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RESEARCH ARTICLE

Verification of determining the curvatures and range of motion of the spine by electromechanical-based skin-surface device

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Abstract

There is an increasing awareness of the risk and dangers of exposure to radiation associated with repeated radiographic assessment of spinal curvature and spinal movement. As such, attempts are continuously being made to develop skin surface devices for use in examining the progression and response to treatment of various spinal disorders. However, devices must be verified before use in research or in a clinical environment. The aim of this study was to examine the reliability of measurements using a skin-surface device, the Spinal Mouse on 30 healthy volunteers. Spinal curvature was measured with the Spinal Mouse during standing, flexion, and extension (each five times by each of two examiners). The method was calibrated by a ZEBRIS ultrasound-based measuring method with WINSPINE software commercially available, and the measurement error rate of the method was determined by statistical calculations. On the basis of calibration and error calculations it could be established that the accuracy and the reproducibility of the method were appropriate, because the maximum value of intraobserver variation is 0.97 degrees (18.8%), that of interobserver variation is 1.54 degrees (27.1%). A second way of verifying the method is to specify the difference between the angles determined by the two methods. The maximum value of the average difference is 1.62 degrees (26.6%).

Keywords

electromechanical-based skin surface device · 3D kinematics · spinal curvature · inter- and intraobserver variation

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1 Introduction

With increasing awareness of the dangers of exposure to radiation associated with the repeated radiographic assessment of spinal curvature and spinal movements [7], attempts are continuously being made to develop skin surface devices for use in examining the progression and response to treatment of various spinal disorders. A number of devices employing different methods of measurement are currently available for the non-invasive assessment of spinal movements – ranging from the simple tape measure to computerized motion analysis systems. The latter (e.g. Fastrak, Isotrak, ZEBRIS CMS) most commonly indicate the curvature and the range of motion of a given section of the whole spine (e.g. the lumbar region, thoracic region) using various movement sensors affixed to the skin surface at positions believed to correspond to the underlying vertebrae, as determined by prior palpation and skin marking [2, 8–10, 12, 13]. These computerized motion analysis devices offer the additional advantage of being able to monitor and record continuously the changing curvature of the spine not only during range-of-motion testing but also during the performance of given activities (e.g. bending, lifting movements etc) [1–3].

Two computer-aided skin-surface devices have recently been developed to measure the spinal curvature of each of the main global regions of the spine (lumbar, thoracic, sacral) as well as that of the motion segments from T1-2 to L5-S1. One of these is the ultrasound-based system (ZEBRIS, Isny, Germany), the second is the electromechanical-based system (Spinal Mouse, Idiag, Voletswil, Switzerland). The ultrasound-based method is verified/validated by statistical methods for measure on calibration objects [14], however of gait [5], of shoulder motion [4] and of spinal curvature [14] on humans. The electromechanical-based system is verified/validated only on calibration object. The accuracy of the system is 1.13 mm measured on length of calibration objects [12]. However, to the author's knowledge there are currently no independent reports in the peer-reviewed literature concerning verification (reliability and accuracy) of Spinal Mouse by other method on human at different position (standing, flexion, extension). The goal of this research is to present a validation of the electromechanical-based measuring method on the basis of repeated intraobserver and interobserver measurements on healthy subjects. Furthermore, a validation of the method will be present based on repeated intra- and interobserver measurements on healthy subjects. The method is verified by the commercially available WINSPINE measuring method with a ZEBRIS ultrasound-based measuring system.

Subjects Thirty healthy volunteers agreed to participate in the study. Only people without any clinical history of diseases or injuries in the lower extremities and in the spine were involved in the study. There were 18 males (mean age 27.12±8.34 years, mean height 171.45±3.16 cm, mean weight 75.12±9.13 kg) and 12 females (mean age 26.87±8.56 years, mean height 166.27±6.16 cm, mean weight 61.97±9.34 kg). The tests were authorized by the Science and Research Ethics Committee of Semmelweis University. Each voluntary subject provided an informed written consent to performing the tests in advance.

2 Measuring method

Firstly, measures of spinal curvature in various postures (Fig. 1) [11] were made using the Spinal Mouse system, a hand-held, computer-assisted electromechanical-based device. The device is guided along the midline of the spine (or slightly paravertebrally in particularly thin individuals with prominent processus spinous) starting at the processus spinous of C7 and finishing at the top of the anal crease (approximately S3); these landmarks are firstly determined by palpation and marked on the skin surface with a cosmetic pencil. The system records the outline of the skin over the spinal column in the sagittal plane. The local angle or inclination relative to a perpendicular line is given at any position by an internal pendulum connected to a potentiometer. An intelligent recursive algorithm computes information concerning the relative position of the vertebral bodies of the underlying bony spinal column. Raw data of the measurements are the superficial back length from C7 to S3, and the local angle of each point of this length relative to the plumb line. The sampling frequency of measurement is approximately 150 Hz. The average total length of the spine is 550 mm and the time required to measure the whole length is 2–4 seconds; thus, approximately 423 measurements are made over about 3 seconds. The relative high speed of measurement guarantees the immobility of the subject.

