Reliability analysis of an innovative technology for the assessment of spinal abnormalities

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Abstract — **Rasterstereography represents a viable alternative as screening tool for the analysis of the spinal abnormalities due to the advantages in comparison with the invasiveness of the radiology. In the last decade, several technologies have been proposed to accomplish with this aim. However, the reliability of such approach is still questioned. Tests were conducted on nine male healthy subjects, asking them to maintain four different upright positions while data was acquired by SPINE3D. Tests were repeated three times for each session, and three sessions were performed one week apart. The technologies allowed to compute indices related to transversal, sagittal and frontal plane associated with the spine posture of the subject. Reliability of the computed indices was performed only for the natural static position by using the inter-class correlation coefficient for both the intra and inter-day reliability. The results showed excellent intra-day and inter-day reliability in almost all analyzed parameters. Lower values emerged for pelvic torsion and trunk imbalance; whereas Trunk length proved to be the most reliable. Differences between NP and other positions were observed in some indices, such as pelvic and shoulder inclination, trunk length and kyphotic angle. These findings can open the possibility to use the SPINE3D as a clinical tool, also for follow-up.**

Keywords — Reliability; 3D SPINE; posture; TOF technology; imaging.

I. Introduction

The vertebral column has to protect the spinal cord, as well to support most of the body weight if considering the lumbar vertebral section [1]. Spinal abnormalities can be considered as the direct consequence of abnormal spinal alignment and wrong posture, leading to a deterioration of the life quality due to pain and reduced physical abilities in performing daily life tasks [2].

In order to customize interventions or in alternative to plan orthopedical surgery, it is mandatory a quantitative evaluation of the spinal characteristics [3]. The gold standard in the diagnosis of spinal abnormalities is still represented by the radiological examination. However, the risks associated with radiological exposure cannot be neglected also considering the necessity to monitor the progresses of the abnormalities and the effects induced by rehabilitative and/or drug treatment over the time [4]. In fact, it is well-assessed that the radiation dose received during a radiological examination can have negative long-terms effects, such as a higher incidence of cancer [5].

In the recent past, some research groups proposed the use of lower-dose solution, such as the EOS imaging system proposed by [6]; however the reduction of the cumulative effective radiation doses is limited and it is shown to be not sufficient to avoid long-term risks [7].

From this perspective, in the last decades it emerged the necessity to propose and validate radiation-free systems in order to perform noninvasive spinal abnormalities assessment. In this context, several back surface topography technologies can be listed, such as the laser scanner [8], the Moirè projection [9] and the topography based on electromagnetic [10] or ultrasound [11] waves. Among the topography-based technology, the rasterstereography is receiving particular attention by the research community. In fact, even though the radiation-free systems are not able to characterize the internal spine shape being based on the evaluation of the back surface, it is considered a viable option in comparison to the traditional radiography [12], [13]. Generally, the rasterstereography is based on the estimation of an approximate 3D image of the spine shape and its main advantages are associated with the economic and fast method without the necessity to provide radiation to the subject. For this reason, rasterstereography is widely used as tool for early screening in the detection of spinal abnormalities, especially related to the scoliosis [4], [13]. In the last decades, several instruments have been proposed for the application of rasterstereography theory, with the first one developed by Drerup and Hierholzer in the 1980s [14], [15].

Over the years, several studies have been published to establish the validity and reliability of rasterstereography approach. Krott *et al.* [16] performed a meta-analysis on the studies that evaluated the reliability and validity of static rasterstereography, leading to the outcomes of high validity level in the assessment of lumbar lordosis, thoracic kyphosis and scoliosis angle. As examples, Mohokum *et al.* [17] proposed a study to evaluate the reliability of the system to identify the kyphotic and lordotic angles, as well the trunk length and inclination. By testing 51 volunteers, authors assessed a intratester and intertester reliability greater than 0.90 for all the examined parameters. Similarly, Guidetti and colleagues [18] examined the intra- and interday reliability of spine rasterstereographic system Formetric 4D by enrolling 26 volunteers. An excellent reliability was found also in pelvic tilt, trunk imbalance and lateral deviation. Most of the studies only evaluated the static upright position with the exception of the one proposed by Michalik et al. [12], who estimated the feasibility to use the Formetric system also under dynamic condition, such as locomotion.

