Reproducibility and repeatability of a new computerized software for sagittal spinopelvic and scoliosis curvature radiologic measurements: Keops®

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European Spine Journal

ISSN 0940-6719

Eur Spine J
DOI 10.1007/s00586-015-3817-1

Springer

Eur Spine J
DOI 10.1007/s00586-015-3817-1

IDEAS AND TECHNICAL INNOVATIONS

Reproducibility and repeatability of a new computerized software for sagittal spinopelvic and scoliosis curvature radiologic measurements: Keops®

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Received: 7 April 2014 / Revised: 14 February 2015 / Accepted: 14 February 2015

Abstract

Purpose The purpose of this study was to evaluate the inter- and intra-observer variability of the computerized radiologic measurements using Keops® and to determine the bias between the software and the standard paper measurement.

Methods Four individuals measured all frontal and sagittal variables on the 30 X-rays randomly selected on two occasions (test and retest conditions). The Bland–Altman plot was used to determine the degree of agreement between the measurement on paper X-ray and the measurement using Keops® for all reviewers and for the two measures; the intraclass correlation coefficient (ICC) was calculated for each pair of analyses to assess interobserver reproducibility among the four reviewers for the same patient using either paper X-ray or Keops® measurement and finally, concordance correlation coefficient (rc) was calculated to assess intraobserver repeatability among the same reviewer for one patient between the two measure using the same method (paper or Keops®).

Results The mean difference calculated between the two methods was minimal at −0, 4° ± 3.41° [−7.1; 6.4] for frontal measurement and 0.1° ± 3.52° [−6.7; 6.8] for sagittal measurement. Keops® has a better interobserver reproducibility than paper measurement for determination of the sagittal pelvic parameter (ICC = 0.9960 vs. 0.9931; $p = 0.0001$). It has a better intraobserver repeatability than paper for determination of Cobbs angle (rc = 0.9872 vs. 0.9808; $p < 0.0001$) and for pelvic parameter (rc = 0.9981 vs. 0.9953; $p < 0.0001$).

Conclusions We conclude that Keops® has no bias compared to the traditionally paper measurement, and moreover, the repeatability and the reproducibility of measurements with this method is much better than with similar standard radiologic measures done manually in both frontal and sagittal plane and that the use of this software can be recommended for clinical application.

Level of evidence Diagnostic, level III.

Keywords Reproducibility · Repeatability · Spinopelvic angle · Cobb's angle

Background

The measurement of spinal and pelvic alignment in the sagittal plane and scoliosis curve in frontal plane is of prime importance for the evaluation of various disorders of the spine. The Cobb angle is the standard parameter for determining the severity of the scoliosis [1, 2]. Spinal balance is conceived as the result of an optimal lordotic positioning of the vertebrae above a correctly oriented pelvis [3, 4], which therefore with its compensatory

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Published online: 28 February 2015

mechanisms acts as an equalizer of the sagittal balance [5, 6].

Manual radiologic measurement of these angles and curvatures has been shown to yield a relatively high inter- and intra-observer variation [7, 8], thus limiting the interpretation of clinical studies. In clinical practice, a simple system is required to establish the different parameters of the spine and pelvis.

Keops® is a database that provides a powerful software to make analysis on computerized plane radiographic measurement. The database has been created in 2010 by SMAIO (Lyon, France) and an imaging software has been added in 2011. Up to date, more than one hundred centers in 12 countries use Keops® and there are already 25,000 patients in the database.

Purpose

The purpose of this study was to evaluate the inter- and intra-observer variability of the computerized radiologic measurements using Keops® and to determine the bias between the software and the standard paper measurement.

Methods

The standing X-rays of 30 subjects were randomly selected from the databases of the participating medical institutions. The independent evaluator was instructed to conduct a random sampling to ensure a wide range of different pathologies to be included. All the radiographs of the pelvis and entire spine were realized using EOS system®, with each subject in a comfortable standing position, the knees fully extended, and the hips perpendicular to the X-ray cassette. The characteristics of this population were gender ratio of 27 women and three men, a mean age of 43.3 years ranging from 12 to 79 years, and various history of previous spinal pathology as well as lower limb length inequality or scoliotic deformity on clinical examination.

