Radiation-free quantitative assessment of scoliosis: a multi center prospective study

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Abstract Accurate quantitative measurements of the spine are essential for deformity diagnosis and assessment of curve progression. There is much concern related to the multiple exposures to ionizing radiation associated with the Cobb method of radiographic measurement, currently the standard procedure for diagnosis and follow-up of the progression of scoliosis. In addition, the Cobb method relies on 2-D analysis of a 3-D deformity. The aim of this prospective study was to investigate the clinical value of Ortelius800^{TM} that provides a radiation-free method for scoliosis assessment in three planes (coronal, sagittal, apical), with simultaneous automatic calculation of the Cobb angle in both coronal and sagittal views. Analysis of the clinical value of the device for assessing spinal

deformities was performed on patients with adolescent idiopathic scoliosis, deformity angles ranging from 10° to 48°. Correlation between Cobb angles measured manually on standard erect posteroanterior radiographs and those calculated by Ortelius800^{TM} showed an absolute difference between the measurements to be significantly less than $\pm 5^\circ$ for coronal measurements and significantly less than $\pm 6^\circ$ for sagittal measurements indicating good correlation between the two methods. The measurements from four independent sites and six independent examiners were not significantly different. We found the novel clinical tool to be reliable for following mild and moderate idiopathic curves in both coronal and sagittal planes, without exposing the patient to ionizing radiation. Considering the need for further validation of this new method, any change in treatment protocol should still be based on radiographic control.

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Introduction

Children who are diagnosed with a spinal deformity and assessed regularly in an outpatient clinic often undergo repeated radiographic examinations. However, this commonly employed imaging modality bears several problems relative to spinal deformities. Curves are described by their appearance on plain films and quantified by the magnitude of the Cobb angle derived from the radiograph [7]. Interpretation of these results is difficult because radiographs represent oblique projections of the twisting spine, and Cobb angle can vary

widely depending on the angle of the beam to the patient [8]. Moreover, intra- and inter-observer errors have been observed in the calculation of the Cobb angle as well [20]. The average intra-observer standard deviation (SD) has been reported as approximately 3.5° and inter-observer SD ranging from 2.8° to 7.2° [3, 6, 15].

Scoliosis patients typically undergo numerous spinal radiographs (average of 25) during which they are exposed to relatively high doses of ionizing radiation (average of 10.8 cGy) [10]. Bone and Hsieh [4] studied a group of children surgically treated for idiopathic scoliosis, hip dysplasia and leg length discrepancy. In this group, the risks for developing leukemia, breast cancer or a heritable defect, respectively, were 0.8, 2.1 and 3% higher than the baseline risks.

In addition, Levy et al. [12] found that women who received a surgical correction of scoliosis and referred before the age of 13 years old were at greatest risk for cancer, with 238 excess cases per 100,000. In an earlier study, Levy et al. [13] found 1–2% excess lifetime risk of cancer (12–25/1,000) among women treated for scoliosis. Another effect of radiation exposure in patients with scoliosis was studied by Goldberg et al. [11]. The authors reported that radiation exposure of the ovaries in patients with scoliosis adversely affected future reproductive outcomes.

Doody et al. [10] found that exposure to multiple diagnosis radiographic examinations during childhood and adolescence may increase the risk of breast cancer among women with scoliosis. The overall mortality risk among 5,573 women in their study was two times greater than that estimated in the general population. Moreover, the risk of dying from breast cancer was shown to increase significantly with the number of radiographic examinations. Importantly, exposure to radiation in patients with adolescent idiopathic scoliosis (AIS) occurs during the growth spurt, which may amplify the deleterious biologic effects [16, 22]. Although modern radiographic techniques usually employ lower radiation doses, recent publications suggest that the risks of exposure to low doses of ionizing radiation (10 cGy or less) cannot be considered insignificant, and recommend that all efforts be made to reduce exposure [5, 18].