Although the Formetric (DIERS Medical Systems, Chicago, IL, United States) is the most widespread solution for the application of rasterstereography, the scientific soundness of the published papers about it is still questioned [19]–[22].

To the best of authors' knowledge, it is still missing the analysis of the intra- and interday reliability of other system as alternative of the Formetric. In addition, no studies have been proposed to understand if the rasterstereography is able to discriminate changes in the upright position. From this perspective, this paper aims at evaluating the intra- and interday reliability of the Spine3D system, as well to understand if the system has the capability to discriminate among four different upright positions in order to simulate the validity of such system as tool for follow-up.

II. Materials and methods

A. Participants

Nine healthy male subjects (median age 33 years, age range [24 42] years, height 173 ± 5 cm, weight 73 ± 8 kg) were recruited for the experimental protocol. Participants were involved if they have not suffered back injuries in the past three years, had never been diagnosed with any back dysfunction or pathology, and they were free from any physical condition that could affect the required tasks. All participants were initially briefed on the purpose of the study and asked to sign a written consent. The experimental procedures were in accordance with the principles stated in the Declaration of Helsinki.

B. Experimental setup

Data were gathered with the innovative Spine3D non-invasive three-dimensional optoelectronic detection system designed by Sensor Medica (Guidonia Montecelio, IT). The system is equipped with an infrared (IR) and time-of-flight (ToF) 3D RGB camera that can be positioned along a column by means of an electric motor controlled by a joystick. The camera resolution is 1920x1080 pixels at 30 fps, the depth resolution is 512x424 pixels at 30 fps and the field of view is 70° and 60°, in the horizontal and vertical direction, respectively. The operating range of measurement is from 0.5 to 4.5 m. The ToF-camera is an instrument that allows estimating in real time the distance between the camera and the framed objects, measuring the time it takes for a light pulse to travel the camera-object-camera path. [23]. Thus, the system is able to reconstruct the shape of the back, according to the approach reported in [24]. The camera is connected to a PC with vertical and touch screen and interfaces with the dedicated software Spine3D (version 1.1.11.34).

C. Experimental protocol

Participants were asked to remove all upper body clothing, position themselves with their back towards the camera at a distance of 110 cm with the heels aligned and lower their pants so that the intergluteal sulcus was visible. The positioning of the feet was standardized by using ad-hoc designed footprints.

Once the participant was positioned in front of the camera, with his arms relaxed, he was asked to look forward at a target, which was placed at a distance of 2 m, in order to stabilize the posture as much as possible (Figure 1).

Figure 1 - Spine3D setup.

Then, the operator adjusted the camera position with the joystick in order to frame the subject from the nape to the glutes. The duration of the Spine3D acquisition was 7 s. Once the acquisition was complete, the subject removed himself from the front of the camera and then repositioned himself in front of it. During the experimental protocol, four positions were tested: (i) the natural position (NP), in which the participants assumed the most comfortable position; (ii) a natural position but with a rise (NPR) of 5 mm under the right foot; (iii) Forced Inspiration (FI), in which the participant was asked to perform a maximum inspiration and to hold the breath for the entire duration of the data acquisition; and (iv) Forced Exhalation (FE), in which the participant was asked to perform a maximum exhalation and then did not breathe during the test. For each position, the acquisition was repeated three times and a break of 30 s between each repetition was considered. The entire experimental protocol was repeated on three different days, one week apart. The order of the different positions was randomized over the three days to avoid bias in the results due to the same sequence.