Each X-ray was examined four times by each reviewer: two measurements were realized on paper X-rays and two measurement using Keops®. To generate a geometric model of the spine and pelvis with Keops® from which the computerized geometric measurements are obtained, the followings steps are done:

- For sagittal measurement (Fig. 1a): first, eight points are identified on the pelvis and recorded on each radiograph using a mouse pointing device—one at each end of the sacral plate and three on the contour of each acetabular rim to determine the center of the right and left femoral heads and the pelvic parameter are calculated automatically. Second, the following points need to be identified on the vertebral bodies and recorded on each radiograph using a mouse pointing device: four points at the corner of the L5 vertebral body, two points at the inferior corner of C2 and one point located in the anterior inferior corner of C7. A method for calculating the best-fit arcs passing through these points acquired on the spine is then used to display automatically the sagittal shape of the spine, which is then modeled by the software as a succession of curved segments representing thoracic kyphosis and lumbar lordosis. Finally, a local analysis is done by pointing the contour of each vertebral body of interest.
- Fig 1 a for sagittal measurement, 12 points are identified and recorded on each radiograph using a mouse pointing device—one at each end of the sacral plate, three on the contour of each acetabular rim to determine the center of the right and left femoral heads. Finally, a local analysis is done by pointing the contour of each vertebral body of the apex vertebra of each scoliosis curve. Fig 1 b for frontal measurement, two points on the iliac crest and two on the acromion are selected.

Four individuals from four different centers, three residents' spine surgeons and one rehabilitation PhD, measured all variables (pelvic incidence, pelvic tilt, sacral slope, lumbar lordosis, thoracic kyphosis and Cobbs angle) on the 30 X-rays on two occasions (test and retest conditions). All of them had different level of experience. The reviewers were blinded to all case identifiers and to the results of their co-investigators.

A commercial software, Medcalc® (MedCalc Software, Acacialaan 22, B-8400 Ostend, Belgium), was used to do the statistical analysis. Each parameter for each X-rays was recorded. The Bland–Altman plot was used to determine the degree of agreement between the measurement on paper X-ray and the measurement using Keops® for all reviewers and for the two measures; and for each dataset the bias and the 95 % limits of agreement were calculated. This analysis is the only recommended for measuring agreement in method comparison studies [9]. In addition, the intraclass correlation coefficient (ICC) was calculated for each pair of analyses to assess interobserver reproducibility among the four reviewers for the same patient using either paper X-ray or Keops® measurement. Finally, concordance correlation coefficient (rc) was calculated to assess intraobserver repeatability among the same reviewer for one patient between the two measure using the same method (paper or Keops®).

Results

The average time needed for calculation of all parameters for one subject varied depending on the

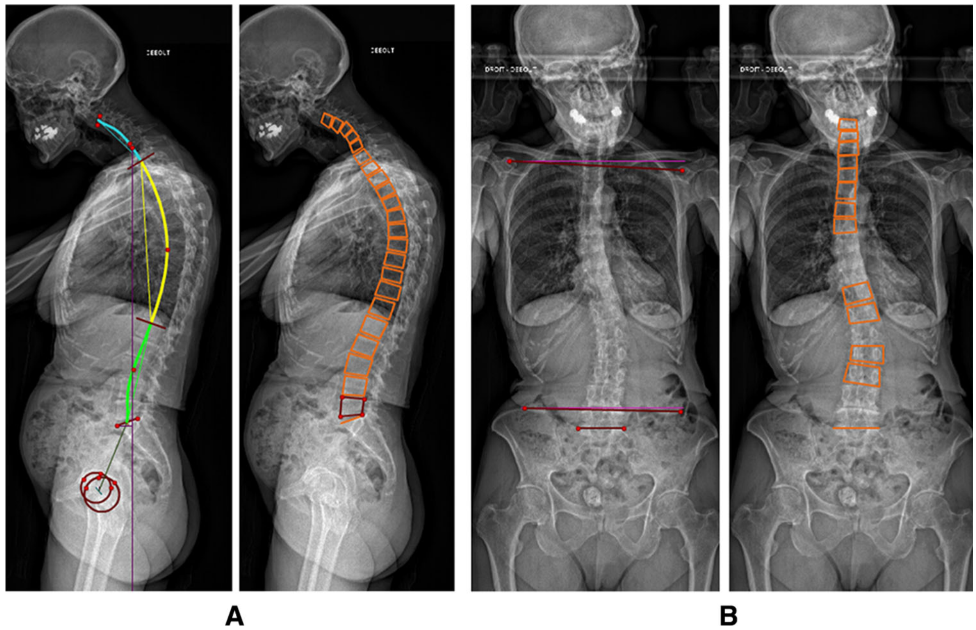


Fig. 1 Examples of geometric model of the spine and pelvis using Keops®

experience of the user, but generally took between 2 and 5 min with Keops® whereas 8–10 min with manual method.