This concern has prompted the development of alternative methods for quantifying spinal deformity without ionizing radiation, such as those based on the assessment of the surface topography of the back in various ways. Two basic types of technologies have been implemented to assess the topography. Measurements are either made by direct contact with the patient's back, or by various methods of scanned light or photographic techniques to map the surface (i.e.,

Moiré Contourgraphy, Quantec) [17]. Position, body-build, and fat folds contribute to the inaccuracies of surface topography. On the basis of the clinical experience acquired using this method, some authors have concluded that there is poor correlation between the observed body asymmetry and the underlying scoliosis. In a study carried out by Sahlstrand [23] on 139 patients with scoliosis, no correlation between the Moiré asymmetry and the Cobb angle was revealed.

We conducted a prospective multi-center study in order to evaluate a different approach made possible by a new, radiation-free system. It is a user-friendly system designed to provide a three-dimensional (3-D) assessment of the scoliotic deformity (Fig. 1), which is based on the direct measurement of the position of spinous processes tips in space. A low intensity electromagnetic field records the spatial position of a sensor attached to examiner's finger while palpating the patient's spinous processes. The signals received during the examination of spinous processes provide a graphical reconstruction of the spine, simultaneously with automatic presentation of the location of each vertebra as well as deformity angle calculation (Fig. 2).

We investigated the reliability of the curve measurements made by the new system and the correlation of results with the standard radiographically measured Cobb angles in both the coronal and sagittal planes.

Materials and methods

One hundred and twenty-four patients diagnosed with AIS from four different independent medical centers [Israel (1)—51 patients, Israel (2)—22 patients, France—26 patients, Spain—25 patients] were included in this study with the approval of institutional

Fig. 1 Ortelius800™ system and procedure. Palpation of the spinous processes with the fingertip sensor during the examination procedure

Fig. 2 Comparison of standard full spine radiographs to Ortelius800™ measurements. **a** Standard coronal and sagittal radiographs. **b** Corresponding Ortelius800™ graphical image with automatic Cobb angle analysis. **c** Corresponding Ortelius800™ three-plane assessment

review board of each center. Informed consent was obtained from the parents or guardians. The average age of the examined adolescents was 13 years (SD 3.17; range 10–26). The patient population was comprised of 35 males and 89 females, all of them being older than 10 years of age and having curves less than 55°. None of the subjects had previous spinal operations or radiographs taken while wearing a brace.

All patients underwent a clinical and radiological assessment (coronal in all cases and sagittal in 38 cases), from which the Cobb angle was measured and in addition, an Ortelius800™ scan was performed. In each participating center, the reading and measuring of Cobb angle on radiographs and the Ortelius800™ scanning were performed by an orthopedic surgeon and by independent trained examiners (technicians, physical therapists, physician's assistants and rehabilitation specialists), respectively. The measurements were done blindly relative to each other.

Radiograph analysis

Standing full-spine coronal radiographs were obtained for each patient and lateral radiographs were taken for 38 patients. The orthopedic surgeons from the different centers analyzed independently the X-rays with the standard Cobb method. Radiograph analysis revealed 249 deformity measurements with a mean Cobb angle of 17.9° (SD 10.2; range 3–48°) that included 142 (57%) thoracic curves (thoracic and thoracolumbar curves) with a mean Cobb angle of 18.3° (SD 11.0; range 3–48°), and 107 (43%) lumbar curves with a mean Cobb angle of 17.4° (SD 9.0; range 3–38°).

Thirty-eight sagittal thoracic measurements that were obtained had a mean Cobb angle of 36.1° (SD 12.7; range 12–62°).

Examination procedure

The Ortelius800™ system (OrthoScan Technologies, Rosh Pina, Israel) consists of a main console and a fingertip scanner (Fig. 1). The examiner first measures

the axial trunk rotation (ATR) at thoracic, thoracolumbar and lumbar levels using a scoliometer with the patient in the forward bending position. After that, the standing patient is positioned adjacent to the device, using the hip bar in order to minimize the movement during the examination. The operator palpates the spinous processes of the vertebrae using the index and middle fingers. Beginning with C7, the examiner records the positions of the spinous processes along the length of the spine by pressing on a footswitch. Additional landmarks recorded are the upper border of the gluteal cleft and the occipital protuberance. The procedure is repeated twice for each patient, and the system proceeds with the deformity angle calculation only if the two measurements match.

The time required for this procedure is less than 2 min for a trained examiner. The system provides an instant graphical presentation of the spinal deformity as well as automatic deformity angle calculations of both the coronal and sagittal views in real time. Details on the patient history, height/weight measurements, and examination results are stored in the patient log for comparisons with those obtained in follow-up visits for monitoring the progression of scoliosis.