D. Data analysis

After the reconstruction of the back shape through ToF technology, the software automatically identifies six anatomical landmarks, following the procedure reported in [25]. Specifically, the prominent vertebra (VP), i.e. the spinous process of C7, the two right (SR) and left (SL) shoulder sepsis, i.e. the midpoint between the upper profile of the shoulder and the axillary concavity, the two lumbar dimples right (DR) and left (DL), at the same time also calculates the midpoint between them (DM), and finally the prominent bone of the sacrum (SP) at the beginning of the intergluteal sulcus were identified, as in Figure 2. After that, several synthetic indices related to the transversal, sagittal and frontal plane were analyzed. As regards the transversal plane, the **shoulder torsion** (ST) and the **pelvic torsion** (PT) were computed. The ST represents the angle formed on the transverse plane between SR and SL; while PT is the angle formed on the transverse plane between DL and DR. By moving to the frontal plane, we computed the t**runk length** (TL), the **trunk imbalance** (TI), the **shoulder inclination** (SI) and the **pelvic inclination** (PI). Specifically, TL is the distance between VP and DM; TI is the angle on the frontal plane between VP and DM; SI is the angle formed between SL and SR in the frontal plane; and PI is the angle formed between DL and DR in the frontal plane (Figure 3a). Finally, in the sagittal plane the **column inclination** (CI), the **cervical arrow** (CA), the **lumbar arrow** (LA), the **kyphotic angle** (KA) and the **lordotic angle** (LOA) were computed (Figure 3b and 3c). More in detail, CI is the angle formed between VP and DM in the sagittal plane; CA is the distance between the point of the cervical tract furthest from the axis perpendicular to the ground and tangent to the kyphotic curve; LA is the distance between the point of the lumbar spine furthest from the axis perpendicular to the ground and tangent to the kyphotic curve; KA is the upper angle formed by the intersection of the two tangents in the cervico-thoracic and thoraco-lumbar inversion points; and LOA is the upper angle formed by the intersection of the two tangents at the thoraco-lumbar and lumbo-sacral inversion points.

E. Reliability analysis

For the reliability analysis, only the data acquired during the NP tests were used since NP represents the actual position used during the clinical tests. The data collected during the three repetitions of the same day were used for the intra-day analysis, allowing to quantify the robustness of the proposed indices with respect to the physiological variability. Instead, the inter-day analysis was conducted on the data collected during the three different days, leading to the evaluation of the effects induced both by the positioning of the camera by the operator and by the replacement of the subject in front of the camera. To evaluate the intra-day reliability of the NP, ICC was computed individually for all the computed indices and for each of the three sessions; finally, the range of ICC values was reported for each parameter. To quantify the inter-day reliability, the mean value of each parameter was firstly computed considering the three repetitions within the same day and then the ICC values were computed considering the three obtained average values. ICC values were then discussed according to the following ranges: (i) poor reliability if ICC value is lower than 0.50; (ii) moderate reliability if ICC value is ranged from 0.50 to 0.75; good reliability if ICC value falls in the interval 0.75-0.90; and (iv) excellent reliability when ICC is equal or greater to 0.90, as in [26].

F. Effects of different positions

In order to test the effects induced by different positions and to understand if the selected synthetic indices are sensitive to these forced changes in participant's positioning, we performed statistical analysis as follows. For each index, we computed the mean value across all the repetitions, independently for each participant and each tested position. Data were then tested for normality with the Shapiro Walking test. Successively, paired samples T-tests were performed between the NP and each of the others to elucidate statistical differences in comparison with the natural position. Statistical significance was set at $p < 0.05$ for all the performed tests. Power analysis was conducted by using G*power [27], founding a power value equal to 0.81 for a medium effect size (0.5).

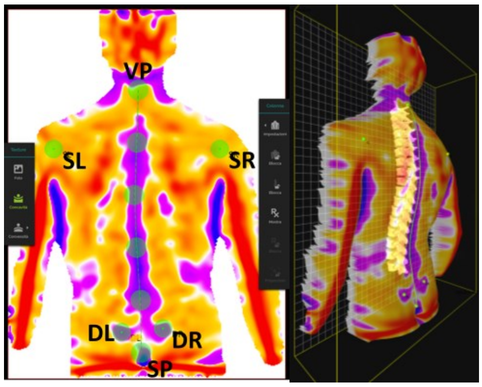
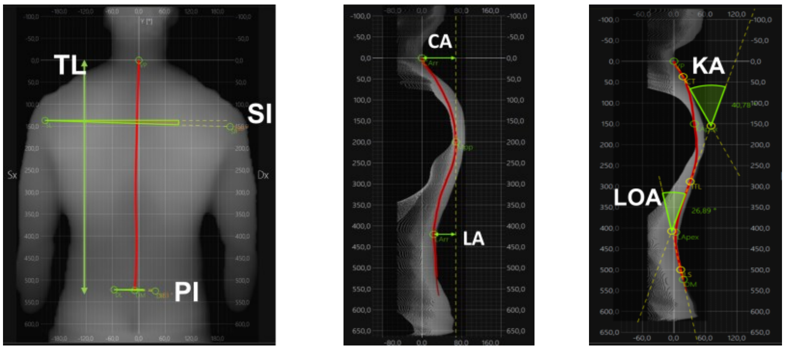


