TITLE: Clinical Evaluation of Spinal Coronal and Sagittal Balance in 584 Healthy Individuals : Normal Plumb Line Values and Their Correlation With Radiographic Measurements

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Background. Plumb line distances (PDs) are widely used in conservative clinical practice to evaluate the sagittal shape of the spine.

Objective. The objective was to assess the normative values of PDs in a large, healthy population in an age range representative of the adolescent population with spinal deformities, and to correlate it with x-ray measurements.

Design. This was a cross-sectional study.

Methods. Participants were 584 healthy individuals (341 females) with x-rays showing no spine deformities. The whole sample (OVERALL) was divided into 5 groups: 6-9 years old (n = 106); >10 years, Risser 0 with triradiate cartilage open (n = 129) or closed (n = 104); Risser 1-2 (n = 126); and Risser 3-5 (n = 119).

PDs were taken by maintaining a tangent to the thoracic kyphosis apex at C7, T12, L3, and S2. Sagittal index (C7 + L3), and sagittal and coronal balances (C7 related to S2) were calculated.

Results. In OVERALL, PDs at C7, T12, L3, and S2 were 39.9 ± 16.7, 21.4 ± 15.3, 39.9 ± 15, 20.6 ± 17.0 mm, respectively. Sagittal index was 79.8 ± 26.8, sagittal balance was 19.3 ± 17 mm anterior to S2 plumb line; 13.5% had a coronal imbalance of 11.4 ± 5.4 mm to the right and 24.7% of 13.2 ± 6.0 mm to the left. C7 and L3 PDs, sagittal index, and sagittal balance were significantly lower in ages 6-9 compared to older patients in Risser 1-2 group. C7 and S2 PDs and sagittal index were significantly larger in males. Sagittal index correlated with thoracic kyphosis Cobb degrees (r = 0.47).

Limitations. The participants were not randomly chosen from the general population; and, they had an x-ray because of spine pathology suspicion**.**

Conclusions. This study shows normative data to be used in clinical practice.

Sagittal spinopelvic alignment has gained more and more importance in the last decades because of its high correlation to Health-Related Quality Of Life scores in adults.[1]

The current standard to measure spinal sagittal parameters is lateral projection x-rays which are routinely used for the diagnosis and monitoring of conditions such as idiopathic scoliosis and hyperkyphosis. However, they have significant limitations. X-rays expose the patient to potentially harmful ionizing radiations.[2] Moreover, there is a lack of standard for positioning arms during lateral x-rays and any arm position other than standing posture with arms hanging down involves a significant change in both thoracic kyphosis and lumbar lordosis, with a difference related to the increase in the degree to which the arms are lifted.[3]

Several non-invasive, skin-surface methods have been adopted for clinical use as well as technology based methods including rastereography and 3D ultrasound.[4-6] Some of them have proven validity and are useful during clinical evaluations and to monitor patients during follow-up.[7] All these technologies may be expensive and time consuming and not always feasible in routine clinical practice in different settings around the world.

Several studies showed that sagittal parameters change from childhood to adolescence and adulthood.[6-8] Moreover, sagittal alignment shows differences according to sex before and at the peak of the growth spurt.[8] This may impact the differences in prevalence of some pediatric spinal deformities that normally develop and progress around the pubertal growth spurt, i.e. girls are more often affected by adolescent idiopathic scoliosis whereas boys are more often affected by Scheuermann's kyphosis.

Plumb line is a device frequently used in routine clinical practice and in school screenings by many different professionals. Described by Stagnara in 1988,[9] plumb line distances (PDs) are well known and diffused. They show good intra-rater reliability, a fair correlation to detect thoracic hyperkyphosis and lumbar lordosis[10] and have been recommended for the assessment of C7 coronal shift showing a good level of reliability and validity as well as a good correlation with measurements obtained via radiograph.[11-13] Even though PDs do not measure any angles, they describe the sagittal profile. The sum of C7 and L3 PDs is the sagittal index[10] and values of sagittal index ≥ 95 mm show a high specificity in detecting thoracic hyperkyphosis of ≥ 60 Cobb degrees in lateral x-ray.[14] Grunstein found high intra- and inter-examiner reliability for the measurement of clinical trunk coronal imbalance using plumb line.[11]

However, no study has provided normative data of plumb line distances for healthy individuals at different ages and bone maturities. A normative value in a large, healthy growing population may be a reference for diagnosis and treatment for all professionals involved in conservative treatment of spinal deformities.

