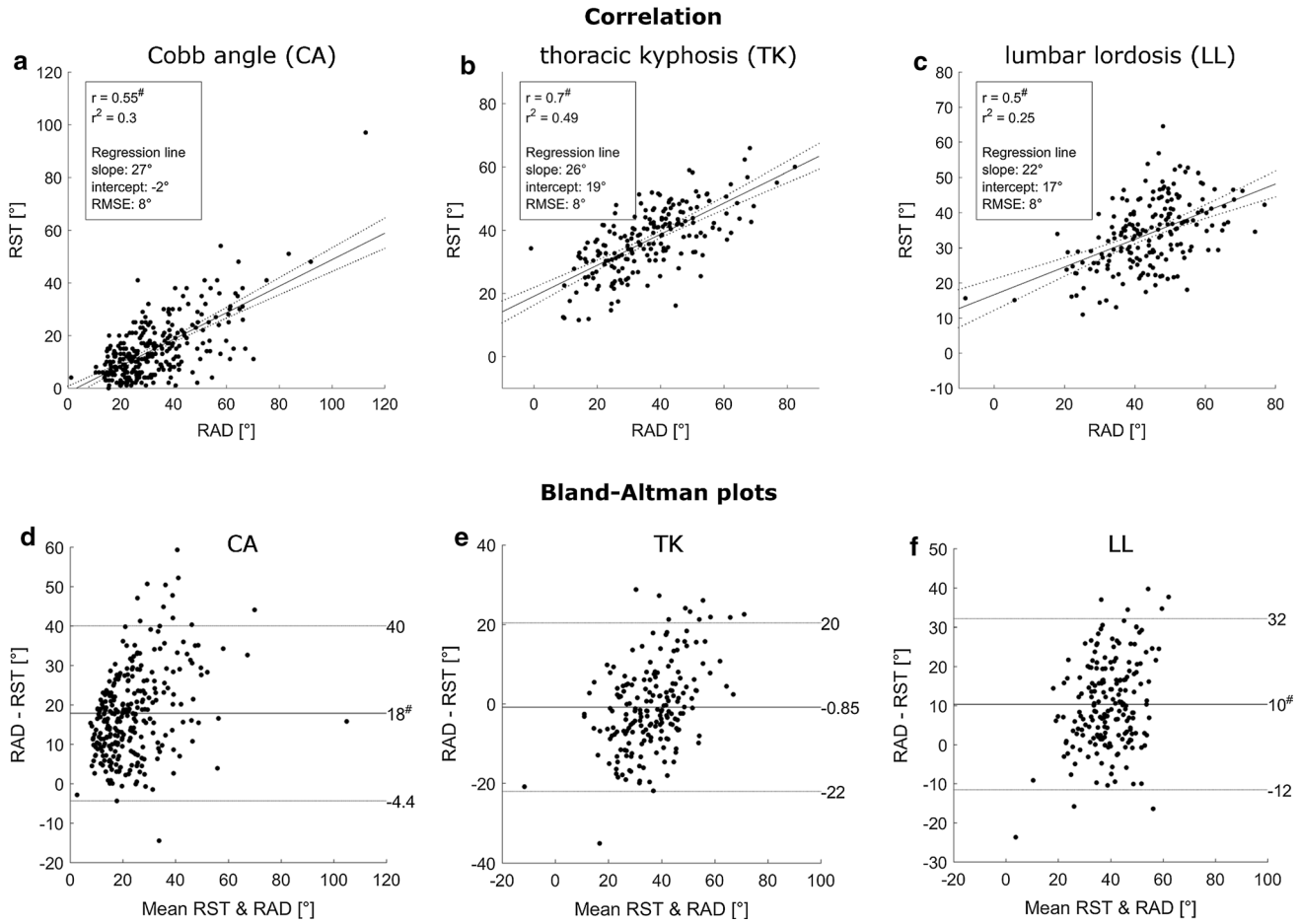

Fig. 3 Upper row: scatter correlation plots of the Cobb angle (CA, in **a**) and anatomical parameters (thoracic kyphosis—TK, in **b**; lumbar lordosis—LL, in **c**) obtained, respectively, with RAD and RST systems. For each parameter, the regression line with 95% confidence interval, the correlation coefficient *r* (followed by the '#' apex if found statistically different from zero), the *r*-squared, and slope, intercept and root-mean-square error (RMSE) of the regression line are reported. Lower row: Bland–Altman plots about CA, TK, and LL, with lines depicting the mean value (followed by '#' if found statistically different from zero), and the 95% (±1.96 SD) limits of agreement

Table 3 Cobb angle (CA), expressed as mean ± SD, at baseline, follow-up, and difference between them (ΔCA, follow-up minus baseline)