Bias analysis

Each reviewer demonstrated excellent agreement between the values for all the sagittal and frontal parameter considered obtained by each of the two methods. The mean difference calculated between the two methods was minimal at

−0.4° ± 3.41° [−7.1; 6.4] for frontal measurement

0.1° ± 3.52° [−6.7; 6.8] for sagittal measurement.

This is depicted in the Bland–Altman plot (Fig. 2) which indicates that both methods have excellent agreement. There did not seem to be a significant variation in agreement depending on frontal analysis; however, there was a slightly greater agreement on sagittal analysis (i.e., <7°).

Interobserver reproducibility

Intraclass correlation coefficient (Table 1) indicated very good agreement between interobserver reproducibility:

- Frontal paper measurement: ICC = 0.9683
- Frontal Keops® measurement: ICC = 0.9706.

There is no significant difference between the two methods ($p = 0.5808$)

Intraclass correlation coefficient also indicated better agreement between interobserver reproducibility:

- Sagittal paper measurement: ICC = 0.9931
- Sagittal Keops® measurement: ICC = 0.9960.

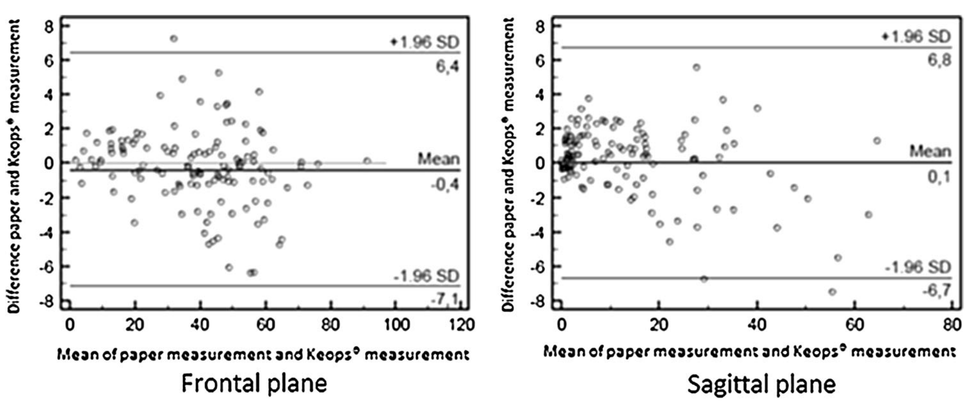


Fig. 2 Bland and Altman plot comparing paper and Keops® measurement in sagittal and frontal planes

There is a significant difference ($p = 0.0001$): Keops® has a better interobserver reproducibility than paper measurement for determination of the sagittal pelvic parameter.

Intraobserver repeatability

Concordance correlation coefficient (Fig. 3; Table 2) indicated very good agreement between intraobserver repeatability for:

– Frontal paper measurement: rc = 0.9808
– Frontal Keops® measurement: rc = 0.9872.

There is a significant difference between the two methods ($p < 0.0001$): Keops® has a better intraobserver repeatability than paper for determination of Cobb's angle.

Concordance correlation coefficient also indicated better agreement between intraobserver repeatability for:

– Sagittal paper measurement: rc = 0.9953
– Sagittal Keops® measurement: rc = 0.9981.

There is a significant difference between the two methods ($p < 0.0001$): Keops® has a better intraobserver repeatability than paper for determination of pelvic parameter.

Table 1 Results of intraclass correlation coefficient for each method of measurement in frontal and sagittal planes

		Paper face	Keops face	Paper profile	Keops profile
Single measures[b]	Intraclass correlation[a]	0.9683	0.9706	0.9931*	0.9960*
95 % confidence interval		0.9632–0.9729	0.9658–0.9748	0.9920–0.9941	0.9954–0.9966
Average measures[c]	Intraclass correlation[a]	0.9919	0.9925	0.9983	0.9990
95 % confidence interval		0.9905–0.9931	0.9912–0.9936	0.9980–0.9985	0.9988–0.9992