The first objective of this study was to define normative PD values in a healthy population, aged between 6 and 18, to verify differences according to sex, age ranges and skeletal maturity stages. And secondly, to correlate sagittal index with lateral x-ray measurements.

[H1] Methods

[H2] Design

Cross-sectional study. Informed consent was obtained from all participants and their parents. The study followed the indications of the Declaration of Helsinki and was approved by the local ethics committee.

[H2] Participants

The prospective clinical database was started in 2003 and includes all patients coming to our institute. It was searched in March 2017 for healthy individuals between 6 and 18 years (ys) old, who underwent a first consultation and had postero-anterior and lateral x-rays. Since it is not ethical to expose a healthy population to ionizing radiation, we included the false positive participants in our study, who presented for a visit with a suspected diagnosis but w-ray results were negative. The participants of this study showed some trunk asymmetries at clinical exam or an apparent hyperkyphotic posture and had a prescription of spinal postero-anterior and lateral radiography by their general practitioner, who referred them to our institute. Since clinical asymmetries do not accurately predict the presence of scoliosis,[15] there are excessive referrals from screening programs generating a burden of care (diagnostic images and MD visits).[16]

Exclusion criteria were:

- scoliosis (≥ 10° Cobb),
- angle of trunk rotation (ATR) measured with Scoliometer ≥ 7°,[17]
- Scheuermann's disease and/or thoracic kyphosis ≥ 60 Cobb degrees,
- spondylolisthesis and other spine deformities,
- self-reported back pain,
- neuromuscolar diseases,
- previous brace wearing.

The whole sample (OVERALL) was divided into five groups:

1. age 6-9,
2. age >10, open triradiate cartilage, Risser 0,
3. age > 10, closed triradiate cartilage, Risser 0,
4. Risser 1-2,
5. Risser 3-5.

Triradiate cartilage closure was chosen as a maturity indicator to better detect individuals not yet in the pubertal growth spurt and individuals in the accelerating phase of pubertal growth.[18] The first phase of the pubertal growth spurt corresponds to the acceleration in the velocity of growth and lasts 2 ys, from approximately 11 to 13 ys of bone age in girls and 13 to 15 ys of bone age in boys. Triradiate closure occurs approximately half-way on the ascending phase of the pubertal growth curve and corresponds to an approximate bone age of 12 ys for girls and 14 ys for boys.[18] The decision to split participants with age >10 and Risser 0 into two distinct groups according to bone maturity (open, ore closed triradiate cartilage, close triradiate cartilage) was made because the age at puberty onset varies greatly between individuals, different ethnic populations, and between sexes.[19] Our aim was to have participants at a similar bone growth stage in each group.

The PD measurement is part of the first consultation according to our protocol**.** The physician detected the C7 spinous process (Fig. 1A). He palpated cervical spinous processes and identified the most prominent vertebra localization in the cervicothoracic region during passive flexion of the cervical spine. Then he returned the participant's head to the neutral position. Flexion-extension testing was performed to confirm the localization of C7. The evaluator kept his middle finger on the most prominent vertebra and placed his index finger on the spinous process of the overlying vertebra. With his other hand, the evaluator conducted an active-assisted extension of the cervical spine (the evaluator pushed the patient's head in a backward direction to provoke extension of the cervical spine). The purpose of this test was to identify the first vertebra that stayed still while the above vertebra moved during the test. The rationale for this assumption is that the free C6 spinous process of the cervical spine is the last (lower cervical spinous process) vertebra to move during the test. Therefore the underlying vertebra, which is the first stationary vertebra, should be C7. If necessary, the test was repeated at different levels until the first stationary vertebra was detected.[20] The pysician marked C7 spinous process with a dermographic pencil and continued down counting spinous process prominences until detecting and marking T12 and L3 spinous processes. Thoracic reference point was the most prominent spinous process in the thoracic spine (the one nearest to the thread) (Fig. 1B). S2 was the midpoint between the left and the right posterior superior iliac spines (PSIS). The subject was asked to stand in a comfortable position, feet 20 cm apart, looking straight ahead. The physician slightly touched the parietal bone of the patient to stabilize his hand and let the plumb line down aligned to the midpoint between the left and the right PSIS, avoiding any contact between the rope and the trunk. The physician measured the distance between the rope and the reference points identified: C7, the most prominent point in the thoracic spine, T12, L3 and S2 (Fig. 1C). All measurements were in millimeters and were rounded to the nearest measurement to reach values with units of 0 or 5 (i.e. 22 mm was rounded to 20 mm and 23 mm was rounded to 25 mm).[10] Afterwards, the measurement of the most prominent point in the thoracic spine was subtracted from all the measurements, in order to get all the distances with the plumb line tangent to the most prominent point in the thoracic spine.

