

Development and Validation of a Simple Tape-based Measurement Tool for Recording Cervical Rotation in Patients with Ankylosing Spondylitis: Comparison with a Goniometer-based Approach

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ABSTRACT. *Objective.* To compare a tape-based tool for measuring cervical mobility in patients with ankylosing spondylitis (AS) with the widely practiced goniometer-based approach.

Methods. We developed a novel tape-based approach to measurement of lateral cervical rotation of the neck that is minimally affected by flexion/extension movements of the neck. This requires measurement of the difference between a mark at the suprasternal notch and the tragus of the ear. Rotation score is measured in centimeters and constitutes the difference in length between the 2 extremes of cervical rotation (<http://www.arthritisdoctors.org/researcher.html>). We assessed the tape-based and goniometer-based methods in a total of 263 patients from 3 countries, Canada (n = 205), Australia (n = 29), and Colombia (n = 29), that included patients from community and tertiary-based practice. Intra- and inter-observer reliability was assessed in a subset of 44 patients by ANOVA and a 2-way mixed effects model. The Bath AS Disease Activity (BASDAI) and Function (BASFI) Indices, and the modified Stoke AS Spinal Score (mSASSS), were also recorded to assess construct validity by correlation coefficient and regression analysis. Responsiveness was assessed in a subset of 33 patients that were either randomized to anti-tumor necrosis factor- α therapy:placebo (n = 22) or received open label infliximab (n = 4) or pamidronate (n = 7) over a period of 24 weeks.

Results. Scores obtained with the tape-based method were normally distributed, while those obtained using the goniometer were skewed towards normal values. Reliability for the goniometer-based approach was excellent [intraclass correlation coefficient (ICC) > 0.90] and very good for the tape-based approach (ICC > 0.80). Significant correlations were noted between age, disease duration, function and structural damage scores, and scores obtained with both methods. Responsiveness was high using raw scores obtained with the goniometer (standardized response mean > 0.80) but was not evident when the grading scheme proposed for the Bath AS Metrology Index (BASMI) was employed.

Conclusion. The tape-based approach we describe provides a simple, feasible, and reliable index of cervical rotation that is comparable to the information obtained from the use of a goniometer. If the goniometer-based approach is used, raw scores should be used in the calculation of responsiveness rather than the grading scheme suggested in the BASMI. (First Release Oct 1 2006; J Rheumatol 2006;33:2242–8)

Key Indexing Terms:

CERVICAL ROTATION
VALIDATION

MEASUREMENT
GONIOMETER

ANKYLOSING SPONDYLITIS
TAPE MEASURE

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The cervical spine is affected in several forms of arthritis, notably osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis (AS). Measurement of spinal mobility is an established practice in the evaluation of patients with AS in both routine clinical practice as well as in research and clinical trials. Impairment in cervical mobility has been recognized as a significant factor contributing to the impairment of function in patients with AS¹. Several approaches have been described for the measurement of cervical flexion/extension, lateral flexion, and lateral rotation based on the use of either a goniometer or a tape measure^{2,3}. However, these approaches have generally not been rigorously validated from the perspective of the Outcome Measures in Rheumatology Clinical Trials

OMERACT) filter that requires the examination of truth, feasibility, and discrimination⁴.

Previous studies suggested that only lateral rotation is sufficiently reliable³ and this led to its inclusion in a 5-item composite index of spinal mobility, the Bath AS Metrology Index (BASMI)⁵. In this approach, lateral cervical rotation is measured with the patient in a supine position with the use of a gravity-action goniometer. Although this composite index was shown to be responsive in patients attending an intensive 3-week inpatient course of physiotherapy, the responsiveness of individual components comprising this index were never reported. Similarly, though the BASMI has been shown to discriminate between treatment groups in placebo-controlled trials of infliximab in AS^{6,7}, the responsiveness of individual components has not been reported.