Intra-observer variability

Sixty-five patients from one center (1) were examined twice by same examiner during the same outpatient visit. The time interval between the repeated exams was at least 5 min, during which the patient was instructed to move, seat and rest, and then repositioned again for the second exam. Examination of these 65 patients yielded 122 pairs of coronal deformity angles and 65 pairs of sagittal thoracic angles that were compared to assess the intra-observer reliability.

Inter-observer variability

Twenty-nine patients from one center (2) were examined twice by two examiners during the same outpatient visit. Examination of these 29 patients yielded 49

pairs of coronal deformity angles and 29 pairs of sagittal thoracic angles that were compared to assess the inter-observer reliability.

Statistical analysis

Pearson correlation coefficient was calculated for matched pair measurements according to the spinal curve type (thoracic, lumbar and combined curves) and subsequently compared with the Fisher Z-transform test. The mean difference and the absolute mean difference between measurements with the two methods were estimated. In addition, descriptive statistics with 95% confidence intervals, Student's *t* test and Wilcoxon signed-ranks test were carried out.

To compare the results from the four centers, one-way analysis of variance with fixed effects on the differences between the matched measurements with both methods and Kruskal–Wallis rank sum test were used.

Results

Correlation between Cobb and Ortelius800^{TM} calculated coronal angles

The measurements of the coronal angles showed a statistically significant correlation with the corresponding radiograph measurements (Table 1). Pearson's correlation coefficient between deformity angles

obtained by the two methods was significant (0.86) with a *P* value < 0.0001 (Fig. 3).

The mean radiographic Cobb angle was 17.9° (SD = 10.15°) and the mean deformity measurement obtained with the new device in the same patient population was 17.7° (SD = 10.77°). The mean absolute difference between deformity angle measurements with the two methods was 4°–4.8° and a *t* test for matched pairs showed that these differences are not statistically significant (*P* = 0.63). As shown by the absolute differences histogram (Fig. 3b) 76% of the differences are within 6°, while 93% are within 10°. When the curve location is considered, the correlation between the two matched measurements was highly significant with a Pearson's coefficient of 0.87 (*P* < 0.0001) for thoracic curves and a Pearson's coefficient of 0.84 (*P* < 0.0001) for the lumbar curves. A detailed analysis showed that 67% of the differences in thoracic curves between the methods are within 6°, and 93% are within 10°. A very similar distribution can be seen in the differences in the lumbar curves, 65% of the differences being within 6° and 94% within 10°. The differences falling outside this range of error represent those cases in which an accurate palpation of the spinous processes that is an essential part of the examination was difficult to perform.

Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of the coronal measurements with the new device were calculated according to specific different thresholds, between 10° and 25°, which had been previously determined from the radiographs (Table 2).

Table 1 Descriptive and comparative statistics of Ortelius800^{TM} and radiographic measurements—coronal plane

Curve type	Measurements (degree)	N	Mean	SD	95% Confidence interval	Median	Inter-quartile range	Pearson	<i>t</i> Test for matched pairs
Thoracic	Radiograph	142	18.30	10.95		17	11–23	0.87	Pv = 0.7744
	Ortelius800 ^{TM}		18.17	11.00		18	10–26	Pv < 0.0001	
	Difference		0.13	5.55	(−0.79; 1.05)	0	−4 to 4		
	Absolute diff.		4.47	3.27	(3.93; 5.00)	4	2–6		
Lumbar	Radiograph	107	17.35	9.00		17	11–22	0.84	Pv = 0.6979
	Ortelius800 ^{TM}		17.13	10.46		18	8–24	Pv < 0.0001	
	Difference		0.21	5.71	(−0.88; 1.31)	0	−4 to 3		
	Absolute diff.		4.31	3.73	(3.60; 5.02)	3	2–7		
All curves	Radiograph	249	17.89	10.15		17	10–24	0.86	Pv = 0.6357
	Ortelius800 ^{TM}		17.72	10.77		17	9–25	Pv < 0.0001	
	Difference		0.17	5.61	(−0.53; 0.87)	0	−4 to 4		
	Absolute diff.		4.40	3.47	(3.97; 4.83)	4	2–6		