Secondly, measures of spinal curvature were made using a ZEBRIS ultrasound-based measuring system with WINSPINE software (Fig. 2). The sampling frequency of the system is 150 Hz. The speed of measurement is similar as at measuring by Spinal Mouse. The details of the measuring method are summarized in [14].The examiner specifies the position of the processus spinosus of each vertebra using the pointer (Fig. 2). He/she simply touches the pin of the pointer to the processus spinosus and fixes the position of the processus spinosus by pushing the button on the pointer. The angles between the different vertebrae and between the different segments are calculated from the 3D positions of processus spinosus.

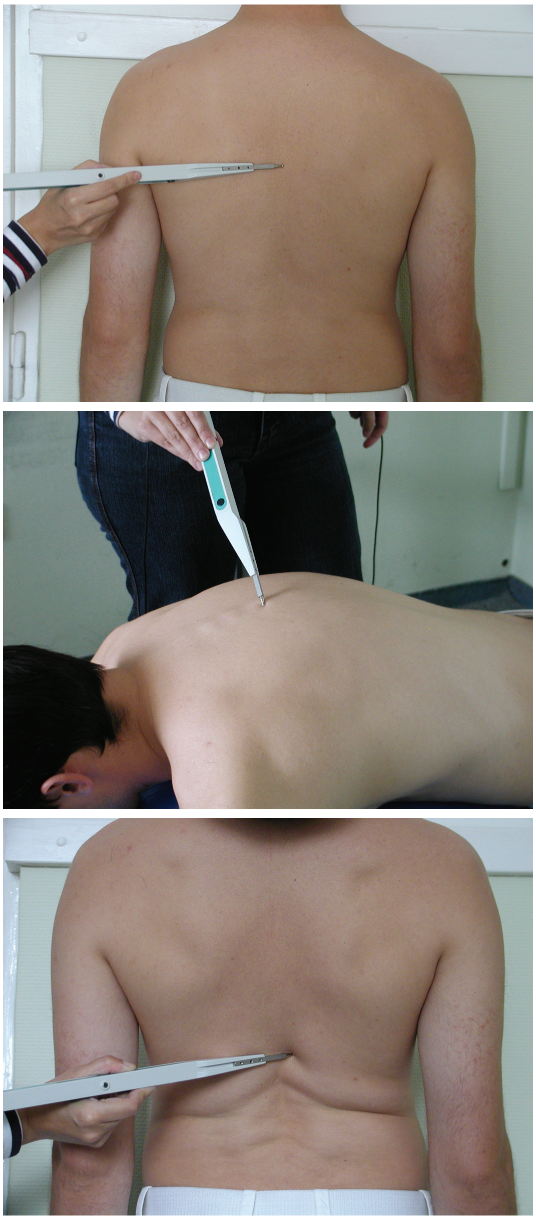
a.
b.
c.

Fig. 1. Measuring by Spinal Mouse a. standing b. flexion c. extension

3 Measurement protocol

The volunteers were randomized to go firstly to Examiner 1 or Examiner 2. The corresponding examiner then palpated the volunteer with Spinal Mouse, marked the landmarks on the skin, and made a set of measurements in the postures described below (one 'set' of measurements will always refer to the three positions of standing, flexion, and extension). Further sets of measures were then carried out approximately 1–2 min apart. The skin marks were then completely removed, and the volunteer went to the second examiner to be palpated, and to carry out the same three sets of measures. The patient then returned to the first examiner, who performed the further sets of measurements with the ZEBRIS ultrasound-based system.

On the 2^{nd}, 3^{rd}, 4^{th} and 5^{th} days of testing, at approximately the same time of the day for each subject, all the tests described



a. b. c.

Fig. 2. Measuring by ZEBRIS ultrasound-based system a. standing b. flexion c. extension

for the 1st day were repeated. The test order was retained to maintain as constant any errors arising from slight increases in curvature with repeated testing (these were expected to be peculiar to the experimental situation of multiple testing and would not therefore contribute to the normal error of measurement). Before starting the study, the examiners discussed and agreed upon the method of palpation and the instructions to be given to the volunteers, but did not confer with each other during the measurements themselves.

4 Test positions

The three test positions adopted for each set of measures comprised:

1 Standing upright (in a relaxed position, feet shoulder width apart, knees straight, arms hanging by the side, and both spina iliaca anterior superior touching the wall) (Figs. 1a and 2a);

2 Flexion (the patient is kneeling before a ball of 65 cm and the upper body flexes on the ball, arms hanging) (Figs.1b and 2b);

3 Extension (legs straight, arms hanging by the side, head in a neutral position, both spina iliaca anterior superior touching the wall, trunk extended as far as comfortably possible) (Figs. 1c and 2c).

