Reliability of the Cervical Spine Device for the Assessment of Cervical Spine Range of Motion in Asymptomatic Participants

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Abstract

Objective: The purpose of this study was to assess the inter- and intra-assessor reliability of the cervical spine device (Formetric, DIERS International GmbH, Schlangenbad, Germany) in measuring cervical range of motion.
Methods: The cervical spine device was used to measure the cervical range of motion of 65 asymptomatic participants. Flexion-extension, right and left rotation, and right and left lateral flexion were analyzed. Two different assessors performed the measurements on the same day to estimate inter-assessor reliability and 2 days later to examine intra-assessor reliability. Intra-assessor and inter-assessor reliability was assessed using the intraclass correlation coefficient (ICC). The standard error of measurement (SEM) and the smallest detectable difference (SDD) were also estimated.
Results: Inter-assessor reliability ICCs for flexion + extension and total lateral flexion movements were >0.90. The ICCs for rotation movements and for left lateral flexion were >0.70. The ICCs for flexion (0.64), extension (0.58), and right lateral flexion (0.56) indicated moderate correlation. Mean SEMs ranged from 2.28° (SDD = 6.31°) for left rotation to 8.08° (SDD = 22.38°) for total rotation. As for intra-assessor test-retest reliability, all ICCs were >0.70. Mean SEMs ranged from 3.14° (SDD = 8.70°) for total lateral flexion to 7.50° (SDD = 20.77°) for extension.
Conclusion: Both inter- and intra-observer reproducibility correlation values are moderate to high for measurements obtained using the cervical spine device. (J Manipulative Physiol Ther 2018;41:342-349)
Key Indexing Terms: *Range of Motion; Spine*

Introduction

Cervical spine disorders are common and have a significant impact on individuals, communities, and health care systems.[1,2] Patients with cervical spine disorders usually complain of pain and reduced active and passive cervical ranges of motion (ROMs). Restoring physiological ROM is crucial in the management of cervical spine disorders, and, therefore, its proper assessment is extremely important in quantifying the physical disability, determining the best therapeutic interventions, and evaluating their effectiveness.[3] Several tools have been developed to evaluate cervical ROM (CROM), ranging from simple visual estimation to complex 3-dimensional (3-D) motion analysis.[3,4] Selecting a measurement tool requires taking into consideration the purpose for the testing and the very tool's own psychometric properties such as reliability and validity.[5] Both visual estimation[6] and goniometric measurements are often used in clinical practice because of their versatility and simplicity. However, these methods cannot quantify combined movements (eg, lateral flexion and rotation), require experienced training, and are affected by the use of standardized methods of application. For research, the use of more accurate measuring systems may be necessary.[7]

Dynamic radiographic intervertebral motion has long been considered a "gold" standard for studying CROM, but today, the use of this invasive measurement system is limited by the small number of radiographs that may be obtained so as to minimize a patient's exposure to radiation.[8] Three-dimensional kinematic analysis is accurate in calculating CROM, but it is expensive and restricted to a laboratory environment that requires experienced staff.[7] These drawbacks limit its applicability in clinical settings.

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The Formetric (DIERS International GmbH, Schlangenbad, Germany) is a radiation-free analysis system used in assessing spinal posture and pelvic position, both of which are often evaluated in research and clinical settings.[9-11] It has been reported to have a high correlation with radiographic assessments of the anatomy of spine and pelvis, as well as high accuracy and reliability in static and dynamic conditions.[12,13] The cervical spine device is an opto-electronic infrared device, conceived as an additional module for the Formetric, that assesses cervical motion on 3 planes of space and the associated coupled movements. The introduction of a reliable ROM cervical measuring system as an additional module to raster stereography could provide parameters additional to those obtained with the Formetric and could make it possible to measure cervical kinematic data.

To be clinically useful on a daily basis, a measurement system needs to be accurate, easy to use, and able to generate reliable results.[14] Reliability must present both absolute and relative consistency that may be quantified using the standard error of measurement (SEM) and the intraclass correlation coefficient (ICC), respectively.[15] Absolute consistency refers to the consistency of scores of individuals, whereas relative consistency is the consistency of the position or rank of individuals in the group with respect to others. More specifically, the SEM evaluates the precision of a score, thereby allowing the construction of confidence intervals (CIs) for scores.[16]

The aim of the present study was to evaluate the reliability of the cervical-spine device in the measurements of neck movements on 3 planes of space in a sample of assymptomatic participants in terms of absolute and relative consistency.