SD Standard deviation, *difference* difference between radiographic and Ortelius800^{TM} angles, *absolute diff.* absolute difference between matched radiographic and Ortelius800^{TM} measurements, *95% confidence interval* for mean difference under Student's *t* distribution, *95% confidence interval* for mean absolute difference under normal approximation for mean distribution (central limit theorem), *inter-quartile range* third quartile of distribution–first quartile, *Pearson* Pearson's correlation coefficient, *Pv* significance of correlation

Fig. 3 Comparison of Ortelius800™ and radiographic measurements—coronal plane. **a** The Ortelius800™ measurements showed a significant statistical correlation with the corresponding radiograph measurements. **b** Small absolute differences between the measuring methods are most frequent and large absolute differences are scarce and appear in the tail of the distribution

Correlation between Cobb and Ortelius800™ calculated sagittal angles

Pearson's correlation coefficient between sagittal angles obtained by the two methods (Table 3) was highly

Table 2 Performance of Ortelius800™ at different Cobb angle thresholds

	Cobb angle threshold			
	10°	15°	20°	25°
True positive (patients)	171	127	79	49
True negative (patients)	42	91	126	176
False positive (patients)	14	11	19	15
False negative (patients)	22	20	25	9
Positive predictive value (%)	92	92	81	77
Negative predictive value (%)	66	82	83	95
Sensitivity (%)	89	86	76	84
Specificity (%)	75	89	87	92

significant (0.85) with a P value < 0.0001 (Fig. 4a). The mean radiographic thoracic kyphosis Cobb angle was 36.1° (SD = 12.65°) and the mean measurement in the same patient population obtained with the new system was 36.7° (SD = 12.29°). The mean absolute difference between deformity angle measurements with the two methods was 5° – 6.2° and t test for matched pairs shows that these differences are not statistically significant ($P = 0.60$). The absolute differences histogram (Fig. 4) shows that 63 and 87% of the differences are within 6° and 9° , respectively.

Comparison of results from four independent medical centers

Statistical analysis found no significant difference between the two methods of measurement as compared between the four independent centers participating in this study (Fig. 5). One-way analysis of variance and Kruskal–Wallis rank sum test failed to find the differences between measurements from the independent centers to be statistically significant, with P values of 0.9417 and 0.2318, respectively.

Intra-observer reliability

The results of both coronal and sagittal angles when measured twice by the same examiner (Fig. 6) were analyzed. The mean absolute difference between the paired coronal measurements was 2.74° (SD = 2.4°), with a Pearson's correlation coefficient of 0.86. Paired t test found no significant difference between these coronal angles ($P = 0.11$). Between the paired sagittal measurements, the mean absolute difference was 4.83° (SD = 4.28°) and the Pearson's correlation coefficient was 0.87. Paired t test showed no significant difference between the sagittal measurements ($P = 0.67$).

Inter-observer reliability

Coronal and sagittal angles were measured by two different examiners (Fig. 7). The analysis of the paired coronal measurements yielded a mean absolute difference of 6.3° (SD = 4.9°) and the Pearson's correlation coefficient of 0.76, while paired t test revealed no significant difference between the coronal measurements ($P = 0.08$). The analysis of the paired sagittal measurements revealed a mean absolute difference of 6.1° (SD = 4.9°) and a Pearson's correlation coefficient of 0.79, while paired t test showed no significant difference between the measurements ($P = 0.11$).

Table 3 Descriptive and comparative statistics of Ortelius800™ and Radiographic measurements—sagittal plane (kyphosis)

Measurements (degree)	N	Mean	SD	95% Confidence interval	Median	Inter-quartile range	Pearson	t Test for matched pairs
Radiograph	38	36.08	12.65		33.5	25–46	0.85 Pv < 0.0001	Pv = 0.6035
Ortelius800™		36.66	12.29		36.5	26–44		
Difference		0.58	6.81	(-1.66; 2.82)	0.5	-5 to 5		
Absolute diff.		5.63	3.77	(5.02; 6.24)	5	3–8		