The positions were first described and demonstrated by the investigator and practiced once by the volunteer before the three sets of measurements in each posture were made. The patient was instructed to move at a speed of his/her choice and to hold the end position for a few seconds while the measurement was made.

The relevant parameters calculated form the data (position of processus spinosus of each vertebra) measured by the Spinal Mouse and by the ZEBRIS WinSpine in each position were:

- all the individual angles between the vertebrae (from T1-2 through to L5-S1),
- thoracic curvature (T1-T2 to T11-T12),
- lumbar curvature (T12-L1 to L5-S1).

5 Analysis of data

Identification of the measurement error rate consists of two parts. The intraobserver variation of the measurement represents the standard deviation of different angles (angles between the vertebrae and angles between the segments) determined by measurements performed on the same subject performing the examination by the same person. In order to specify the intraobserver variation, the standard variation of coordinates was calculated for both investigators and an F-test was performed. The F-test was considered to be statistically significantly different if $p < 0.05$. The width of the 95% confidence intervals was determined from the standard deviation of five subsequent measurements.

The interobserver variation of the measurement represents the average difference between the angles determined by measurements on the same subject, with examinations performed by two different people. The average of the differences in the angles specified in the course of the measurements performed by the two persons as well as the width of the 95% confidence intervals was calculated.

In order to identify the accuracy of the new method, calculations were made as regards the average of the difference between the angles, determined by two different methods, as well as the width of the 95% confidence intervals.

The statistical analyses required to identify the interobserver and intraobserver variations were performed by the computer software named Statistica (version 7, 2004.).

Tab. 1. Statistical parameters characterizing the intraobserver and interobser variations of the measurement method at standing position

Angles between	Intraobserver								Interobserver		
	Examiner 1				Examiner 2						
	Standard deviation	95% confidence	F-test	Relative errors [%]	Standard deviation	95% confidence	F-test	Relative errors [%]	Average difference	95% confidence	Relative errors [%]
T1-T2	0.49	0.46	77.56	5.4	0.53	0.44	69.12	6.3	0.98	0.89	10.8
T2-T3	0.48	0.34	89.45	8.0	0.44	0.39	71.23	7.4	0.78	0.69	13.0
T3-T4	0.46	0.38	86.56	11.2	0.45	0.34	77.89	10.9	0.66	0.56	16.1
T4-T5	0.45	0.36	88.97	11.0	0.43	0.35	76.56	10.8	0.65	0.61	15.9
T5-T6	0.44	0.35	98.67	9.1	0.37	0.33	89.92	8.6	0.64	0.58	13.2
T6-T7	0.42	0.34	98.45	8.4	0.41	0.40	123.45	8.2	0.56	0.51	11.2
T7-T8	0.34	0.23	99.34	8.3	0.35	0.31	125.56	8.6	0.59	0.54	14.4
T8-T9	0.56	0.55	99.12	11.2	0.37	0.34	127.89	7.4	0.66	0.59	13.2
T9-T10	0.33	0.31	100.34	7.0	0.33	0.31	131.34	7.0	0.61	0.52	12.9
T10-T11	0.43	0.41	98.56	4.3	0.41	0.38	103.56	4.1	0.65	0.55	6.5
T11-T12	0.48	0.47	123.56	6.5	0.46	0.38	108.89	6.2	0.78	0.73	10.5
T12-L1	0.55	0.51	111.51	5.5	0.56	0.54	111.56	5.6	0.88	0.74	8.8
L1-L2	0.57	0.55	89.12	5.7	0.55	0.49	117.78	5.5	0.86	0.79	8.6
L2-L3	0.56	0.54	88.65	8.7	0.55	0.51	97.67	8.5	1.11	0.96	17.2
L3-L4	0.59	0.58	83.45	9.7	0.58	0.54	99.34	9.6	0.98	0.94	16.1
L4-L5	0.66	0.61	76.56	9.4	0.67	0.66	86.67	9.5	1.23	1.02	17.5
L5-S1	0.67	0.66	73.45	8.5	0.68	0.65	71.34	8.6	1.45	1.23	18.4
thoracic curvature	0.45	0.41	112.43	4.5	0.46	0.44	127.88	4.6	0.97	0.94	9.7
lumbar curvature	0.71	0.68	78.67	5.2	0.69	0.67	87.56	5.0	1.26	1.17	9.2

Tab. 2. Statistical parameters characterizing the intraobserver and interobser variations of the measurement method at flexion position