Methods

Participants

From January 2014 to June 2014, 65 assymptomatic participants of both sexes were recruited from staff and postgraduate students from the Department of Physical Medicine and Rehabilitation.

To be included, participants had to be aged 25 to 45 years. They were excluded if they had reported or complained of neck, shoulder, and/or head pain in the preceding month. Those with a history of neck and/or shoulder disorders, including traumas and fractures, and a history of neurologic and/or rheumatologic disorders were also excluded.

A blinded physician ascertained the eligibility of participants through a screening questionnaire that evaluated demographic data and overall health.

All procedures were in accordance with the Declaration of Helsinki on human experimentation. The ethics committee of the University of Rome approved the experimental protocol. All participants provided written consent.

Instrumentation

The cervical spine device uses 2 infrared cameras to detect the position of 18 passive reflective markers. Sixteen are placed on a very light cylindrical helmet with a known radius and a known fixed set of reflecting markers, worn by the participant during the exam; one is placed on the spinous process of the seventh cervical vertebra and the other on the mastoid process of the temporal bone.

During movement, the system tracks the markers in the stereographic set of images and thus reconstructs the spatial coordinates of the head piece in the reference coordinate system with a frequency of 40 frames/s. The resulting trajectory curves are projected onto the 3 standard planes, and the angles are calculated with respect to the initial positions.

The system is calibrated with 2 cameras spaced approximately 100 cm apart. The 3-D reconstruction is accurate to 1 mm within the patient's ROM. The *x-y* reference plane is perpendicular to the optical axis of the system. The *z* axis goes straight out from the system, with the positive axis pointing toward the operator (Fig 1). The C7 marker is used to reference the spatial position of C7 within the fixed calibration space of the system (as determined by the system calibration). The device calculates cervical movements on the 3 planes as follows:

1. Flexion-extension in sagittal plane: The trajectory is projected on a reference plane going through C7 and the extrema on the helmet. It corresponds to the pitch angle in the Euler system.
2. Rotation of head in transversal plane: Angles are calculated with respect to the initial (start) angle. The start angle is defined as zero. The trajectory of the movement is projected on the axial *x-z* plane going through the midpoints of the helmet. This angle corresponds to the yaw angle in a Euler system.
3. Lateral flexion in coronal plane: The trajectory of the movement is projected on the plane going through the left and right points of the crown. This angle corresponds to the roll angle in a Euler system.

The mastoid marker and the C7 marker represent real anatomical landmarks. Thus, distances, angles, and positions (in the calibrated reference space) can be calculated between the 2 "systems": (i) trunk (spine, C7) and (ii) head (skull, mastoid). This is used in some of the 3-D visualizations as well as in specific data analysis of the extension-flexion movements, where anatomical and physiological accuracy are significant for the operator.

Procedure

Prior to this study, 2 physicians (assessor 1 and assessor 2) with 5 years of clinical experience and knowledge of CROM measurements received a training course on understanding the conceptual framework, application, and

