The Validity and Reproducibility of the Flexicurve in the Evaluation of Cervical Spine Lordosis

Eduardo G. Raupp, MS, Cláudia T. Candotti, PhD, Bárbara V. Marchetti, MS, Adriane Vieira, PhD, Fernanda S. Medeiros, PT, and Jefferson F. Loss, PhD

Abstract

Objective: The purpose of this study was to measure the validity and reliability of flexicurve measurements of cervical curvature in the sagittal plane in adults.

Methods: One hundred thirteen adults were assessed in the seated position with flexicurve radiographs. Two groups were measured: (1) the validity group (n = 55), and (2) the reliability group (n = 58). Both groups were subdivided into 3 subgroups according to body mass index: underweight, normal weight, and overweight. Radiographs were simultaneously taken with flexicurve molded on the cervical spine. Pearson's correlation and the root mean square error were used for the concurrent validity. The reliability of the flexicurve was assessed by 3 raters using the intraclass correlation coefficient (ICC), the standard error of the measurement (SEM), and minimal detectable change (MDC).

Results: For the concurrent validity, a high correlation ($r = 0.570$, $P < .001$, root mean square error = 9.8°), and excellent results were obtained for intra-rater (ICC = 0.771, $P < .001$, SEM = 4.4°, MDC = 8.6°) and inter-rater (ICC = 0.775, $P < .001$, SEM = 4.3°, MDC = 8.5°) reliability. The subgroups had different results, whereas the underweight subgroup consistently had the best results.

Conclusion: These findings suggest that the flexicurve can be a valid instrument for evaluating the curvature of the cervical spine in the sagittal plane in adults classified according to the body mass index as underweight and normal weight. Reliable measurements were provided for its use whether by the same or different raters. The flexicurve can be recommended for use both in clinical practice and in research settings as long as the suggested protocol is followed. (J Manipulative Physiol Ther 2017;40:501-510)

Key Indexing Terms: *Cervical Spine; Neck; Evaluation; Validation Studies; Lordosis*

Introduction

Complaints of the cervical spine are common in our society,[1] with annual variance in prevalence ranging from 16.7% to 75.1% (average: 37.2%) of the adult population.[2] It has been suggested that a normal cervical curvature is a desirable clinical outcome.[3,4]

In clinical practice, the radiograph is the gold standard and the most widely used method of assessing and identifying alterations in the curvature of the cervical spine.[5] In this type of examination, the Cobb angle is considered the method of choice for analyzing the curves of the cervical spine in the sagittal plane, with good to high inter- and intra-rater correlation.[6,7] However, because of its invasive and potentially harmful nature, x-rays are considered unsuitable for repeated use when accompanying postural treatments, because the patient is exposed to cumulative levels of radiation. In addition, the lack of portability of radiographic equipment, the time necessary to obtain and interpret the radiographic image, as well as the costs involved in its use, encourage the use of alternative methods of assessing the curvature of the vertebral spine.[8-12]

In this context, the skin contour may be an interesting option for analyzing the alignment of the spine in the sagittal plane.[13] Thus, in several studies, the flexicurve has been used to analyze the thoracic and lumbar curvatures of the spine in the sagittal plane,[10,14-16] indicating the internal validity of the instrument. This instrument consists of a piece of flexible lead covered in plastic that can be molded to an individual's back to replicate the surface shape of the vertebral spine. Once it is molded, the flexicurve maintains the shape and thereby permits that shape to be traced onto paper and, subsequently, the angle of the curvature to be calculated. However, in the cervical curvature, the

Postural Department, Federal University of Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil.

Corresponding author: Eduardo G. Raupp, MS, 249 Farroupilha Street, Estancia Velha, Rio Grande do Sul, Brazil, 93600-000. Tel.: +55 051 97010605. (e-mail: *eduardorauppdc@yahoo.com.br*).

Paper submitted August 15, 2016; in revised form February 18, 2017; accepted June 5, 2017.

0161-4754

https://doi.org/10.1016/j.jmpt.2017.06.010

flexicurve sagittal skin contour measurement has poor concurrent validity compared with the established radiograph-based measurement of cervical lordosis.[17,18] The fact that the methods of calculating the angle with radiographs and flexicurve differ may represent a source of error.[18] For example, Harrison et al[17] considered the curvature obtained using the flexicurve as a perfect circle, whereas the Cobb angle is calculated based on the inclination of 2 vertebrae in the limits of the cervical spine.[7] Another potential source of error between the measurements obtained with radiographs and those obtained at the skin surface might be related to the quantity of subcutaneous fat in the cervical region,[19] which may explain why the surface curvature tends to be greater than that of vertebral bodies.[17,20]

Therefore, the present study aimed to identify whether the flexicurve is capable of providing valid and reliable information regarding the angle of cervical curvature in the sagittal plane in adults. In addition, given there is a very high correlation between subcutaneous fat in the cervical region and the body mass index (BMI),[21] we also intended to investigate whether the results for validation and reliability are altered in relation to BMI.