Angles between	Intraobserver								Interobserver		
	Examiner 1				Examiner 2						
	Standard deviation	95% confidence	F-test	Relative errors [%]	Standard deviation	95% confidence	F-test	Relative errors [%]	Average difference	95% confidence	Relative errors [%]
T1-T2	0.56	0.51	88.99	6.2	0.57	0.55	78.65	6.3	1.19	1.11	13.1
T2-T3	0.57	0.52	87.56	9.5	0.55	0.46	77.77	9.2	1.23	1.22	20.5
T3-T4	0.67	0.59	98.67	16.3	0.55	0.53	76.89	13.4	1.14	1.05	27.8
T4-T5	0.56	0.55	134.78	13.7	0.61	0.60	87.34	14.9	1.03	0.94	25.2
T5-T6	0.55	0.48	123.56	11.4	0.60	0.56	98.34	12.4	1.02	1.00	21.1
T6-T7	0.54	0.46	133.56	10.8	0.59	0.55	123.78	11.8	1.09	0.98	21.8
T7-T8	0.62	0.57	144.67	15.1	0.57	0.51	122.45	13.9	1.01	0.87	24.7
T8-T9	0.61	0.55	121.45	12.2	0.59	0.54	132.34	11.8	1.12	0.98	22.4
T9-T10	0.59	0.58	103.56	12.5	0.63	0.57	128.12	13.4	0.98	0.87	20.8
T10-T11	0.66	0.57	112.45	6.6	0.63	0.59	128.96	6.3	1.34	0.99	13.4
T11-T12	0.64	0.58	100.56	8.7	0.64	0.56	100.12	8.7	1.33	0.96	18.0
T12-L1	0.67	0.59	78.98	6.7	0.71	0.63	98.67	7.1	1.41	1.23	14.1
L1-L2	0.76	0.74	79.67	7.6	0.69	0.62	87.56	6.9	1.26	0.80	12.6
L2-L3	0.79	0.78	99.76	12.3	0.72	0.71	88.56	11.2	1.19	1.12	18.5
L3-L4	0.79	0.71	101.23	13.0	0.77	0.75	78.67	12.7	1.35	1.00	22.2
L4-L5	0.75	0.67	88.34	10.7	0.76	0.71	81.34	10.8	1.34	0.98	19.1
L5-S1	0.81	0.74	76.56	10.3	0.84	0.81	88.99	10.7	1.33	1.29	16.9
thoracic curvature	0.75	0.69	100.34	7.5	0.59	0.58	98.78	5.9	1.12	0.90	11.2
lumbar curvature	0.88	0.84	97.45	6.4	0.88	0.82	102.56	6.4	1.11	1.06	8.1

Tab. 3. Statistical parameters characterizing the intraobserver and interobser variations of the measurement method at extension position

Angles between	Intraobserver								Interobserver		
	Examiner 1				Examiner 2						
	Standard deviation	95% confidence	F-test	Relative errors [%]	Standard deviation	95% confidence	F-test	Relative errors [%]	Average difference	95% confidence	Relative errors [%]
T1-T2	0.77	0.67	87.98	8.5	0.89	0.85	67.67	9.8	1.01	1.02	11.1
T2-T3	0.73	0.68	88.88	12.2	0.86	0.84	69.56	14.3	1.04	1.01	17.3
T3-T4	0.75	0.67	91.25	18.3	0.78	0.76	76.56	19.0	1.09	0.98	26.5
T4-T5	0.77	0.71	91.67	18.8	0.75	0.72	111.34	18.3	1.11	0.99	27.1
T5-T6	0.68	0.67	93.56	14.1	0.88	0.78	127.89	18.2	1.23	1.12	25.4
T6-T7	0.89	0.79	99.17	17.8	0.81	0.79	98.78	16.2	1.12	1.03	22.4
T7-T8	0.65	0.59	100.13	15.9	0.85	0.76	99.34	20.8	1.06	1.03	25.9
T8-T9	0.87	0.86	99.87	17.4	0.85	0.75	99.12	17.0	1.08	1.03	21.6
T9-T10	0.87	0.81	121.27	18.5	0.88	0.83	91.45	18.7	1.11	0.98	23.5
T10-T11	0.82	0.78	117.67	8.2	0.78	0.75	102.45	7.8	1.33	1.05	13.3
T11-T12	0.88	0.79	115.46	11.9	0.89	0.82	105.67	12.1	1.16	1.01	15.7
T12-L1	0.92	0.81	97.88	9.2	0.96	0.87	134.89	9.6	1.23	1.09	12.3
L1-L2	0.88	0.84	134.67	8.8	0.91	0.88	134.67	9.1	1.26	1.16	12.6
L2-L3	0.89	0.81	138.56	13.8	0.92	0.91	136.81	14.3	1.38	1.25	21.4
L3-L4	0.94	0.87	131.34	15.5	0.94	0.89	129.61	15.5	1.43	1.38	23.5
L4-L5	0.93	0.90	87.56	13.2	0.97	0.93	98.67	13.8	1.54	1.44	21.9
L5-S1	0.97	0.92	128.67	12.3	0.93	0.91	102.67	11.8	1.52	1.49	19.3
thoracic curvature	0.78	0.76	139.16	7.8	0.89	0.82	100.02	8.9	1.10	0.98	11.0
lumbar curvature	0.96	0.92	131.56	7.0	0.93	0.91	107.02	6.9	1.45	1.34	10.6

Tab. 4. Absolute, relative errors, and 95% confidence values of angles specified by the SPINAL MOUSE and the ZEBRIS ultrasound-based WIN-SPINE measurement methods at standing