A practical limitation of the approach recommended in the BASMI is that most practitioners do not routinely use a specialized goniometer in patient evaluation. So it is not surprising that this approach has already been adapted by some practitioners by having the patient seated and a conventional goniometer being placed on the crown of the head. However, it is often difficult to fix the position of the goniometer on the head during the process of measuring cervical rotation, and this approach has not been validated despite its use in clinical trials⁷. This might account for the lack of inclusion of cervical rotation as one of the measures in the spinal mobility domain that was recommended by experts of the Assessments in AS Working group (ASAS) for the evaluation of disease-controlling therapies and for clinical recordkeeping⁸. A simple tape-based measure might lead to greater acceptance of cervical rotation in routine clinical practice. Although one approach has been described that records the distance between the chin and the coronoideus process of the clavicle, the reliability of this method might be compromised by flexion/extension movements of the neck².

In this report, we describe a novel approach to the assessment of lateral cervical rotation that only requires a measuring tape, has well-defined anatomical landmarks, and is unlikely to be compromised by flexion/extension movements of the neck. We described its validation according to the OMERACT filter and compared its performance to cervical rotation measured using a goniometer.

MATERIALS AND METHODS

Patients. The patient sample consisted of 263 individuals of whom 205 were consecutive outpatients followed by rheumatologists in the city of Edmonton at both tertiary (University of Alberta Hospital) and community-based sites; 29 were outpatients at a community-based site in Townsville, Australia; and 29 attended a tertiary-based facility in Bogota, Colombia. All patients met the modified New York criteria for AS and reflected a broad spectrum of patients with axial and peripheral disease. The study was approved by the ethics committee at the University of Alberta, the ethics committee of Townsville hospital, and the ethics committee of the military hospital of Bogota. All patients provided written informed consent.

Tape-based method. A video file describing this approach is available at <http://www.arthritisdoctors.org/researcher.html>. The subject is positioned sit-

ting on the examination couch (Figure 1). A pen mark is made in the suprasternal notch. Looking directly ahead, the patient is asked to rotate the head as far as possible towards the right shoulder. The distance between the pen mark in the suprasternal notch and the tragus of the right ear is recorded using a tape measure (cm) (D1). The subject is then asked to rotate the head as far as possible towards the left shoulder. The distance between the pen mark in the suprasternal notch and the tragus of the right ear is recorded with the tape measure (D2). Total lateral cervical rotation is recorded as the distance (cm) between the 2 measurements (D1-D2). Since the tragus overlies the axis of rotation for flexion/extension movements of the neck, this approach should be less susceptible to measurement error arising from such movement during assessment of rotation⁹. This approach to the measurement of cervical rotation has been incorporated into a 4-item index that assigns a scores of 1, 2, 3, and 4 based on the cumulative centile distribution and cut-offs representing the 80, 60, 40, and 20th centiles, respectively, the Edmonton AS Metrology Index (EDASMI)¹⁰.

Goniometer-based method. A video file describing this approach is available at <http://www.arthritisdoctors.org/researcher.html>. The patient is seated with the back of the chair against a wall and the flat portion of the goniometer positioned against the wall. The other end of the goniometer is placed on the crown of the patient's head. One arm of the goniometer is moved over the plane of the nose as the patient rotates the head in both directions. The mean of right and left scores is recorded. Scores of 0, 1, and 2 are assigned for cervical rotation > 70, 20–70, and < 20 degrees of movement, respectively, in the BASMI⁵.

Study protocol. All measurements were performed from mid-morning to allow for resolution of morning stiffness. The first 44 consecutive patients with AS [men = 33, mean age = 42.7 yrs (range 22–68), mean disease duration 14.5 yrs (range 2–44)] studied in Edmonton had repeat assessments by a trained clinician nurse and a rheumatologist to assess intra- and interobserver reproducibility. The order of assessment was randomized and observers were blinded to the results of their own previous assessment and those of their colleagues. All subsequent assessments were performed by a clinician nurse at the Canadian site, by a rheumatologist in the Colombian site, and by a trained medical student at the Australian site.