Discussion

Non-invasive assessment of spinal deformities

The “gold standard” for routine monitoring of scoliosis is the Cobb angle measurement on radiographs of the spine. It presents several drawbacks and limitations that include multiple radiation exposures and 2-D projection of a 3-D deformity, as well as intra- and inter-observer variability [3, 6–8, 15, 20]. These reasons have provided the rationale for an ongoing search for

non-invasive alternative methods that would be capable to supply 3-D information on the spine deformity, such as surface topography. Notwithstanding its advantages, some authors have concluded that there is a poor correlation between the observed body asymmetry and the underlying scoliosis [1, 19, 23]. Since Cobb angle and rib hump measurements do not correlate well [24], topographic measures alone are not good indicators of Cobb angle. In one study carried out by Sahlstrand [23] on 139 patients with scoliosis, the assessment with Moiré topography yielded 23 false positive findings and there was no correlation between the Moiré asymmetry and the Cobb angle. While clinicians are familiar with radiographs and the resultant simple geometric measures, surface topography techniques produce unfamiliar, abstract images that are difficult to interpret. For these reasons, surface topography has not been widely accepted and integrated into the standard of care and assessment of patients with spinal deformity. The system we evaluated in the present study introduces a new approach to non-invasive assessment of spinal deformities. It provides the familiar Cobb angle radiation-free, by

Fig. 4 Comparison of Ortelius800™ and radiographic measurements—sagittal thoracic spine. **a** The Ortelius800™ measurements showed a significant statistical correlation with the corresponding radiograph measurements. **b** Small absolute differences between the measuring methods are most frequent and large absolute differences are scarce and appear in the tail of the distribution

Fig. 5 Comparison of results from four independent medical centers. There is no significant difference in the correlation of Ortelius800™ and radiographic measurements between the four independent centers

Fig. 6 Intra-observer reliability. Significant statistical correlation was observed between the paired coronal measurements (a), and between the paired sagittal measurements (b)

combining data on the surface of the back with a simultaneous 3D visualization of the spatial position of spinous processes. Of note, however, since the acquired information is based on the palpation of the spinous processes, the approach might be inadequate in patients in whom the spinous processes have been surgically removed or altered. Considering this limitation, we excluded such patients from the study. We also found that many of the patients for whom the differences were beyond the accepted range of error (10°) had a high body mass index (BMI), which proved to be another obstacle for achieving an accurate measurement.

Correlation between deformity angles measured by the two techniques

The reliability of the new device was assessed by comparing the scan results with those obtained by Cobb measurements of standard radiographs of patients with AIS. Despite the fact that the intra-observer reliability of Cobb angle measurements of radiographs is not ideal [6, 20], it is the current gold standard for the measurement of the deformity, as well as the accepted instrument for clinical decision-making. Previous studies [2, 25] have monitored

Fig. 7 Inter-observer reliability. Significant statistical correlation was observed between the paired coronal measurements (a), and between the paired sagittal measurements (b)

diurnal variation in Cobb angle and have reported wide differences that were explained by disc shrinkage. As first stated by Risser in 1958 [21] and now widely accepted, a 10° increase in Cobb angle indicates a clinically significant change that may require a major treatment decision. Our results suggest that the new system is sufficiently reliable to be used in combination with other patient's data (child's age, physical exam and prognosis) to provide the necessary information for routine scoliosis monitoring. Measurements with the new device showed sensitivity and specificity of 89 and 75%, respectively, for the detection of coronal angles higher than 10° . Sensitivity was slightly lower when a threshold of 20° was used (76%). However, with thresholds of 15° or 25° as cutoff points, the performance improves (84 and 86% sensitivity), which can be considered reasonable if we take into account the error of radiograph measurements currently in use.