The anterior-posterior position of C7 relative to the sacrum is a reflection of the global trunk sagittal balance and varies during growth.[8] Sagittal balance is a linear clinical parameter to evaluate the global balance of the trunk and was calculated by subtracting the S2 PD from the C7 PD. A positive value indicates a posterior position of C7 relative to the sacrum and a negative value indicates an anterior position of C7 relative to the sacrum. To evaluate the coronal imbalance of the trunk, the horizontal deviation between C7 ans S1 spinous processes was measured using a rigid ruler (Fig. 2).[11] Measurements were always positive since the direction of the imbalance (left or right) was noted.

[H2] Statistical analysis

To summarize sample characteristics, descriptive statistics was used. Pearson's correlation coefficient was used to evaluate the correlation between sagittal index and thoracic kyphosis Cobb degrees. Alpha level was set at 0.05 to be considered significant.

To investigate differences among age groups and gender groups we first run a oneway anova for each PDs measures and, for each significant effect, the Bonferroni post hoc test was performed to identify which groups differed from each other. Having multiple dependent variables we decided to perform a two-way multiple variables analysis of variance (MANOVA) to check for differences among age groups and gender. MANOVA showed statistically significant differences. Therefore, a regression model was run to estimate the coefficients able to predict PDs values in age groups and according to gender. The marginal effect of each covariate was finally explored for comparisons among covariates.

Statistical analysis was performed using Stata 14 SW (StataCorp LP, Texas USA).

[H1] Results

On the search date (September 1, 2016), 25,292 individuals were present in the database. A total of 584 individuals (341 females) satisfied eligibility criteria, with mean age 12.4 ± 2.5 ys. Table 1 shows the characteristics (age and sex) of OVERALL and of the five groups.

Table 2 shows PD values, sagittal index, and sagittal balance in OVERALL. Rounding PDs of OVERALL at C7, T12, L3 and S2 to the nearest measurement to reach values with units 0 or 5, the distances will be easily remembered for routine clinical practice (mean value ± SD) and they were: 40 ± 15 mm, 20 ± 15 mm, 40 ± 15 mm and 20 ± 15 mm, respectively.

There was a low positive linear correlation between the increase of age and bone maturity and the increase of Sagittal Index (r= 0.3, $P<0.0001$).

Sixty two percent of OVERALL had no coronal imbalance of the trunk. Thirteen percent had a coronal imbalance of the trunk of 11.4 ± 5.4 mm (95% CI 10.2-12.6) to the right and 25% percent had a coronal imbalance of the trunk of 13.2 ± 6.0 mm (95% CI 10.2-12.6) to the left.

Pearson's correlation between Sagittal index and the corresponding lateral x-ray measurement of thoracic kyphosis Cobb degrees was moderate ($r=0.47$, $p < 0.0001$), the higher the sagittal index, the larger the thoracic kyphosis Cobb degrees.

A statistically significant difference was found among age groups and gender, specifically, the Bonferroni post hoc test pointed out statistically significant differences between the youngest (Age 6-9 years) and all the other groups. The PD levels involved in these changes are C7 for all groups compared to the youngest and L3 after Risser 1 ($p < 0.001$). In all comparisons the SI and the SB changed significantly in age groups compared to the youngest ($p < 0.001$).

In the whole sample, C7 and S2 PDs, and sagittal index were significantly larger in males compared to females ($p < 0.005$) (Tab. 3). Table 4 shows mean PD values of males and females according to age and bone maturity groups.

The MANOVA test confirmed that there was a statistically significant difference in age groups and in males and females, but when we combined both group age and gender the significance was lost.