	Baseline	Follow-up	ΔCA
RAD	26° ± 9°	25° ± 8°	0° ± 7°
RST	12° ± 8°	13° ± 7°	1° ± 9°
	(RAD, RST)		Number of cases
Agreement	(↑, ↑) and (↓, ↓)		20 (67%)
Disagreement	(↑, ↓) and (↓, ↑)		10 (33%)

In the lower section: agreement between RAD and RST in identifying increased (↑) or decreased (↓) CA from baseline to follow-up

an underestimation (15° vs. 33° in mean value and average difference equal to 18°, Table 2, Fig. 3d). The low value of the slope of the regression line (27°, Fig. 3a) indicates that this tendency is more pronounced in correspondence of larger CA. The Bland–Altman analysis confirms that the agreement is lower in correspondence of larger average CA (Fig. 3d). The observed correlation (0.55) is in accordance with the lowest value found by other authors. The previous works reported indeed correlation coefficients ranging from 0.5 to 0.8 [30, 34–36]. In particular, 0.5 was pointed

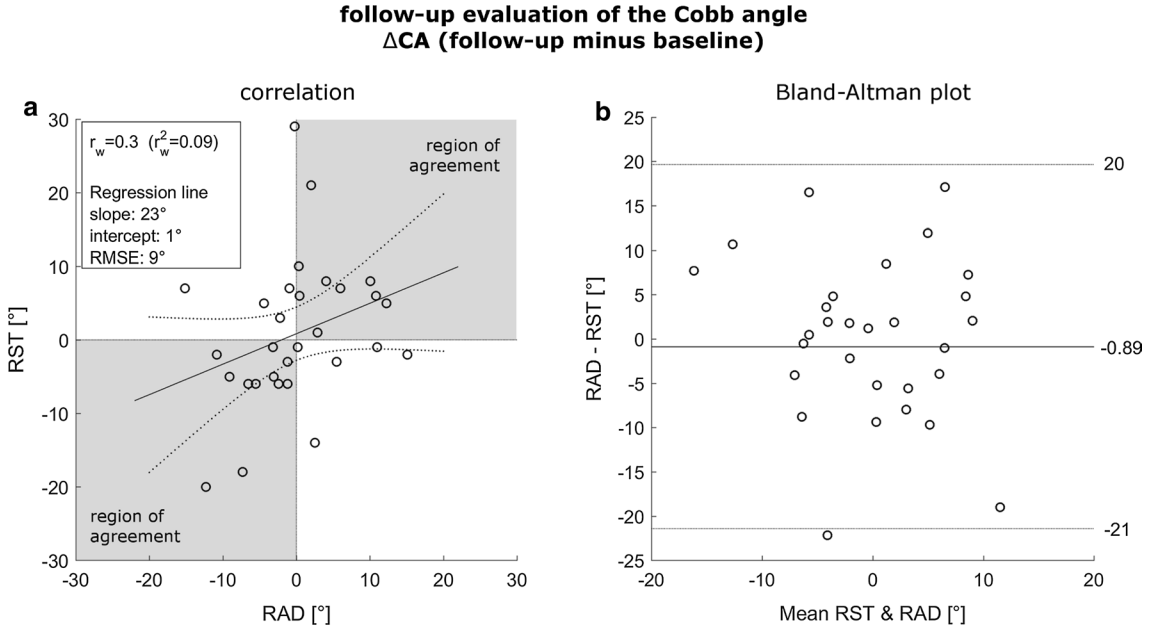

Fig. 4 Scatter correlation plot (**a**) and Bland–Altman plot (**b**) of the Cobb angle difference, ΔCA, measured with RAD and RST and defined as the difference between the CA obtained at follow-up and that previously measured at baseline for the same scoliotic curve. The correlation plot reports the within-subjects correlation coefficient r_w (found not statistically different from zero), r_w-squared, and slope, intercept and root-mean-square error (RMSE) of the regression line (with 95% confidence interval). The Bland–Altman plot depicts the line of the mean value (found not statistically different from zero) and the 95% (± 1.96 SD) limits of agreement