Figure 2 - Landmark identification.

III. RESULTS

The ranges of the ICC values for the intra- and inter-day reliability related to the parameters computed for the NP are reported in Table 1. Regarding intra-day reliability, ICC values range from moderate to excellent. Specifically, moderate results were found in two cases, PT and TI with an ICC equal to 0.72 and 0.74, respectively. However, it is worth noting that this condition was unrelated to all three sessions tested, as demonstrated by the upper limit of the ICC range. In all three sessions, the TL always show values in the excellent range. All the remaining parameters shows values from good to excellent range. Moving on to inter-day reliability, the parameters ST, PT, CI and KA fall into the good range 0.83, 0.76, 0.89 and 0.87 respectively, whereas all others are in the excellent range.



(a) (b) (c)

Figure 3 – Definition of: (a)Trunk Length (TL), Shoulder Inclination (SI) and Pelvic Inclination (PI); (b) Cervical Arrow (CA), Lumbar Arrow (LA); and (d) Kyphotic Angle (KA) and Lordotic Angle (LOA).

TABLE 1 – ICC VALUES FOR THE INTRA- AND INTER-DAY RELIABILITY

Indices	Intra-day	Inter-day
ST [°]	[0.85-0.92]	0.83
PT [°]	[0.72-0.85]	0.76
TL [mm]	[0.92-0.99]	0.99
TI [°]	[0.74-0.85]	0.90
SI [°]	[0.79-0.89]	0.96
PI [°]	[0.78-0.82]	0.97
CI [°]	[0.79-0.91]	0.89
CA [mm]	[0.85-0.88]	0.96
LA [mm]	[0.86-0.94]	0.91
KA [°]	[0.76-0.81]	0.87
LOA [°]	[0.80-0.94]	0.97

The paired samples T-test results are shown in Table 2. No difference between NP and other postures was found for the ST, PT, TI, LA and LOA parameters. The KA parameter seems to be the most sensitive to the position variation as it shows differences between the NP position and all the others, *p=0.022, p=0.009* and *p=0.003* respectively for NPR, FI and FE. Between NP and NPR there are significant differences in the parameters SI (*p=0.042*) and PI (*p=0.003*). Between NP and FI there are significant differences in the parameters TL (*p<0.001*), CI (*p=0.004*) and CA (*p<0.008*) respectively. Finally, between NP and FE there is significant difference in CA (*p<0.043*).

IV. DISCUSSIONS

The study aimed to verify the reliability of the measures of the various indices proposed by the instrument and to verify if the instrument was able to identify differences between different postural situations.

Are the indices analyzed reliable?

The results reported for the intra- and inter-reliability are in line with those highlighted by other studies on similar parameters [16]. In particular, the trunk length is the most reliable parameter; similarly to the results reported by [18], [28].

TABLE 2 – MEAN (SD) FOR ALL THE PARAMETERS AND THE FOUR POSITIONS. * INDICATE STATISTICAL DIFFERENCES.