The post hoc linear regression showed that there was a statistically significant difference among males and females for PD at C7 and L3. Being females decreases C7 by 6.8 mm, (CI95% -12.93—0.67 p=0.03) and L3 by 5.35 (CI95% 11.23-0.54, p=0.08). When we considered the interaction of gender and age groups it was not possible to find any significant difference.

[H1] Discussion

Plumb line distances are an option with proven reliability and specificity in detecting thoracic hyperkyphosis and lumbar lordosis[10,14] and this study aimed to define the normative values of a healthy population. Since sagittal alignment changes during growth,[8] it was essential to divide the population according to age and bone maturity.

Zaina et al[10] showed in a general population aged 11-16 ys that PDs in 100 females were 34 ± 11 mm and 34 ± 15 mm and in 80 males were 34 ± 11 mm and 48 ± 10 mm, in C7 and L3, respectively. In our sample, PDs were 37.0 ± 15.3 mm and 44.1 ± 17.8 in females and 38.9 ± 14.8 mm and 41.1 ± 15.3 mm in males, at C7 and L3, respectively. The difference between these values and our results may be explained by the different ages of the participants.

In the study by Negrini et al[14] that validated plumb line distances, Pearson's correlation between sagittal index and thoracic kyphosis Cobb degrees was 0.54 in scoliosis patients and 0.58 in hyperkyphosis patients, aged 14.3 ± 2.2 ys. In our study, Pearson's correlation between sagittal index and thoracic kyphosis Cobb degrees was 0.47. Arm position in lateral x-rays can modify thoracic kyphosis and lumbar lordosis.[3] In our study arm position was not standardized since patients arrived with x-rays done at different clinics using different protocols, this may explain the lower value of Pearson's correlation in our study. Besides, it is not uncommon in normative studies to see lower correlations due to restriction of the range.

Schlosser et al showed that before, during, and after the adolescent growth spurt, thoracic kyphosis was smaller in girls compared to boys at the same stage of development, as well as compared to girls after the growth spurt.[21] This implies that the spine of girls during the growth spurt is more posteriorly inclined and thus rotationally less stable, compared to boys at the same stage of development and may explain why initiation and progression of adolescent idiopathic scoliosis are more prevalent in girls around puberty.[21] These results are consistent with our findings. In our study, sagittal index had a low (r=0.3) but highly significant positive ($p < 0.0001$) correlation with age. These data confirm the results of Schlosser et al[21] who found a significant increase of thoracic kyphosis at the end of the pubertal spurt as compared to both before and at pubertal spurt, as well as the results of MacThiong, who found a tendency for a positive direct linear correlation between age and thoracic kyphosis in 180 individuals 4-18 ys of age.[22]

Normal values of PDs are useful to monitor the variations of the sagittal profile of hyperkyphosis and scoliosis patients during therapy. Since sagittal index correlates with thoracic kyphosis Cobb degrees (an increase of thoracic kyphosis correlates to an increase of sagittal index), with specific exercises and/or brace therapy a reduction of this parameter is expected, resulting in values closer to a normal value. Conversely, in an adolescent with thoracic idiopathic scoliosis, sagittal index is expected to be small due to the reduction of thoracic kyphosis.[23] During therapy, in these patients sagittal index should not reduce and, if possible, should rather increase, getting closer to normal values.

This study has the major strength of filling a gap in helping clinicians to interpret plumb line distances by reporting normal values derived from a large sample.

The main limitation of this and other similar studies[22,24] is that the participants included were not randomly chosen from a healthy population. Unfortunately, such methodology would require serial radiographs in normal children and would not be ethical. The participants of this study had an x-ray because their general practitioner suspected either scoliosis or hyperkyphosis. Even though the x-rays did not confirm this suspicion, it is possible that this sample could lead to under or overestimated sagittal values.

[H1] Conclusion

PDs are a harmless and low cost tool to evaluate sagittal shape of the spine. This study provides normative data to be used as a reference in routine clinical practice.

Author Contributions

Concept/idea/research design: A. Negrini, M. Vanossi, S. Donzelli, F. Zaina, S. Negrini
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Fund procurement: M. Vanossi
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Providing facilities/equipment: A. Negrini, M. Vanossi
Providing institutional liaisons: M. Vanossi
Clerical/secretarial support: M. Vanossi
Consultation (including review of manuscript before submitting): M. Vanossi, F. Zaina, S. Negrini

Ethics Approval

The study followed the the Declaration of Helsinki and was approved by Ethics Committee, Milan, Area 2. Informed consent was obtained from all participants and their parents.