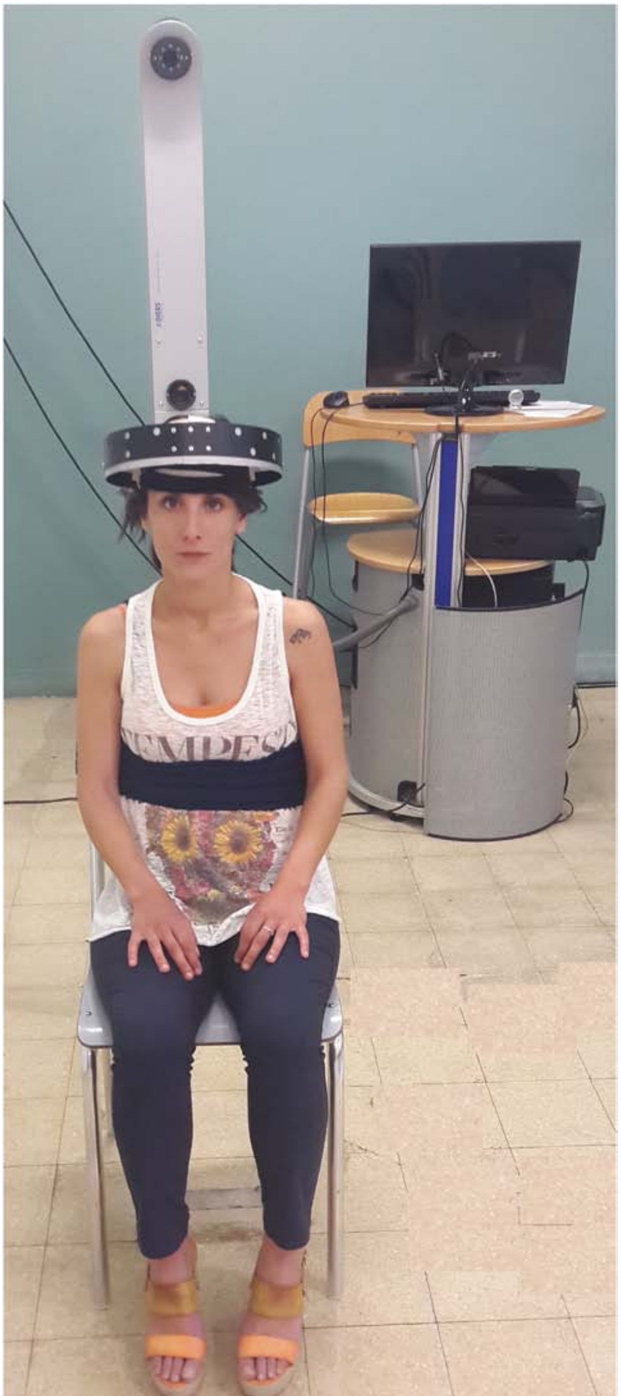

Fig 1. *Cervical spine device and patient setting.*

Fig 2. *Patient setting in sagittal plane.*

use of the cervical spine device. To estimate inter-assessor reliability, the examination was performed by both assessors on the same day (evaluation 1). Assessor 1 and assessor 2 made their evaluations independently and were blinded to each other's procedures and results. Two days later, evaluation 2 was performed by assessor 1 to examine intra-observer reliability. It was assumed that the participants' clinical condition had not changed over 2 days. First, the helmet was positioned firmly on the forehead of each participant. Then 2 passive reflective markers were located on the spinous process of the seventh cervical vertebra and on the mastoid process of the temporal bone. The marker positioned on the C7 spinous process had a cylindrical shape to ensure its visibility during flexion-extension movements. Skin displacement is ignored in this application and may generate an error of 1° to 2°.

The spinous process of C7 was located through the palpation of the most prominent cervical spinous process and the flexion-extension method that is more accurate than the conventional method.[17] The mastoid process, an easily palpable structure, is just posterior to the ear.