All patients were recruited to a prospective, longitudinal cohort of patients with AS where data is systematically recorded on patient demographics, extraarticular features, comorbidity, disease-specific health status [Bath AS Disease Activity Index (BASDAI)¹¹, Bath AS Functional Index (BASFI)¹²], BASMI, EDASMI¹⁰, and structural damage as recorded on plain

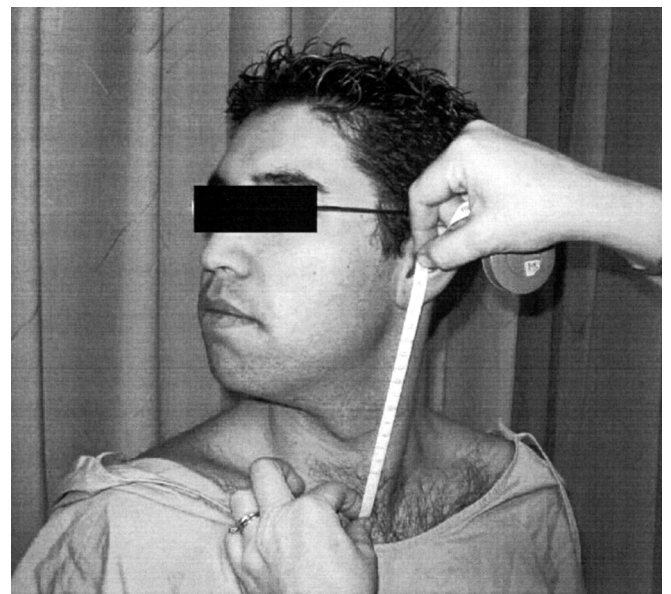


Figure 1. Approach to measurement of lateral cervical rotation using a tape positioned at the suprasternal notch and at the tragus of the ear.

radiography in the spine [modified Stoke AS Spinal Score (mSASSS)¹³]. These data were used to examine construct validity. The contribution of cervical mobility to functional impairment was determined according to item 8 of the BASFI: "Looking over your shoulder without turning your body."

Of the 205 patients studied in Edmonton, 33 were subsequently recruited to clinical trials of open label treatment with infliximab (n = 4) or pamidronate (n = 7), and randomized double-blind placebo-controlled trials of infliximab (n = 11; randomization 3:8 for placebo:infliximab) and adalimumab (n = 11; randomization 1:1). Mobility assessments were then repeated at 24 weeks after the start of treatment. These data were used to analyze responsiveness.

Statistics. Descriptive statistics (mean, median, standard deviation), frequency histograms, and box-plots with median, interquartile ranges, maximum and minimum values, were used to describe the overall distribution of scores.

The intra- and interobserver reproducibility was calculated using ANOVA to provide an intraclass correlation coefficient (ICC). A 2-way mixed effects model with observer as a fixed factor was used. A value greater than 0.6 was designated as representing good reproducibility, greater than 0.8 represented very good reproducibility, and greater than 0.9 represented excellent reproducibility. Reproducibility was also examined using Bland-Altman plots and 95% limits of agreement. These plots allow the visualization of interobserver differences across the whole range of scores. The interrater variance was used to calculate the smallest detectable difference (SDD) between 2 readings by 2 raters for a single patient. This was calculated by multiplying the SD of the differences by 1.96.

Construct validity was assessed by analyzing correlations (Pearson's for normally distributed data, Spearman's rho for nonparametric data, 2-tailed test) between mobility scores and age, disease duration, disease activity (BASDAI), function (BASFI), and structural damage scores on plain radiograph (the cervical component of the mSASSS-cmSASSS¹³). The contribution of age, disease duration, disease activity (BASDAI), and structural damage on radiograph (cmSASSS) to the variance in each mobility measure was examined by regression analysis. Hierarchical (sequential) linear regression was used to assess the contributions of the cervical rotation scores to the variance in the BASFI (item 8), adjusted for age, disease duration, and the BASDAI. This method is used to order the entry of independent variables based on the purpose and logic of the research. The incremental proportion of variance in the dependent variable (R^2 change) is accounted for by a given independent variable or set of independent variables, beyond what has been accounted for by prior sets. The variance explained by the model (R^2) is the sum of the R^2 change for the independent variables in the model. The independent variables for the model were entered in 2 sets in the following order: (1) age, disease duration, and the BASDAI; (2) the cervical rotation raw score.

Two statistical methods were used to assess responsiveness: the effect size (ES), and the standardized response mean (SRM). Values of 0.20, 0.50, and

0.80 or greater were considered to represent small, moderate, and large degrees of responsiveness, respectively. Differences between pre- and post-treatment scores were assessed by the paired t-test. Discrimination was not assessed as the open label phase of the clinical trials is still ongoing and treatment codes remain unbroken at this time.