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Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest. A. Negrini, M. Romano, and S. Negrini disclose that they own stock in the Italian Scientific Spine Institute (ISICO).

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Table 1. Number of Participants, Mean Age, and Number of Males and Females of the Whole Sample (OVERALL) and of the Five Groups.

Group	N	Mean Age (SD)	Males/Females
OVERALL	584	11.92 (2.54)	243/341
Age 6–9 y	106	8.49 (1.09)	37/69
Age >10 y Risser 0 Open triradiate	129	11.74 (1.08)	72/57
Age >10 y Risser 0 Closed triradiate	104	12.45 (1.28)	40/64
Risser 1–2	126	13.68 (1.35)	48/78
Risser 3–5	119	15.29 (1.36)	46/73

Table 2. Mean, Standard Deviation, and 95%CI of Plumb Line Distances in C7, T12, L3, and S2 in the Whole Sample (OVERALL).

Plumb Line Levels	Mean ± SD (95% CI)
C7	**39.9 ± 16.7** (38.6 – 41.2)
T12	**21.4 ± 15.3** (20.2 – 22.7)
L3	**39.9 ± 15.0** (38.6 – 41.1)
S2	**20.6 ± 17.0** (19.3 – 22.0)
Sagittal index[a]	**79.8 ± 26.8** (77.7 – 82.0)
Sagittal balance[b]	**19.3 ± 17** (17.9 – 20.7)

[a] Sagittal index (specific in detecting thoracic hyperkyphosis) was obtained by adding C7 and L3 plumb line distances.

[b] Sagittal balance (C7 related to S2) was obtained by subtracting plumb line distance of S2 to C7.

Table 3. Plumb Line Distances (Mean, Standard Deviation, and 95%CI) of Females and Males in the Whole Sample (OVERALL).

OVERALL	PDs ± SD (95% CI)		
Plumb Line Levels	**Females n = 341**	**Males n = 243**	***P***
C7[a]	**36.9 ± 15.2** (35.3 – 38.5)	**44.1 ± 17.7** (41.9 – 46.3)	**< .001**[b]
T12	**21.0 ± 11.2** (19.8 – 22.2)	**21.9 ± 19.6** 19.4 – 24.4	**.46**
L3	**38.9 ± 14.8** 37.3 – 40.5	**41.1 ± 15.2** 39.2 – 43.1	**.07**
S2[a]	**18.5 ± 15.6** (16.8 – 20.2)	**23.7 ± 18.0** (21.4 – 26)	**< .005**[b]
Sagittal index	**75.9 ± 25.4** (73.2 – 78.6)	**85.3 ± 27.8** (81.8 – 88.8)	**< .001**[b]
Sagittal balance	**18.5 ± 16.0** 16.8 – 20.2	**20.4 ± 18.3** (18.1 – 22.7)	**.18**

[a] C7 and S2 plumb line distances and sagittal index were significantly larger in males compared to females.