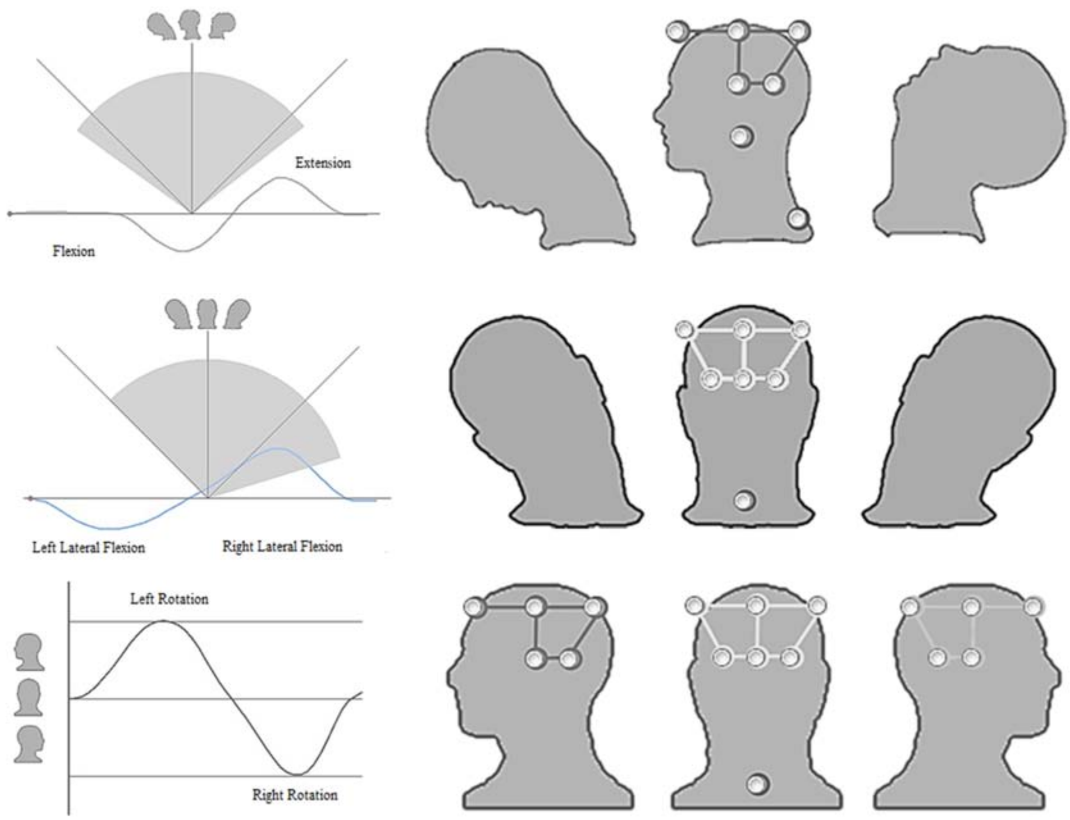

Fig 3. *Sequence of movements and marker setting.*

The marker on the mastoid process (Fig 2) is used in flexion-extension processing only. Its purpose is to have a fixed point on the skull, that is, a position not depending on jaw displacement during movement. The angles are spatial angles projected on the 3 standard planes that correspond to the roll, pitch, and yaw Euler angles. The fixed coordinate system is determined by calibration of the system and corresponds to the natural space where the system is positioned: *y* axis determined by gravity; *x* axis from left to right as seen from the camera; and *z* axis toward the camera.

The participants were instructed to sit up straight, with their feet flat on the floor and their arms hanging at their sides; participants were positioned approximately 1.5 meters from the imaging unit. Trunk and shoulders were stabilized using straps to detect the cervical motion as a pure movement (Figs 1, 2). To obtain a reference position, we ensured that the auricular-orbital plane was parallel to the *x-z* reference plane. Moreover, participants were asked to close their eyes and assume a relaxed posture with feet located parallel on the ground and hands resting freely on the thighs.

Before data collection, the assessors verbally defined and visually demonstrated the sequences that had to be performed over an average time of 10 minutes. After this brief warm-up period, each participant performed flexion-extension, right and left rotation, and right and left lateral flexion (Fig 3). Movements on each plane were repeated 3 times to obtain 3 different acquisitions for each measure. The sequences had to be performed naturally to obtain the maximum ROM. The mean of 3 movements was taken as the real ROM value.

The flexion-extension movement (reference system *y-z* plane) on the sagittal plane starts with the patient looking away from the cameras at an angle of approximately 45°. Patients tilt their head forward, go back as far as possible, and then reassume the initial position. The angles are calculated with respect to the initial orientation of the head piece and the position of C7.

The rotation of the head on the transversal plane starts with the patient looking away from the cameras (reference system *x-z* plane). Patients turn their head to the right and left sides and then reassume the initial position. The angles are calculated with respect to the initial orientation of the head piece and the position of C7.

Lateral flexion on the coronal plane (reference system *x-y* plane) starts with the patient looking away from the cameras. Patients incline their heads to the right and then left side and then reassume the initial position. The angles are calculated with respect to the position of C7.