RESULTS

Descriptive data. Compared to patients in the Edmonton and Australian cohorts, those from Colombia had shorter disease duration and a higher prevalence of peripheral synovitis (Table 1). Descriptive statistics for the tape-based cervical rotation method in the 3 cohorts are provided in Table 2 and Figure 2. Colombian patients differed from patients in the Canadian and Australian cohorts in demonstrating a greater degree of cervical rotation, which could be due to the much shorter disease duration.

The frequency histogram distributions for scores derived using the tape-based and goniometer-based methods of recording cervical rotation were compared for the entire cohort of patients (Figure 3). A broader distribution of scores was recorded using the tape-based method, although a significant correlation was noted between scores obtained with the 2 methods (Spearman's rho = 0.47, $p < 0.001$). With the goniometer-based method, 20.6%, 66.2%, and 13.2% of patients had cervical rotation of > 70 , 20–70, and < 20 degrees, respectively, corresponding to the 0, 1, and 2 scores recorded as one component of the BASMI.

Reproducibility. Intraobserver reproducibility was very good for 2 observers using the tape-based method (ICC = 0.80 and 0.89) and excellent for the goniometer-based method (ICC = 0.98 and 0.97). Interobserver reproducibility was similarly somewhat better for the goniometer-based as compared to the tape-based method (ICC = 0.95 and 0.82, respectively). Bland-Altman plots show that the variation between observers is evident across the whole range of scores, although there were relatively few scores in the lower half of the range using the goniometer-based method (Figure 4). Limits of agreement

Table 1. Patients' characteristics.

	Edmonton, n = 205	Colombia, n = 29	Australia, n = 29
M:F	158:47	15:14	18:11
Mean age, yrs (SD)	41.5 (12)	40.6 (10)	44 (15.1)
Mean height, cm (SD)	172.4 (9.7)	160 (9.3)	171.8 (8.6)
Mean disease duration, yrs (SD)*	17.1 (12.4)	6.7 (6.2)	18.9 (12.2)
Peripheral synovitis, %	10.7	37.9	17.2
AAU, %	19.5	13.8	17.2
Psoriasis, %	7.3	3.4	24.1
IBD, %	8.3	3.4	0
Mean BASDAI (SD)	4.7 (2.4)	4.8 (2.1)	4.3 (2.1)
Mean BASFI (SD)	3.8 (2.7)	3.6 (2.4)	3.9 (2.7)
Mean total back pain (SD)	5.2 (2.8)	4.9 (2.6)	3.6 (2.4)
Mean BASMI (SD)	2.9 (2.5)	3.1 (2.1)	3.0 (2.7)

* Duration from symptom onset. BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath AS Functional Index; BASMI: Bath AS Metrology Index; AAU: acute anterior uveitis; IBD: inflammatory bowel disease.

Table 2. Descriptive statistics for tape-based and goniometer-based cervical rotation in 263 patients with AS from Canada, Colombia, and Australia.

	Canada	Tape-based Cervical Rotation		Total
		Colombia	Australia	
Number	205	29.00	29.00	263
Mean	2.59	3.29	2.44	2.65
Median	2.50	3.00	2.00	2.50
SD	1.40	2.06	1.46	1.50
Minimum	0.00	0.50	0.00	0.00
Maximum	6.50	8.50	5.80	8.50
Percentiles				
25	1.50	1.50	1.65	1.50
75	3.50	5.25	3.10	3.70

	Canada	Goniometer-based Cervical Rotation		Total
		Colombia	Australia	
N	199.00	29.00	29.00	257.00
Mean	56.54	56.52	55.69	56.44
Median	60.00	62.50	60.00	60.00
SD	19.72	17.41	23.42	19.85
Minimum	0.00	15.50	0.00	0.00
Maximum	90.00	87.50	94.00	94.00
Percentiles				
25	44.00	45.00	44.50	45.00
75	72.50	66.75	72.00	71.50