out by the study which accounted for the largest number of subjects, i.e., 193, when evaluating lumbar scoliotic curves [30]. Furthermore, the observed tendency of RST of providing lower CAs, compared to the radiographic evaluation, confirms the underestimation found in the other studies (ranging from 6° to 10°, in average value). To this regard, the difference in the 3D spine reconstruction obtained with RAD and RST is observable comparing that performed for one female subject (Figs. 1c, d, 2c, d). In this case, in the frontal plane, RAD provided CA = 33° for the curve T9-L3 (Fig. 1c), whereas the corresponding value from RST was 17° (Fig. 2b). Overall, the limitations in the 3D spine reconstruction affected also the measurement of the anatomical parameters in the sagittal plane (TK and LL). TK exhibited comparable values between RAD and RST (Table 2) and strong correlation considering all the subjects ($r = 0.7$, Fig. 3b), but the coefficient decreased to 0.56 in the presence of scoliotic curves (Table 2). Furthermore, RST revealed to be less accurate in determining LL ($r = 0.51$, Fig. 3c), with the tendency toward underestimation (10° in average value, Table 2). The Bland–Altman analysis showed that the discrepancies found in measuring TK and LL were similar in the parameters' ranges (Fig. 3e, f). To this regard, in the reconstructed spine model, RST accounts for the vertebra prominens to compute TK (i.e., VP-T12, Fig. 2d), and for the middle point between the sacral dimples to obtain LL (i.e., T12-DM). RAD accounts for the vertebral slope in the sagittal plane (i.e., T1–T12 and L1–L5, Fig. 1d). This difference can contribute to explain the low or moderate correlations found between the two methods.

Overall, the findings reveal thus that despite RST can recognize the presence of a spine deformity, it does not have sufficient accuracy for clinical purposes, i.e., to measure the angle of the actual scoliotic curve. As mentioned above, the correlation coefficients found evaluating CA ranged from 0.5 to 0.8. These values are similar to those pointed out assessing other radiation-free systems. The coefficients ranged from 0.6 to 0.8 in case of rasterstereographic devices [39, 40] and of Moirè topography [17, 41], whereas were larger (from 0.8 to 0.9) for ultrasound imaging [21, 22, 42, 43] and poor-to-moderate (from 0.3 to 0.6) for electromagnetic topography [20].

The accuracy of RST in monitoring the scoliosis progression was evaluated in 30 subjects selected for conservative treatment with corrective brace; the progression of the curve was quantified as the difference in the scoliosis degree between follow-up and baseline (ΔCA, Table 3). RST demonstrated low accuracy compared to RAD. Indeed, the correlation index was found to be weak ($r_w = 0.3$, Fig. 4a), and the difference between the two methods was generally scattered and not dependent on the average value of ΔCA (Fig. 4b). To this regard, it is worth noting that the use of brace can affect trunk growth (by modifying ribs shape and muscle mass) and the topography of the back surface,

without concomitantly changing the degree of the scoliotic curves. This aspect contributes to explaining the weak correlation found between RST and RAD. Indeed, the former method computes CA by exploiting the spine model based on the back surface topography (Fig. 2), whereas the latter allows for a direct measurement of the spine curves on the radiographic image (Fig. 1). The agreement in observing a similar progression was reported in the 67% of the subjects (Table 3). This value corresponds to the accuracy of RST as a test to correctly identifying ameliorated and deteriorated subjects. To this regard, sensitivity and specificity (the ability to identify the deteriorated and the ameliorated ones, respectively) were 64% and 69%. These findings do not sufficiently support the use of RST as alternative method for the evaluation of the scoliosis progression. However, two limitations have to be considered in this respect: a small sub-group of 30 subjects was evaluated, and the most of them presented from 'baseline' to '6-months follow-up', a moderate increase or decrease (lower than 10°) in the CA (Fig. 4a). Accordingly, a larger number of subjects and a longer follow-up period should be evaluated in future studies.

Concerning the comparison with previous works and other radiation-free systems, few studies investigated the potential exploitation for monitoring the scoliosis progression. Assessing the RST, other authors reported a correlation of 0.7 over a mean follow-up period of 8 years [37]. However, the coefficient was calculated without considering the within-subjects factor, accounted for in the present study by r_w, thus potentially providing an overestimated correlation value [38]. Moreover, the validity of RST was assessed by comparing the lateral vertebral deviation of the reconstructed spine (which interprets the presence of spine deformity), and not the Cobb angles characterizing the actual scoliotic curves. Other works evaluated sensitivity and specificity about devices based on laser scanner or RST at 1-year follow-up [44–46]. In these cases, sensitivity ranged from 73 to 93% and specificity from 44 to 80%, respectively.

In conclusion, although previous studies supported the use of RST in monitoring the presence of spine deformity in JIS and AIS subjects, the present findings pointed out moderate accuracy in measuring the scoliosis degree and low accuracy in monitoring the curve progression. Thus, RST (specifically Formetric 4D) cannot be considered as a valid noninvasive alternative to low-dose radiographic evaluation, for clinical or prognostic purposes. However, since demonstrated to be capable of recognizing the presence of spine deformity (but not sufficiently accurate for quantifying it), RST could be in principle considered for the early screening in large JIS and AIS populations (e.g., in school context). To this regard, cost-benefit analysis with respect to other traditional approaches (e.g., Adam's test) should be previously performed.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

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