Measurements were taken during the daytime (between 9 AM and 2 PM) in a quiet, air-conditioned room.

Table 1. *Cervical Range of Motion Values* [a]

	Assessor 1	Assessor 2	Assessor 1, Day 2	*P* Value	
				Assessor 1 vs Assessor 2	Assessor 1 vs Assessor 1, Day 2
Flexion	53.8 ± 14.3	54.2 ± 12.1	53.0 ± 8.7	.81	.82
Extension	63.0 ± 15.7	62.0 ± 15.1	60.0 ± 14.3	.63	.76
Extension + flexion	98.8 ± 21.5	100.0 ± 19.4	98.5 ± 22.5	.51	.98
Right lateral flexion	47.3 ± 11.8	46.5 ± 11.3	48.8 ± 8.9	.38	.92
Left lateral flexion	50.5 ± 12.4	51.4 ± 12.6	49.7 ± 11.2	.50	.76
Total lateral flexion	87.5 ± 14.8	89.8 ± 16.3	89.9 ± 21.7	.07	.26
Right rotation	83.1 ± 9.0	83.8 ± 13.8	81.1 ± 9.3	.72	.08
Left rotation	80.1 ± 8.0	82.3 ± 9.4	79.6 ± 8.7	.06	.84
Total rotation	152.8 ± 16.5	152.8 ± 20.6	153.0 ± 21.6	.99	.91

[a] Sample mean.

Sample Size

With respect to measurement of reliability, power calculation was based on the ICC. On assumption of a 2-tailed α value of 0.05 (sensitivity = 95%), a β value of 0.20 (study power = 80%), a null hypothesis $\rho0$ of 0.4, and an alternative hypothesis $\rho1$ of 0.5, we determined that at least 60 participants were required (Power Analysis and Sample Size System software) (G*Power 3, Heinrich Heine University, Düsseldorf, Germany).

Statistical Analysis

A Kolmogorov-Smirnov test was used to verify the normal distribution of the data, and a paired *t* test was used to compare the differences between the measurements taken by the 2 assessors.

The paired *t* test was used to investigate differences in mean CROM values of each assessor and between assessors.

On the basis of a 2-way random effects analysis of variance, we estimated the ICCs (95% CIs) to measure variations among participants. The ICC[1,2] and ICC(2,k) were used to determine intra-assessor and inter-assessor reliability, respectively.[18] The ICC ranges from 0 to 1, with 1 indicating perfect reliability. ICCs were interpreted as follows: 0.00-0.25 = little, if any, correlation; 0.26-0.49 = low correlation; 0.50-0.69 = moderate correlation; 0.70-0.89 = high correlation; and 0.90-1 = very high correlation.[19]

The SEM provides an absolute index of reliability. It was estimated as follows: SEM = SD × $\sqrt{(1 - ICC)}$.

The smallest detectable difference (SDD), defined as the minimal change that falls outside the measurement error in the score of an instrument used to make a measurement, was calculated as 1.96*$\sqrt{2}$*SEM.

All analyses were conducted using MedCalc Version 10.2.0.0 for Windows (https://www.medcalc.org). The level of statistical significance was set at $P < .05$.

Results

Sixty-five participants (mean age ± SD: 33 ± 12 years, range: 26-43 years)—34 women and 31 men—participated in the study. Cervical ROM values of the 2 assessors at evaluation 1 are reported in Table 1.

Inter-assessor and intra-assessor test-retest reliability values are reported in Table 2.

With respect to inter-assessor reliability, the ICCs for both flexion+ extension and total lateral flexion movements were >0.90, exhibiting a very high correlation. The 95% CIs of ICCs ranged from 0.84 to 0.96 for flexion + extension and from 0.85 to 0.96 for total lateral flexion. The ICCs for rotation movements and for left lateral flexion were >0.70, indicating a high correlation. The 95% CIs of ICCs ranged from 0.59 to 0.88 for right rotation, 0.57 to 0.87 for left rotation, 0.57 to 0.87 for total rotation, and 0.54 to 0.86 for left lateral flexion. The ICCs for flexion (0.64), extension (0.58), and right lateral flexion (0.56) exhibited a moderate correlation. The SEM mean values ranged from 2.28° (SDD = 6.31°) for left rotation to 8.08° (SDD = 22.38°) for total rotation.