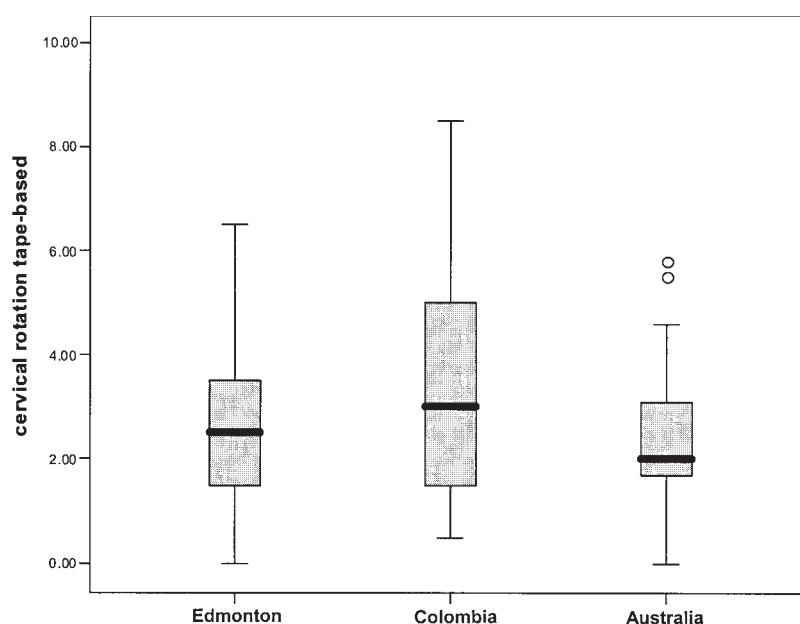


Figure 2. Median, interquartile range, maximum and minimum values for tape-based cervical rotation in 3 cohorts of patients with AS from Canada, Colombia, and Australia.

(95%) were -1.13 , 1.48 and -10.1 , 12.0 for the tape-based and goniometer-based methods, respectively.

Construct validity. Significant correlations were evident between cervical rotation scores recorded using either method and age, disease duration, self-reported functional disability (item 8 of the BASFI), and structural damage scores recorded

on plain radiograph of the cervical spine (cmSASSS; Table 3). Age, disease duration, and the BASDAI accounted for 8% (R^2 adjusted = 0.08) and 34% (R^2 adjusted = 0.34) of the variance in the tape-based and goniometer-based scores, respectively ($p < 0.001$ for both). The goniometer-based score also contributed significantly to the variance in the cBASFI (R^2