Angles between	Examiner 1			Examiner 2		
	Average difference	95% confidence	Relative errors [%]	Average difference	95% confidence	Relative errors [%]
T1-T2	0.86	0.82	9.5	0.87	0.83	9.6
T2-T3	0.87	0.84	14.5	0.86	0.84	14.3
T3-T4	0.81	0.74	19.7	0.87	0.85	21.2
T4-T5	0.83	0.75	20.3	0.88	0.82	21.5
T5-T6	0.75	0.67	15.5	0.79	0.75	16.3
T6-T7	0.77	0.69	15.4	0.76	0.72	15.2
T7-T8	0.82	0.76	20.0	0.76	0.73	18.6
T8-T9	0.97	0.92	19.4	0.85	0.81	17.0
T9-T10	0.99	0.94	21.0	0.91	0.89	19.3
T10-T11	1.03	0.96	10.3	1.07	1.04	10.7
T11-T12	1.08	0.97	14.6	1.09	1.03	14.8
T12-L1	1.14	1.08	11.4	1.11	1.10	11.1
L1-L2	1.13	1.12	11.3	1.15	1.11	11.5
L2-L3	1.21	1.16	18.8	1.28	1.24	19.9
L3-L4	1.22	1.18	20.1	1.29	1.26	21.2
L4-L5	1.25	1.24	17.8	1.28	1.24	18.2
L5-S1	1.22	1.27	15.5	1.29	1.27	16.4
thoracic curvature	0.76	0.73	7.6	0.81	0.78	8.1
lumbar curvature	1.15	1.09	8.4	1.17	1.12	8.6

Tab. 5. Absolute, relative errors, and 95% confidence values of angles specified by the SPINAL MOUSE and the ZEBRIS ultrasound-based WIN-SPINE measurement methods at flexion

Angles between	Examiner 1			Examiner 2		
	Average difference	95% confidence	Relative errors [%]	Average difference	95% confidence	Relative errors [%]
T1-T2	0.85	0.81	9.4	0.83	0.77	9.1
T2-T3	0.87	0.82	14.5	0.88	0.81	14.7
T3-T4	0.82	0.76	20.0	0.87	0.86	21.2
T4-T5	0.83	0.69	20.3	0.81	0.77	19.8
T5-T6	0.72	0.66	14.9	0.71	0.65	14.7
T6-T7	0.76	0.63	15.2	0.69	0.66	13.8
T7-T8	0.79	0.74	19.3	0.79	0.76	19.3
T8-T9	0.85	0.86	17.0	0.87	0.87	17.4
T9-T10	0.97	0.95	20.6	0.99	0.96	21.0
T10-T11	0.99	0.98	9.9	0.94	0.92	9.4
T11-T12	1.03	1.01	13.9	1.06	1.05	14.4
T12-L1	0.99	0.96	9.9	1.07	1.06	10.7
L1-L2	1.02	1.00	10.2	1.06	1.05	10.6
L2-L3	1.23	1.18	19.1	1.13	1.09	17.6
L3-L4	1.25	1.17	20.6	1.25	1.22	20.6
L4-L5	1.27	1.19	18.1	1.28	1.26	18.2
L5-S1	1.26	1.21	16.0	1.31	1.23	16.6
thoracic curvature	0.97	0.95	9.7	1.01	0.99	10.1
lumbar curvature	1.26	1.23	9.2	1.29	1.25	9.4

Tab. 6. Absolute, relative errors, and 95% confidence values of angles specified by the SPINAL MOUSE and the ZEBRIS ultrasound-based WIN-SPINE measurement methods at extension

	Examiner 1			Examiner 2		
Angles between	Average difference	95% confidence	Relative errors [%]	Average difference	95% confidence	Relative errors [%]
T1-T2	1.03	0.98	11.4	1.04	1.03	11.5
T2-T3	1.04	1.00	17.3	1.04	1.01	17.3
T3-T4	0.99	0.91	24.1	1.05	1.02	25.6
T4-T5	0.98	0.93	24.0	1.01	0.96	24.7
T5-T6	0.95	0.90	19.6	1.03	0.99	21.3
T6-T7	0.97	0.94	19.4	0.98	0.92	19.6
T7-T8	0.95	0.93	23.2	0.92	0.84	22.5
T8-T9	1.03	1.01	20.6	0.97	0.85	19.4
T9-T10	1.07	1.04	22.7	0.99	0.95	21.0
T10-T11	1.19	1.13	11.9	0.99	0.96	9.9
T11-T12	1.23	1.21	16.7	1.03	0.99	13.9
T12-L1	1.25	1.23	12.5	1.17	1.13	11.7
L1-L2	1.35	1.31	13.5	1.25	1.19	12.5
L2-L3	1.38	1.36	21.4	1.32	1.28	20.5
L3-L4	1.49	1.42	24.5	1.62	1.58	26.6
L4-L5	1.54	1.50	21.9	1.59	1.54	22.6
L5-S1	1.56	1.52	19.8	1.55	1.50	19.7
thoracic curvature	1.16	1.11	11.6	1.12	1.10	11.2
lumbar curvature	1.51	1.47	11.1	1.49	1.45	10.9