For intra-assessor test-retest reliability, all ICCs were >0.70, indicating a high correlation. The 95% CIs of ICCs ranged from 0.63 to 0.87 for flexion, 0.57 to 0.85 for extension, 0.67 to 0.90 for flexion + extension, 0.74 to 0.90 for right lateral flexion, 0.77 to 0.93 for left lateral flexion, 0.68 to 0.89 for total lateral flexion, 0.58 to 0.85 for right

Table 2. *Inter-assessor and Intra-assessor Reliability*

	Inter-assessor Reliability				Intra-assessor Reliability			
	ICC [a]	SEM (°)	95% CI	SDD (°)	ICC [a]	SEM (°)	95% CI	SDD (°)
Flexion	0.64	5.21	0.34-0.80	14.43	0.77	6.80	0.63-0.87	18.83
Extension	0.58	6.30	0.22-0.77	17.45	0.74	7.50	0.57-0.85	20.77
Flexion + extension	0.92	5.99	0.84-0.96	16.60	0.81	3.40	0.67-0.90	9.42
Right lateral flexion	0.56	3.94	0.46-0.76	10.91	0.84	3.58	0.74-0.90	9.91
Left lateral flexion	0.75	2.54	0.54-0.86	7.03	0.86	3.75	0.77-0.93	10.38
Total lateral flexion	0.92	4.20	0.85-0.96	11.63	0.81	3.14	0.68-0.89	8.70
Right rotation	0.78	2.53	0.59-0.88	7.01	0.75	5.76	0.58-0.85	5.95
Left rotation	0.76	2.28	0.57-0.87	6.31	0.80	4.25	0.67-0.89	11.7
Total rotation	0.76	8.08	0.57-0.87	22.38	0.82	3.22	0.69-0.90	8.92

CI, confidence interval; *ICC,* intraclass correlation coefficient; *SDD,* smallest detectable difference; *SEM,* standard error of measurement.
[a] Average values.

rotation, 0.67 to 0.89 for left rotation, and 0.69 to 0.90 for total rotation.

Mean SEMs ranged from 3.14° (SDD = 8.70°) for total lateral flexion to 7.50° (SDD = 20.77°) for extension.

Discussion

The present study was conducted to investigate the reliability of CROM measurements obtained using the cervical spine device on a sample of asymptomatic participants. A preliminary evaluation of the reliability of a device should be performed before regular use in clinical practice.

The mean CROM values for all 3 planes of movement were comparable to those already reported in the present literature,[20] thereby confirming that the cervical spine device is suitable for proper assessment of the studied movements.

With respect to the reliability of measurements throughout the total ROM, the cervical spine device provided very high ICCs for inter-assessor reliability and high ICCs for intra-assessor reliability. On the other hand, the ICCs calculated on half a plane (ie, left or right rotation/lateral flexion, flexion and extension) ranged from moderate to high for inter-assessor reliability and high for intra-assessor reliability, suggesting that, from the point of view of reliability, computing movement over the whole plane could lead to even better results. One possible explanation of these differences may be related to the difficulties encountered in locating a consistent starting (neutral) point when assessing the half-plane movement.

The SDDs of the cervical spine device are comparable to those of other CROM tools, ranging from 10° to 19°.[21]

With respect to reliability, study obtained ICCs comparable to those obtained using other cervical spine devices.[3,22] The CROM device and the single inclinometer are considered the most appropriate clinical measurement instruments.[3,8,23,24] They are inexpensive, are easy to use, and have been reported to have an acceptable, and in some cases even good, level of reliability.[3] In their systematic review, Williams et al[3] reported that both the CROM device (ICCs = 0.58-0.99) and the EDI-320 inclinometer (ICC = 0.89-0.97) have a good reliability for all cervical spine movements. However, these tools have proven to be cumbersome for patients, and an evaluation should be performed by an experienced examiner to increase the accuracy of measurements.[25,26] Inclinometers have been reported to have rather poor resolution (15 u) and are not good tools for follow-up evaluations over a long period.[24]