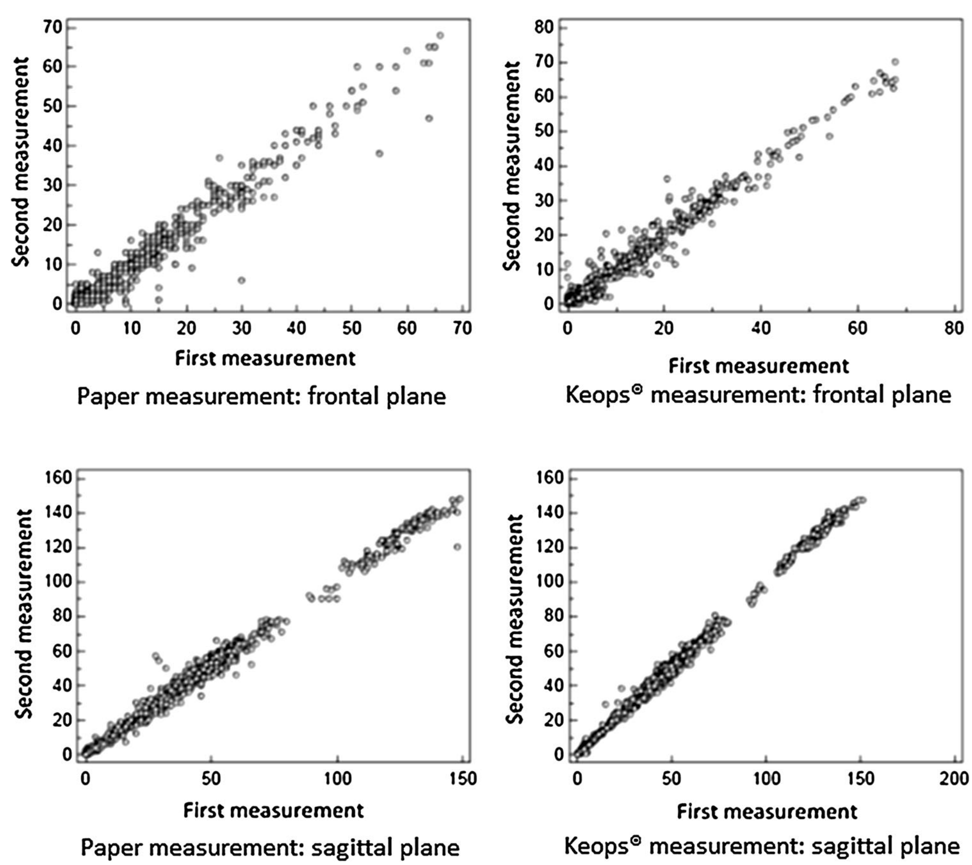
* $p = 0.0001$

[a] The degree of consistency among measurements

[b] Estimates the reliability of single ratings

[c] Estimates the reliability of averages of k ratings

Fig. 3 Concordance correlation graph between the first and the second measurement using each method in frontal and sagittal plane



Discussion

Variability in paper angle measurement

Indeed, a number of studies have been published concerning the variation in the determination of the Cobb angle by different observers measuring the same radiograph: the interobserver standard measurement error is up to 11.8° and the standard deviation is up to 3.3°; the intraobserver standard measurement error is up to 6° and the standard deviation is 2.0°. Pruijs et al. [10] shown that there were two sources of error: the first in production of a radiograph (the Spearman correlation coefficient was 0.98 for the repeated radiographs variation) and the second in measurement variation (0.98 for the repeated measurements on one radiograph). He reported that differences of less than +4.3 as compared to measurement on the previous radiograph do not carry a real clinical significance since they are within the 95 % probability limits of Cobb angle determination if the measurements are taken by the same investigator. However, the most important decisions in the treatment of scoliosis are made with Cobb angles between 20° and 50°. In this range, Cobb angle increments of 5° or more are believed to be true changes and thus constitute valid arguments concerning bracing and operation. This threshold used by the Scoliosis Research Society to detect a deterioration of scoliosis for manual measurements is still valid. Polly et al. [11] found intraobserver reliability coefficients ranging from 0.83 to 0.92. Nineteen-two per cent of repeat measures were within 10° and the interobserver reliability coefficients ranged from 0.81 to 0.92. He concluded that the measurement of lumbar lordosis is reproducible and reliable if the technique is specified and one accepts 10° as acceptable variation and that the factors that affect the reproducibility of measurement include end vertebra selection (especially with transitional segments) and vertebral endplate architecture. Morrissy et al. [12] studied the intrinsic error; for intraobserver variability was 4.9° if each observer selected the end-vertebrae of the curve, 3.8° if the end-vertebrae were pre-selected and constant, and 2.8° if each examiner used the same protractor rather than the one that he carried with him. The interobserver variability was, respectively, 7.2°, 6.3° and 6.3°. The mean angles differed significantly between observers, but the difference was smaller when the observers used the same protractor.