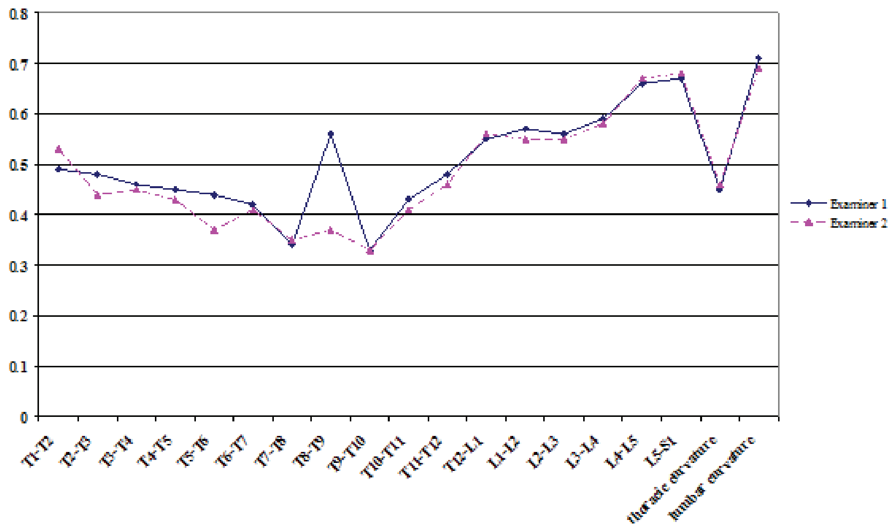


Fig. 3. Intraobserver variation (absolute error) at standing position

Fig. 4. Intraobserver variation (absolute error) at flexion position

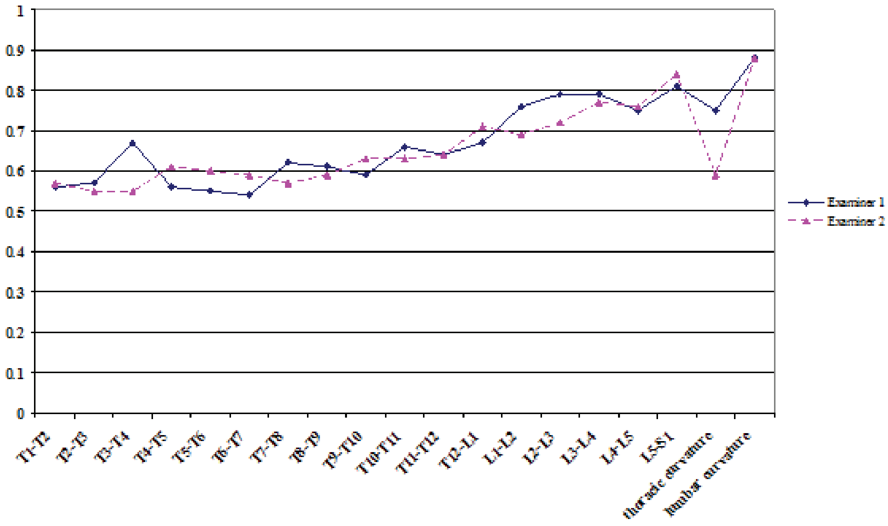


Fig. 5. Intraobserver variation (absolute error) at extension position

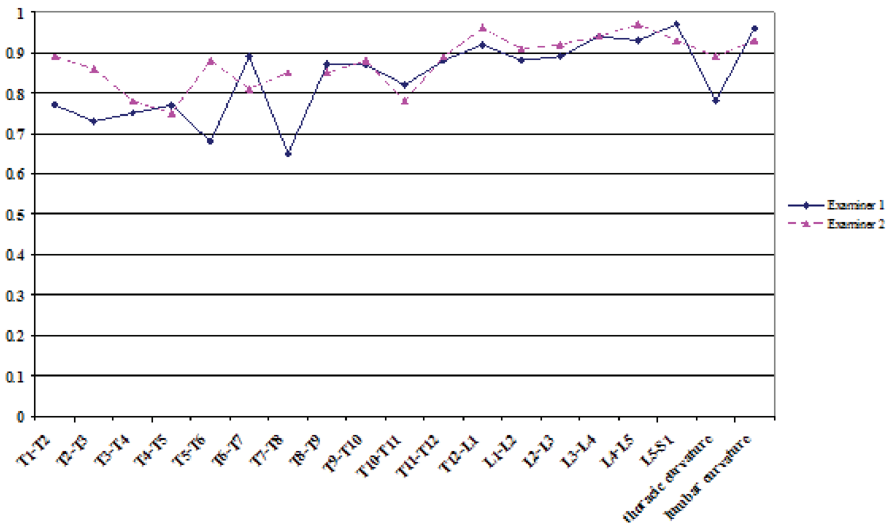
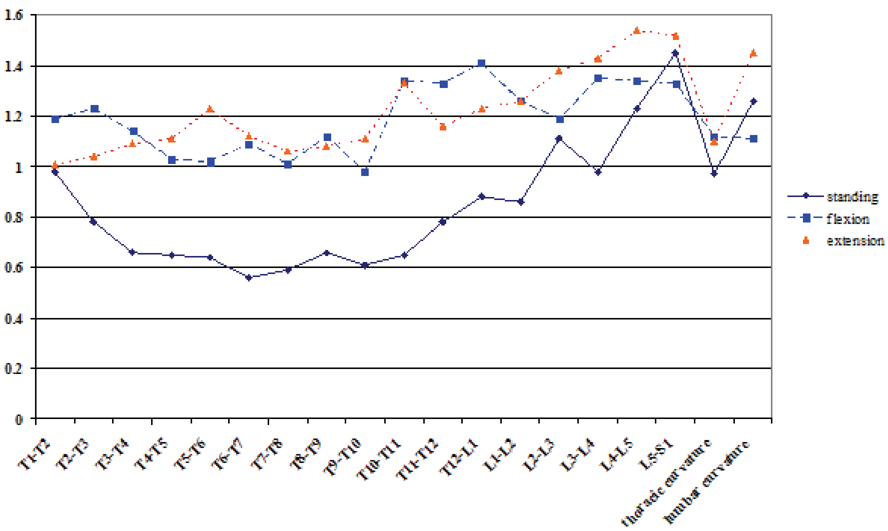


Fig. 6. Interobserver variation at different positions



6 Results

For the sake of transparency, the results of verification and error calculations are summarized in tables. Statistical features are determined separately for each of the three testing positions.

Tables 1-3 show the characteristic statistical parameters of the intraobserver variation for both people performing measurements (in bracket the relative errors are given). The maximum standard deviation of angles between the vertebrae is 0.68 degrees (11.2%) at standing, 0.84 degrees (16.3%) at flexion and 0.97 degrees (20.8%) at extension. The maximum standard deviation of thoracic curvature is 0.46, 0.75, and 0.89 degrees (4.6%, 7.5%, 8.9%), respectively. The maximum standard deviation of lumbar curvature is 0.71, 0.88, and 0.96 degrees (5.2%, 6.4%, 7.0%) respectively. In the event of interobserver variation, the average differences of angles between the vertebrae are 1.45 degrees (18.4 %) at standing, 1.35 degrees (27.8%) at flexion, 1.54 degrees (27.1%) at extension. The average differences of thoracic curvature are 0.97, 1.12, and 1.10 degrees (9.7%, 11.2%, 11.0%), respectively, those of lumbar curvature are 1.26, 1.11, and 1.45 degrees (9.2%, 8.1%, 10.6%), respectively.