Thirty-eight of the patients provided sagittal view radiographs, and with the new device, simultaneous Cobb angle analysis for coronal and sagittal views was obtained. Thoracic kyphosis was measured between T3 and T12 in both Orteliu800^{TM} scans and radiographic measurements. Comparison of results obtained with the new technique correlated well with those obtained

from the radiographs with an absolute difference between the measurements significantly less than 5° ($P = 0.3126$). We found the correlation of sagittal view analysis to be slightly less than those of the coronal plane. Discrepancies in patient positioning between the two methods may explain this difference [14]. For standard lateral radiographs, the patient is required to maintain the upper extremities at approximately 60° forward flexion in order to allow for an optimal and standard imaging of the spine, while the new technique allows the patients to stand in their normal standing position. With the patient in a more natural position, we would expect the results to reflect a more accurate and informative measurement. Sagittal malalignment, which may play an important role in the pathogenesis of scoliosis, should be therefore closely monitored. Thoracic lordosis is an important early sign of developing progressive AIS that can be demonstrated in children before the development of lateral curvature and rotation [9]. Monitoring of thoracic kyphosis can provide an important indication for progression of scoliosis and therefore should be performed routinely. Considering the risks of excessive radiation exposure, physicians may think twice before performing additional radiographs [14]. The advantage of a radiation-free approach is that it allows additional sagittal view during each follow-up visit.

Comparison of results from four independent medical centers

Six different examiners in four independent centers performed the patients' examinations in the present study. Statistical analysis shows that there is no

significant difference between the correlations of measurements with the two techniques between the four independent centers (Table 4).

Intra- and inter-observer reliability

We found a good reliability (Pearson's correlation coefficient > 0.75) both in intra- and inter-observer analyses. Moreover, the deviations obtained are in the same range as those reported for repeated readings and Cobb angle measurements on radiographs [3, 6, 15].

Conclusion

The present prospective multi-center study was held in order to investigate the clinical value of a new device for the diagnosis and monitoring of AIS in patients with a wide range of deformity angles (ranging from 10 to 48°). In all four participating centers from three different countries, the measurements were found to correlate well with radiographically measured Cobb angles in both coronal and sagittal planes, independent of the examiner's professional background or training level. Although the study did not examine the correlation in severe curves, small children, congenital scoliosis and deformity secondary to neuromuscular diseases, it was found to be reliable for following mild and moderate idiopathic curves in both the coronal and sagittal planes, without exposing the patient to ionizing radiation. Further investigations are needed in order to assess the system capability to detect possible changes in the deformity angle with growing age, for which a longitudinal study would be indicated.

Table 4 Descriptive and comparative statistics of Ortelius800™ and radiographic measurements (coronal plane) by four different centers

Center	Measurements (degree)	N	Mean	SD	Median	Inter-quartile range	Pearson
Israel (1)	Radiograph	107	17.11	9.90	16	10–23	0.86 Pv < 0.0001
	Ortelius 800™	(51 patients)	17.27	10.93	15	9.5–23	
	Difference		–0.16	5.51	0	–3.5 to 4	
	Absolute diff.		4.34	3.37	4	2–6	
Israel (2)	Radiograph	44	17.91	11.27	17	9–22.25	0.91 Pv < 0.0001
	Ortelius800™	(22 patients)	17.45	9.73	16.5	8–24	
	Difference		0.52	4.73	0.5	–1 to 3	
	Absolute diff.		3.50	3.21	3	1–4	
France	Radiograph	50	19.24	12.38	18.5	8.25–29.75	0.88 Pv < 0.0001
	Ortelius800™	(26 patients)	19.48	10.84	16.5	7–26	
	Difference		–0.24	6.31	0	–4 to 3	
	Absolute diff.		5.00	3.80	4	2–7	
Spain	Radiograph	48	19.15	8.49	19	14–23.25	0.82 Pv < 0.0001
	Ortelius800™	(25 patients)	18.50	9.87	18	12–27	
	Difference		0.65	5.89	0	–4 to 5	
	Absolute diff.		4.73	3.51	4	2–7	

On the basis of the authors' experience during the study, spine radiographs must be carried out during the first evaluation of a suspected patient with AIS, in order to rule out the presence of vertebral anomalies and to have a baseline for future comparisons. In case of a significant difference (of more than 10°) between the initial X-ray measurements and those obtained using the new method, we do not recommend its further use on routine basis. Otherwise, Ortelius800^{TM} measurements should be performed every 4–6 months during the routine outpatient visit. However, standard X-rays should be taken every third consecutive visit, or when one or more of the following occurs: (a) an increase of more than 10° in the deformity angle; (b) an increase of more than 5° in trunk rotation. (c) any unusual visual changes in body balance. Most importantly, as the new method needs further validation, any change in the patient's treatment protocol should still be based on radiographic control.

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