[b] p < .05

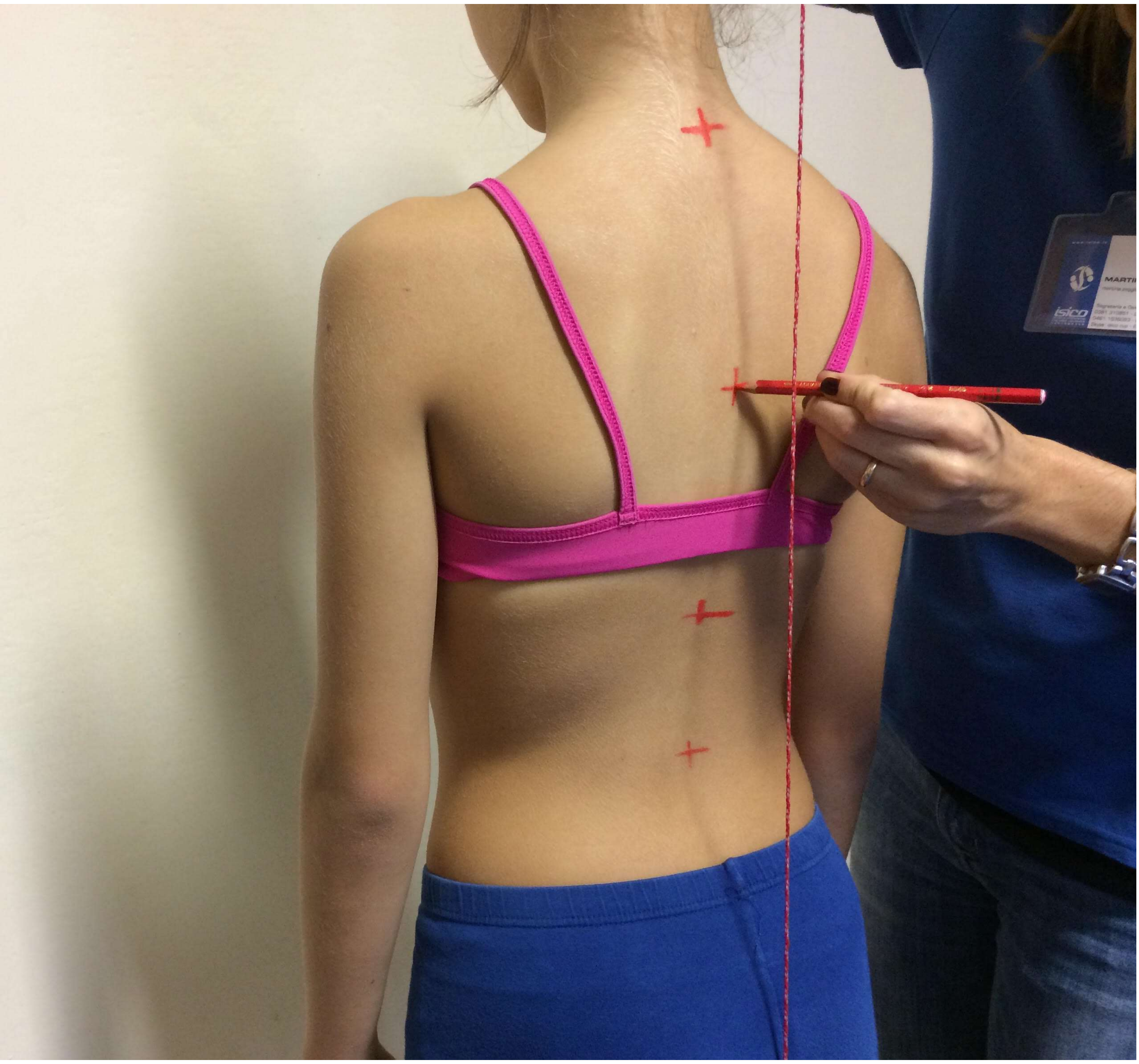
Table 4. Mean Plumb Line Distances of Females and Males According to Age and Bone Maturity Groups.

Groups/Plumb Line Level	Overall		Age 6–9 ys		Age > 10 y Risser 0 Open Trir.		Age > 10 y Risser 0 Closed Trir.		Risser 1–2		Risser 3–5	
	Female	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*
C7	36.9	44.0	28.3	35.1	34.5	37.9	38.5	45.1	43.0	54.1	39.2	49.5
T12	21.0	21.9	19.2	19.8	19.0	20.2	22.1	26.1	21.6	20.6	22.6	24.2
L3	38.9	41.1	32.8	38.2	38.0	37.1	38.9	41.1	41.9	44.1	41.9	46.8
S2	18.4	23.6	15.7	23.6	19.4	19.5	20.2	20.6	20.1	26.2	17.0	30.1
Sagittal Index	75.9	85.2	61.2	73.3	72.6	75.0	77.5	86.2	85.0	98.3	81.1	96.4
Sagittal Balance	18.5	20.4	12.6	11.4	15.1	18.4	18.3	24.5	22.8	27.9	22.1	19.4

[a] This table can be useful to clinicians as a reference for their patients.

Figure Legend

Figure 1. **(A)** The physician palpated cervical spinous processes and identified the most prominent vertebra localization in the cervicothoracic region. With active-assisted extension of the cervical spine, he identified and marked, with a dermographic pencil, the first vertebra that stayed still while the above vertebra moved during the test and considered this vertebra as C7. **(B)** Detection of the reference point in the thoracic spine. The physician slightly touched the parietal bone of the patient to stabilize his hand and let the plumb line down aligned to the midpoint between the left and the right posterior superior iliac spines (PSIS), avoiding any contact between the rope and the trunk. The evaluator marked the most prominent spinous process, the one nearest to the thread. (**C)** S2 was measured in the midpoint between the 2 posterior superior iliac spines.