Indices	NP	NPR	FI	FE
ST [°]	2,1(2,1)	2,0(2)	1,6(1,6)	1,7(2,1)
PT [°]	1,0(1,9)	1,4(1,5)	1,0(1,4)	0,6(2,1)
TL [mm]	500(30,1)	500(30,2)	510(31,1) *	501(31,2)
TI [°]	0,9(0,8)	1,0(0,9)	0,9(0,9)	0,8(0,9)
SI [°]	-0,1(1,4)	0,4(1,6)*	-0,1(1,4)	-0,1(1,5)
PI [°]	1,9(4,5)	3,0(3,9)*	1,2(3,7)	2,2(3,2)
CI [°]	3,8(1,5)	4,0(1,7)	2,5(1,5)*	3,9(2,0)
CA [mm]	59(11,1)	59(11,5)	47(16,1)*	63(12,7)*
LA [mm]	40(8,7)	39(8,7)	40(8,3)	42(10,2)
KA [°]	48,1(6,5)	47,3(6,5) *	42,5(6,4) *	50,9(7,4) *
LOA [°]	34,1(8,5)	32,7(7,0)	34,6(8,0)	34,5(8,5)

The moderate level of variability found for pelvic torsion and trunk imbalance is in agreement with previous works. In particular, pelvic torsion value is in line with the study of Manca *et al*. [29],who found range varied from 0.69 to 0.87, but also greater than those found by Guidetti *et al*. ranged from 0.42 to 0.77 [18]. Such finding can be ascribed to the evidence that pelvic torsion seems to be more influenced by the positioning of the patient as already highlighted by the other authors [18]. As far as trunk imbalance is concerned, the variability of this parameter is most likely given by its nature as a measure derived from the identification of the midpoint of dimples, which in turn depends on the positioning of dimples left and right. Thus, its moderate reliability can be ascribed to the algorithm used for its computation. For these reasons, the use of the pelvic torsion and trunk imbalance as clinical index could be led in misconclusions on health status of the patient.

More in general, as a guideline, we can speculate that the higher values generally found for inter-day reliability suggest the necessity to repeat the evaluation in different days to obtain more robust results. Thus, the effects induced by the replacement of the subject in front of the camera and the adjustment of camera height performed by the operator can be considered negligible.

Can Spine3D detect changes in upright positions?

Firstly, the found average natural position values and its variability are similar to those found by studies with stereophotogrammetric systems [30], allowing to consider the used methodology able to measure such parameters.

The statistical analysis detects differences between natural position and the other positions for some parameters that are strictly connected with the modification applied to each position.

During the forced inspiration condition, we found a significant increase of trunk length and a significant decrease of column inclination, cervical arrow and kyphotic angle values respect the natural position; these changes are consistent with the well-known anatomical modification during inspiration. In fact, when a deep inhalation is performed, the rib cage expands by lowering the diaphragm, the shoulders rise and the spine extends [31]. On the other hand, during forced exhalation condition we have the significant increase of cervical arrow and kyphotic angle is coherent with the anatomical and natural motion of the body during exhalation where the shoulders tend to go down and the head tends to move forward [31]. The use of a rise of 5 mm under the right foot (natural position with a raise) shows a coherent significant modification of shoulder inclination and pelvic inclination and a slight but significant reduction of the kyphotic angle. These modifications can be read as natural postural adaptations to manage the asymmetric rise under the foot [32]. Kyphotic angle confirms to be a very sensitive parameter in all the modified positions respect natural position and it is consistent with the inter-class correlation coefficient values discussion. For this reason, the operators should have to pay attention at the breathing of the subjects during the acquisition process, using a normal, quiet and natural breathing. In addition, we can affirm that, being able to discriminate different upright positions, such proposed methodology can be exploited for follow-up in clinical settings.

V. Conclusion

Paper aims at investigating the intra- and inter-day reliability of the Spine3D and to determine the capability of the system to discriminate among four different upright positions in order to simulate the validity of such system as tool for follow-up. The most of indices fell in the range of good or excellent reliability in both intra- and inter-day analysis. In addition, the proposed methodology seems to be able to discriminate different positions, showing modifications of proper parameters that are linked from an anatomical and physiological point of view with the artificial changes produced in each position.

As a conclusion, the Spine3D is a reliable tool able to discriminate different positions of the spine of the subject and it can be recommended as an easy and fast way to analyze the surface shape of the spine for follow-up in clinical settings. Further studies should be conducted in order to assess the validity of the measurement by comparing the results with gold standard systems, as well to conduct a reliability analysis also for the other acquired positions.

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