Methods

This prospective study had a consecutive sample of 113 participants of both sexes divided into 2 groups: (1) the validation (VAL) group, which participated in the concurrent validation phase, and (2) the reliability (REL) group, which participated in the reliability phase of the flexicurve.

The VAL group sample size was calculated using G*Power software, Version 3.1.7 (available at: http://www.gpower.hhu.de/en.html), based on an expected correlation of 0.6,[16] assuming an error of 0.05 and a power of 90%, resulting in a minimum of 51 participants. Allowing for losses, we invited 55 participants to participate in the study (54.5% female and 45.5% male; age 38.5 ± 15.4 years; weight 76.8 ± 17.8 kg; height 170.2 ± 10.5 cm; BMI 22.4 ± 4.4 kg/m^2).

The REL group sample size was calculated according to Walter et al[22] and Donner and Eliasziw,[23] assuming the null hypothesis value of the intraclass correlation coefficient (ICC) to be 0.40 (eg, on the basis that any value lower than 0.40 might be considered clinically "unacceptable"), 80% power, 2 replicated measurements (once for each rater or twice by the same rater), and a significance level of 95% to detect an ICC value of 0.67[24]; a minimum of 33 participants were found. Allowing for possible losses because the evaluations were conducted on 2 different days, we invited 58 participants to participate in the study (65.5% female and 34.5% male; age 32.9 ± 15.5 years; weight 68.8 ± 12.4 kg; height 163.7 ± 9.7 cm; BMI 21.0 ± 3.4 kg/m^2).

Notices inviting people to participate in the study were posted at various locations around the Federal University of Rio Grande do Sul, as well as on social networks, reaching a potential public of students, employees, and visitors to the campus. Participants were required to be between 18 and 60 years of age. The exclusion criteria were poor-quality radiographic images; failure to attend any of the evaluation meetings or abandonment of the study; and the existence of any previous surgical intervention in the spine that might interfere with the acquisition of angles of lordosis when using the evaluation methods. This study was approved by the ethics committee of the Federal University of Rio Grande do Sul, in accordance with the ethical standards of the Helsinki Declaration of 1975. All subjects signed an informed consent form. The study was registered in *Plataforma Brasil* under No. CAAE: 26737714.0.0000.5347 (http://aplicacao.saude.gov.br/plataformabrasil/login.jsf). The full study protocol can be accessed at https://www.lume.ufrgs.br/bitstream/handle/10183/128041/000975374.pdf?sequence=1.

Data Collection and Analysis Procedures

Validation phase. The flexicurve (Model 1240, Trident, Sao Paulo, Brazil) was used by rater 1 (R1) to assess the members of the VAL group during the course of a radiographic exam conducted by a radiologist at a radiological institute. First, the external occipital protuberance (C0), atlas posterior tubercle (C1), and C2, C7, T1, and T2 spinous processes were palpated and marked with a dermatograph pencil. When the C0 was marked in individuals with long hair, a band was placed around the head and adhesive tape was fixed to the band to mark the point. The subjects were instructed to close their eyes, lower and raise the head twice, stop in the neutral position, open the eyes, and look toward the horizon without moving.[25] Immediately afterward, the flexicurve was molded (Fig 1A) and fixed to the skin covering the cervical spine using Velcro strips (Fig 1B). The use of Velcro strips was required for flexicurve to be fixed during the radiographic exam. Then, magnetic markers were used directly on the flexicurve itself at the points corresponding to the anatomical marks on the skin (Fig 1C). During this assessment, the subjects were positioned seated on a stool with the shoulders perpendicular to the radiographic bucky.

Once the subject was in the correct position and with the flexicurve attached to the body, a sagittal radiographic image of the cervical spine was obtained. Immediately afterward, R1 carefully removed the flexicurve and placed it on graph paper to trace the shape of the cervical spine (Fig 1D).

With the outline of the cervical spine on graph paper (Fig 1D), a system of Cartesian coordinates was defined with the x-axis representing the cranial-caudal direction, and the y-axis representing the anterior-posterior direction (Fig 2A). The coordinates of each anatomical point, together with another 6 intermediate points along the curve, were transferred to BIOMEC-FLEX software (www.ufrgs.br/biomec/). Two equidistant intermediate points were placed between C0