Tables 4-6 show the difference between the angles determined by the two methods and the width of the 95% confidence interval. The maximum values of the average difference of angles between the vertebrae are 1.29 degrees (17.5%) at standing, 1.31 degrees (27.8%) at flexion, and 1.62 degrees (27.1%) at extension. The maximum values of the average difference of thoracic curvature are 0.81, 1.01, and 1.16 degrees (9.7%, 11.2%, 11.0%) respectively, those of lumbar curvature are 1.17, 1.29, and 1.51 degrees (9.2%, 8.1%, 10.6%) respectively.

7 Discussion

The method by the electromechanical-based Spinal Mouse was verified by intra- and interobserver variation calculations and verified by a commercial ultrasound-based system with WINSPINE software (ZEBRIS).

On the basis of the statistical analysis of the angles specified by the Spinal Mouse (Tables 1-3), it can be established that the measurement method is reproducible because the maximum standard deviation is 0.97 degrees (20.8%), established at extension. The standard deviation established at standing (0.68 degrees, 11.2%) and flexion (0.79 degrees, 16.3%) is less than at extension. The most probable reason for such difference is that the measuring conditions are harder than at other measuring positions.

The standard deviation of angles is higher than the values specified by the ultrasound-based motion system (0.12 degrees [14]). The most probable reason for such difference is that the measurement accuracy of an ultrasound-based motion system measured on calibration objects is better (0.15 mm) than that of an electromechanical-based one (1.13 mm).