Several opto-electronic devices have been designed to carry out non-invasive and 3-D dynamic measurements of CROM.[7] They also allow for increased resolution of measurements.[26]

Bulgheroni et al[27] assessed the reliability of a 3-D kinematic system (ELITE System, BTS, Milan, Italy) that measures CROM. The opto-electronic motion analyzer was based on passive markers and 2 infrared TV cameras working at a sampling rate of 50 Hz. The authors obtained reliability values (inter-assessor reliability: ICC = 0.83-0.92; ICC = 0.74 for extension) larger than ours, but it is worth noting that they were based on a smaller sample. Moreover, they calculated cervical movements only on half a plane.

Inokuchi et al[26] evaluated the test-retest repeatability of CROM in 20 healthy participants using a 3-D motion analysis system (VICON). They obtained ICCs and SEMs ranging from 0.78 to 0.96 and from 1.3° to 4.5°, respectively. On the basis of flexion-extension movements, the authors obtained reliability values greater than ours, although their sample was smaller. To determine test-retest repeatability, participants were asked to revisit the laboratory for second measurements after 1 month, without taking account of potential clinical changes in participants. Furthermore, assessment of flexion-extension was computed over half a plane, whereas both lateral flexion and rotation were evaluated over the entire plane.

Three-dimensional kinematic motion analysis systems have upgraded the interpretation of motion data by offering high accuracy, reduction of the examiner-bound error of measurement, and recording of coupled motions. The major drawback of these dedicated systems is their cost, which limits their employment.[21]

The cervical spine device could be a promising alternative solution for evaluation of CROM movements, providing reasonable values of reliability at a lower cost.

With respect to cervical coupled motions, 3-D kinematic motion analysis may be the most suitable method for obtaining specific clinical information while at the same time providing CROM values measured on all 3 planes of space.

Most opto-electronic devices available on the market are expensive and restricted to laboratory settings that require experienced staff, thereby limiting their applicability to clinical practice. Therefore, the cervical spine device could be a promising alternative solution in evaluating CROM movements by providing reasonable reliable values at lower cost.

Limitations

First, this study did not include a group of patients with a documented history of cervical spine pathologies, which would allow for comparison of the results of asymptomatic participants and those with pathology. Future studies are needed to confirm that the system detects differences between these groups to classify specific pathologic patterns on the basis of variations in CROM.

Second, we did not stratify participants according to age, and we limited our observations to a specific age range. Further analyses with participants in wider age ranges would be useful in assessing the reliability of the cervical spine device in older adults as well.

Third, the interval between the 2 repeated measurements, 2 days, might be considered a relatively short interval for inter-reliability evaluation.

Finally, because of the potential movement of the skin and the upper thorax, the use of 1 C7 marker to construct a reference system may influence the reliability of the method, as we used projection of trajectories to compute planar motions.

Conclusion

The cervical spine device exhibited high reliability on all 3 planes of movement. Therefore, it may be potentially useful in objectifying CROM, for both research and clinical purposes.

Funding Sources and Conflicts of Interest

No funding sources or conflicts of interest were reported for this study.

Contributorship Information

Concept development (provided idea for the research): T.V., M.M.
Design (planned the methods to generate the results): M.M., M.P.
Supervision (provided oversight, responsible for organization and implementation, writing of the manuscript): T.V., V.S., M.P.
Data collection/processing (responsible for experiments, patient management, organization, or reporting data): C.R., A.B.
Analysis/interpretation (responsible for statistical analysis, evaluation, and presentation of the results): T.V., M.G.
Literature search (performed the literature search): T.V., M.G., E.D.S., A.B.
Writing (responsible for writing a substantive part of the manuscript): T.V., M.M., M.P.
Critical review (revised manuscript for intellectual content, this does not relate to spelling and grammar checking): M.M., F.I., V.S.

Practical Applications

- The cervical spine device provided high ICCs for inter-assessor reliability and high ICCs for intra-assessor reliability.
- The movement over the whole plane has higher reliability than when separated into its parts.
- We suggest performing the evaluation of the CROM according to movement over the whole plane.

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