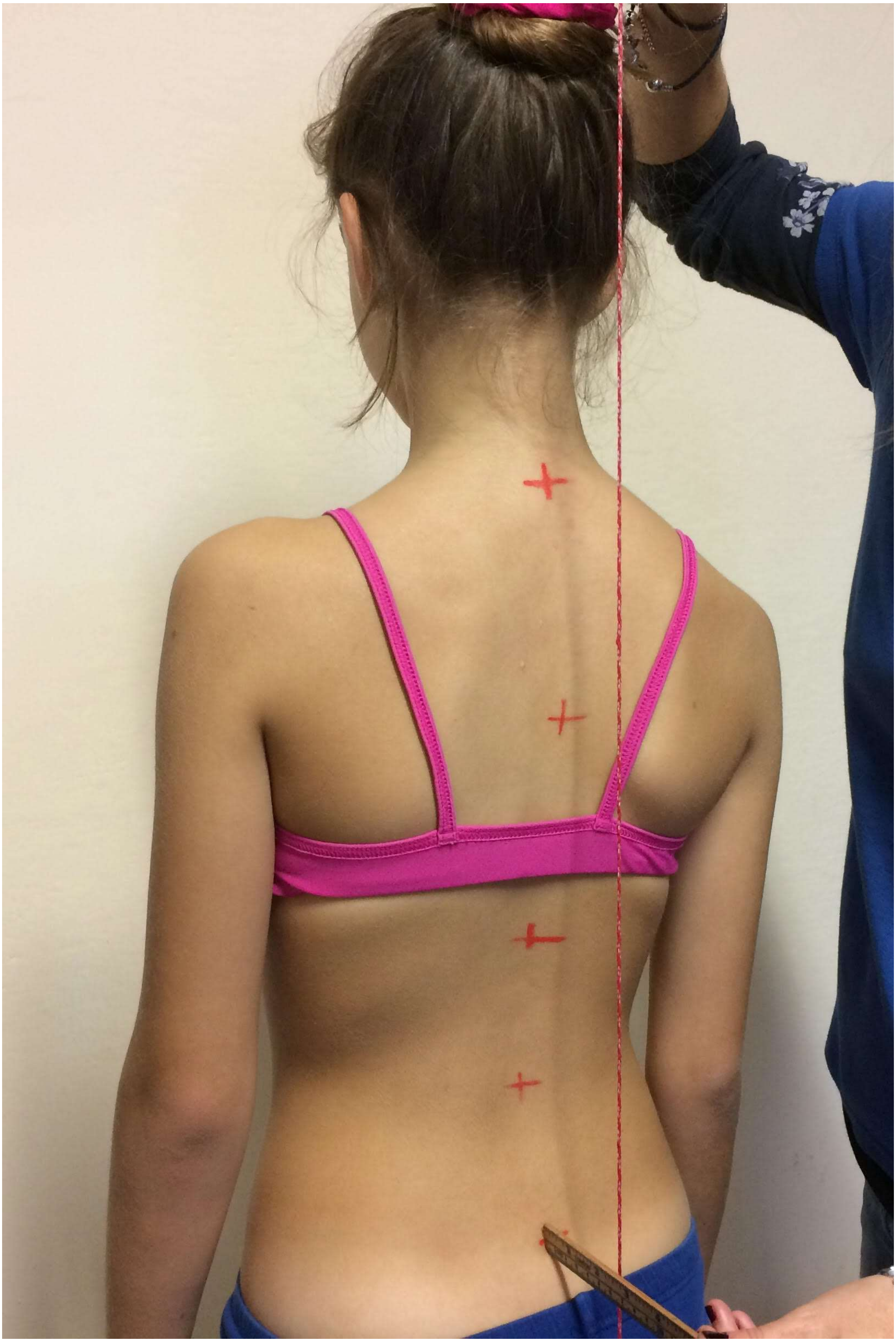


Figure 2. Evaluation of the coronal imbalance of the trunk. Using a rigid ruler, the physician measured the horizontal deviation between C7 and S1 spinous processes.