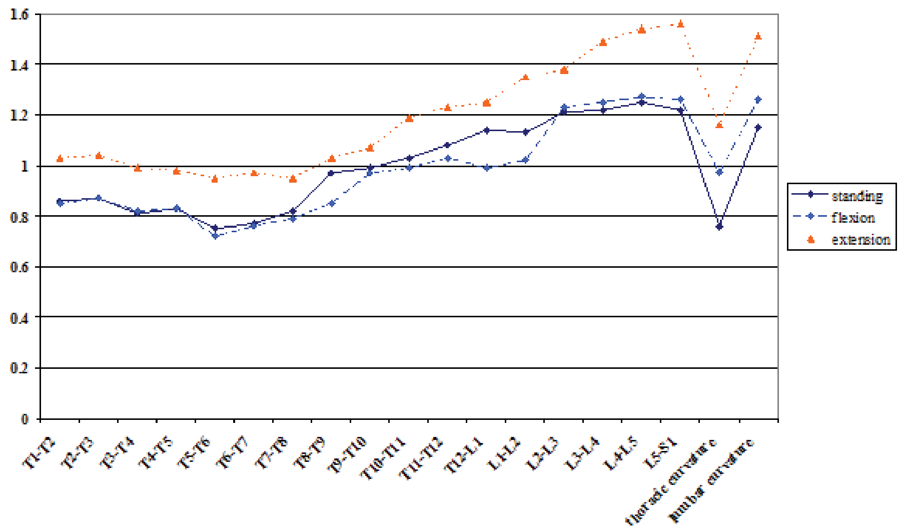
A higher interobserver variation (1.54 degrees, 27.8%) can be explained by the fact that the tests were performed on humans and the width of the determinable surface of the spinal column included in the investigation approximately corresponds to this value. The slight systematic errors between the observers (both reasonably experienced using the Spinal Mouse) could have arisen for a number of reasons. A possible explanation for the interobserver variations could be that different start and end points were used by the two examiners during their measurements, i.e. different landmarks were palpated at the beginning. This is one of the most common sources of interobserver error in measurements of spinal mobility [6]. Other feasible explanations for the interobserver differences include discrepancies in the method of measurement in terms of speed, pressure exerted, and exact path followed during the rolling of the mouse. Furthermore, depending on the sensitivity of the volunteer to the device on his/her back, differences in these factors could have slightly influenced the precise posture adopted during the measurement. The recommended speed of measurement was not explicitly stated before the experiments began (and, indeed, it is not specified by the manufacturers): the examiners simply carried out the tests at speeds with which they were comfortable and as they had been trained. Nonetheless, as long as the Mouse is not rolled so quickly that a signal transmission failure occurs, the speed of movement should not influence the final results. The number of data samples recorded is determined per mm distance rolled in such a way that the speed of rolling would not affect the number of data points that contribute to the final calculated values.

As skin is flexible, the pressure exerted by the examiner in rolling the mouse along the back may influence the values recorded: greater pressure would result in the mouse traversing an apparently greater distance along the back surface and may also result in different curvatures being monitored. Examination of the lengths measured in the various postures, however, revealed no consistent differences between the examiners that could have explained the systematic differences in the angles measured. The exact path followed along the spine, i.e. whether slightly paravertebral or strictly down the midline of the spine, could contribute to slight interobserver errors; this was not assessed in the present study and is indeed difficult to investigate.

Analysis of the results in Figs. 3-5 shows that the standard deviation of angles is nearly identical at various levels of the spine; however, it can be established that the standard deviation in the lumbar region (0.56 degrees at standing, 0.67 degrees at flexion and 0.97 at extension) is higher than in the thoracic region (0.68 degrees at standing, 0.84 degrees at flexion and 0.96 at extension). However the relative errors are higher in the thoracic region (11.2% at standing, 16.3% at flexion and 20.8% at extension) than in the lumbar region (9.7% at standing, 13.0% at flexion and 15.5% at extension). The results of the F-test show that there is no significant difference between the angles, with distribution being normal. We can establish the same in analysis of the interobserver variation (Fig. 6).

A second way of verifying the method is to specify the difference between the coordinates specified by the two methods

Fig. 7. Absolute errors of angles by the Spinal Mouse and the ZEBRIS ultrasound-based WIN-SPINE measurement methods (Examiner 1)



(Fig. 7). The maximum value of the average difference is 1.62 degrees (26.6%). The reason for such difference is probably the fact that errors come from the difference of the measuring devices' accuracy. The second explanation for such difference could be that different measuring methods are concerned: the measuring method by ZEBRIS is a palpation method, and the one by Spinal Mouse is a rolling method.

8 Conclusion

For global regions of the spine, the Spinal Mouse delivered consistently reliable results for standing curvatures and ranges of motion both within and between days and also between examiners. We can establish that two examiners are enough to calculate interobserver variations. This suggests that the device can be used with confidence in both research and clinical environments for the measurement of sagittal profile and/or the range of motion of global regions of the spine, because the relative and absolute errors are smaller than measurable difference between the healthy and non-healthy curvatures. It may find clinical application in the assessment of structural deformities associated with, for example, Scheuermann's disease, osteoporotic kyphosis, scoliosis, or flat-back syndrome or in the monitoring of disturbances / restrictions in movement in connection with 'mechanical' spinal disorders such as herniated disc, simple mechanical back pain, spinal instability, etc. Furthermore, in the areas of ergonomics, workplace, and seating design, the device may be of use in assessing the spinal curvature associated with postures commonly adopted during the performance of given tasks.

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