Likewise, the variations in sagittal pelvic alignment measurement in scoliosis have been investigated by several researchers.

Vrtovec et al. [13] have shown that ambiguous results were yielded for normal and pathologic subjects, as the reported values show a relatively high variability in terms of standard deviation for every anatomic parameter, which amounts to around 10 mm for pelvic thickness and pelvic radius; 10° for pelvisacral angle, pelvic incidence, and sacral anatomic orientation; 9° for sacropelvic angle and femorosacral posterior angle; and 5° for sacral table angle in the case of normal subjects and is usually even higher in the case of pathologic subjects. The specific variability of pelvic incidence measurements was also reported in a number of studies. Duval-Beaupere et al. [14] reported the measurement accuracy and precision of around 2° and 3°, respectively. Lazennec et al. [15] reported the mean reproducibility of 6° when a goniometer was placed on radiographs. In terms of intraclass correlation coefficient (ICC), they were equal to 0.96 and 0.95, respectively [16, 17]. In terms of Pearson correlation coefficient (r), they were equal to $r = 0.89$ for the overall variability [18]. Curylo et al. [19] reported only the intraobserver repeatability of $r = 0.88$. Jackson et al. [20, 21] showed that sacropelvic angle was measured with high intraobserver repeatability of $r = 0.99$ and interobserver reliability of $r = 0.98$, high overall reliability of $r = 0.91$, and a change of up to 8° in the measurements.

Variability in other computerized method measurement

Many other computerized methods have been proposed [22–32] (Table 3). Vialle et al. [33] compared manual and computer-assisted measurements of pelvic incidence. For manual measurements, they reported intraobserver repeatability of $r = 0.86$, ICC = 0.887, and SD = 2.7° and interobserver reliability of $r = 0.65$, ICC = 0.672, and SD = 2.5°. Even higher intraobserver repeatability of $r = 0.96$, ICC = 0.986, and SD = 2.5 and interobserver reliability of $r = 0.99$, ICC = 0.992, and SD = 2.2° was reported for computer-assisted measurements. Dimar et al. [34] found that the interobserver reliability between manual measures was poor, ranging from −0.02 to 0.64 for the different sagittal measures. The intraobserver reliability in manual measures was better ranging from 0.40 to 0.93. Comparing manual to computer-assisted measures, the ICC ranged from 0.07 to 0.75.

However, limited to the studies where reliability estimates were provided, most instruments used under standardized conditions may be considered reliable enough to be used for research purposes on the group level, but it is uncertain if they can be used on the individual patient level.

Variability in other techniques measurement than radiologic analysis

Boulay et al. [35] studied the difference between radiographic and skeletal measurements of pelvic incidence and reported a relatively small mean difference of 1.1° (SD = 2.4°). The intraobserver repeatability and

Table 2 Results of concordance correlation coefficient for each method by rater of measurement in frontal and sagittal planes

	Rater A	Rater B	Rater C	Rater D
Frontal paper measurement				
Sample size	210	210	210	210
Concordance correlation coefficient	0.9838	0.9830	0.9913	0.9649
95 % confidence interval	0.9788–0.9876	0.9778–0.9870	0.9887–0.9934	0.9542–0.9731
Pearson ρ (precision)	0.9842	0.9830	0.9914	0.9656
Bias correction factor Cb (accuracy)	0.9996	1.0000	1.0000	0.9993
Frontal Keops measurement				
Sample size	210	210	210	210
Concordance correlation coefficient	0.9831	0.9807	0.9889	0.9969
95 % confidence interval	0.9779–0.9871	0.9748–0.9853	0.9854–0.9915	0.9959–0.9976
Pearson ρ (precision)	0.9835	0.9807	0.9892	0.9969
Bias correction factor Cb (accuracy)	0.9996	1.0000	0.9997	0.9999
Sagittal paper measurement				
Sample size	210	210	210	210
Concordance correlation coefficient	0.9979	0.9918	0.9962	0.9953
95 % confidence interval	0.9973–0.9984	0.9893–0.9938	0.9950–0.9971	0.9939–0.9964
Pearson ρ (precision)	0.9982	0.9919	0.9965	0.9955
Bias correction factor Cb (accuracy)	0.9997	0.9999	0.9997	0.9998
Sagittal Keops measurement				
Sample size	210	210	210	210
Concordance correlation coefficient	0.9990	0.9970	0.9977	0.9986
95 % confidence interval	0.9987–0.9992	0.9961–0.9977	0.9969–0.9982	0.9982–0.9989
Pearson ρ (precision)	0.9990	0.9970	0.9977	0.9986
Bias correction factor Cb (accuracy)	1.0000	1.0000	1.0000	1.0000

interobserver reliability of measurements were, respectively, up to 2° and 4° SD.

Chaise et al. [36] verify the validity, repeatability and reproducibility of angular measures of sagittal curvatures of the spine obtained using an adapted arcometer, by comparing them with Cobb angles of the respective curvatures obtained by using X-rays. There was significant correlation $r = 0.71$ and $r = 0.94$ ($p < 0.01$), with no significant difference ($p = 0.30$), respectively, for the lumbar curvature and for the thoracic curvature. As the same Czaprowski et al. [37] used Saunders digital inclinometer and found that the reliability of the measurements was good (Cronbach's alpha was $0.9 > \alpha \geq 0.8$), and the measurement error was between 2.8° and 3.8°.

Yeager et al. [38] used digital video fluoroscopic techniques coupled with computer-assisted measurements. The vertebral motion analysis measurements demonstrated substantially more precision compared with the manual technique. Intraobserver measurements were the most reliable, with a coefficient of repeatability of 1.53 (manual, 8.28) for intervertebral rotations, and 2.20 (manual, 11.75) for intervertebral translations, but the least reliable measurements were interobserver intervertebral rotations and translations, with a coefficient of repeatability of 2.15 (manual, 9.88) and 3.90 (manual, 12.43), respectively.

Somoskeöy et al. [39] compared accuracy, correlation of measurement values, intraobserver and interrater reliability of methods by conventional manual 2D and sterEOS 3D measurements in a routine clinical setting. In comparison with manual 2D methods, only small and non-significant differences were detectable in sterEOS 3D-based curvature data. Intraobserver reliability was excellent for both methods, and interrater reproducibility was consistently higher for sterEOS 3D methods that was found to be unaffected by the magnitude of coronal curves or sagittal plane deviations. Furthermore, Mieritz et al. [40] in a systematic review, have shown that there is uncertainty with respect to the degree that repeated measurements by 3D regional spinal motion instruments are reproducible.

A tomographic study by Hioki et al. [41] found that although spinal length was significantly decreased with axial loading, test–retest ICC of spinal length under lying down and axial loading conditions suggested moderate-to-good repeatability and the differences in all parameters studied between lying down and axial loading conditions showed the same tendencies.

Table 3 Review of literature for computerized method measurement using different software

References	Variability in paper measurement	Variability in computerized method
Sardjono et al. [29]	SD = 3.37°	SD = 2.84°
Kim et al. [27]	IOR = 0.914	IOR = 0.996
Pearson et al. [28]	IAR = 0.870	IAR = 0.997
	IOR = 0.693	IOR = 0.962
Aubin et al. [22]	np	IAR = 0.94
		IOR = 0.93
		SD = 4.2°
Zhang et al. [32]	np	IAR = 0.990
		IOR = 0.981
Wang et al. [31]	np	IAR = 0.967
		IOR = 0.957
Tanure et al. [30]	IOR = 0.95	IOR = 0.096
	SD = 3.45°	SD = 3.18°
Bolesta et al. [24]	IOR = 0.67	IOR = 0.84
Guglielmi et al. [26]	np	IAR = 1.61 %
		IOR = 2.93 %
Dimar et al. [25]	IAR = 0.93	IAR = np
	IOR = 0.64	IOR = 0.75
Berthonnaud et al. [23]	np	IAR = 0.99
		IOR = 0.98

SD standard deviation, *IOR* interobserver reproducibility, *IAR* intraobserver repeatability, *np* non-provided

Conclusions

We conclude that Keops® has no bias compared to the traditional paper measurement, and moreover, the repeatability and the reproducibility of the measurements with this method is much better than with similar standard radiologic measures done manually in both frontal and sagittal plane and that the use of this software can be recommended for clinical application.

Conflict of interest The authors declare that they have no conflict interests.

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