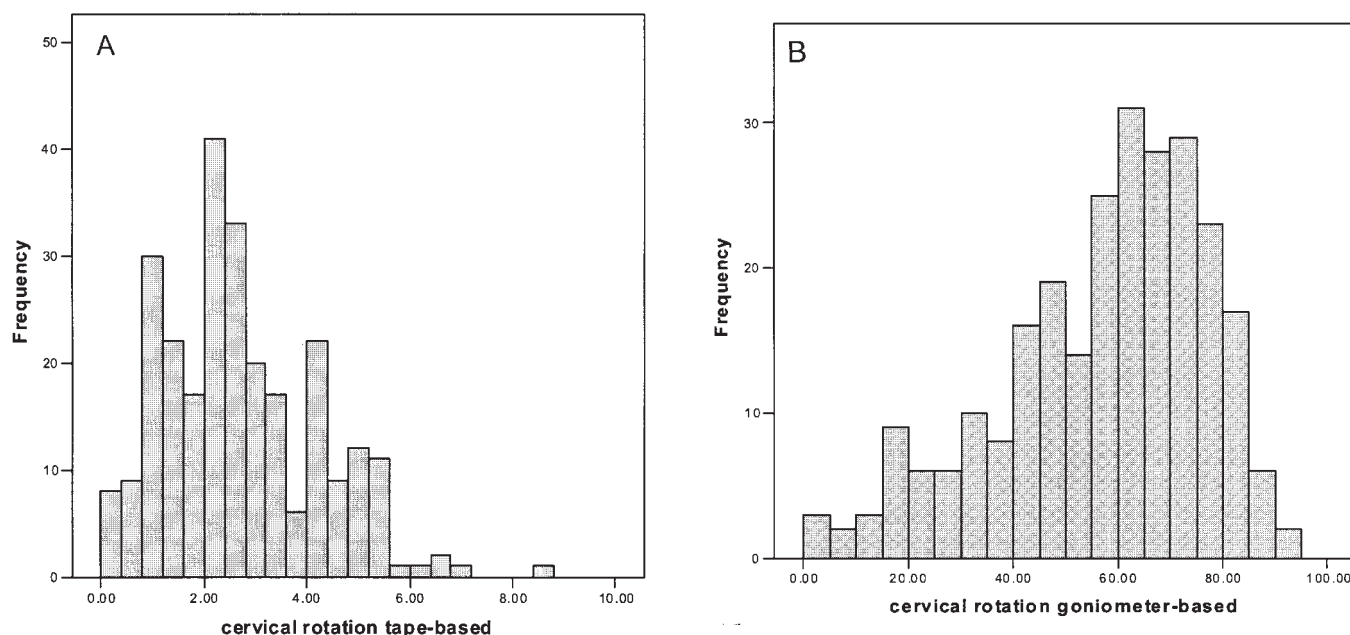


Figure 3. Frequency histogram distribution for cervical rotation scores in 263 patients with AS measured using (A) tape-based, and (B) goniometer-based methods.

adjusted = 0.09; $p < 0.001$) when adjusted for age, disease duration and the BASDAI.

Responsiveness. The goniometer-based method of recording cervical rotation was more responsive than the tape-based method, demonstrating significant change after 24 weeks in a group of 33 patients who either received open label treatment (infliximab = 4, pamidronate = 7) or were randomized to anti-tumor necrosis factor therapy or placebo ($n = 22$) (Table 4). However, recoding the scores according to the BASMI scoring scheme showed that this measure was no longer responsive.

DISCUSSION

We described and validated a novel approach to the measurement of cervical rotation that requires only the use of a tape measure. While it is somewhat less responsive than measurement of rotation using a goniometer, this advantage of the goniometer-based method is lost when scores are graded according to the BASMI 0–2 grading scheme. If cervical rotation recorded with a goniometer is to be used in research and clinical trials it would be preferable to use raw scores rather than the grading scheme recommended in the BASMI. In addition, our data show that cervical rotation can be reliably assessed in the upright posture as opposed to the supine posture recommended in the BASMI approach.

The reliability of cervical mobility measures has been very good among studies at single sites that mostly assessed reliability using 2 observers and either inclinometers or goniometers^{5,14–16}. Studies in which several observers were used to assess reliability have supported the reliability of lateral cervical rotation assessed using a neck protractor³ and less so using a goniometer¹⁷. The latter study included 10 observers, comprising rheumatologists with an interest

in spondyloarthropathies, who evaluated 10 patients in a Latin square design. Although such a design might promote measurement error related to factors such as warming up and training, analysis showed that the major component of variability was related to observer effects. This may have significant implications for the reliability of assessment in multicenter clinical trials. A systematic review of the literature concluded that measurement of cervical rotation was highly reliable and better than that noted for other cervical mobility measures¹⁸. However, neither inclinometers nor goniometers appear to be routinely available or used in the course of normal clinical practice. Although highly reproducible in our hands and somewhat more reproducible than the tape-based method, a potential limitation of the grading scheme used to score cervical rotation in the BASMI is the marked skewing of scores, with only 13% of patients being assigned a score of 2 on the 0–2 scale (data not shown). Even though the developers of the BASMI have also proposed a 0–10 scale for each of the 5 items that make up the BASMI¹⁹, the frequency histogram (Figure 3B) indicates that most patients would still have relatively low scores for cervical rotation.

Assessment of responsiveness of cervical mobility measures has been limited primarily to intensive physiotherapeutic interventions. Effect sizes have varied from 0.29 to 0.86 in various studies^{9,20–22}. In addition, one study reported responsiveness in patients reporting transition in health status²³. Our data showed that the goniometer-based approach is sensitive to change, but responsiveness is no longer apparent once the 0–2 grading scheme proposed in the BASMI is used. This was evident in a previous study from our group, where minimal responsiveness was evident in patients receiving pamidronate

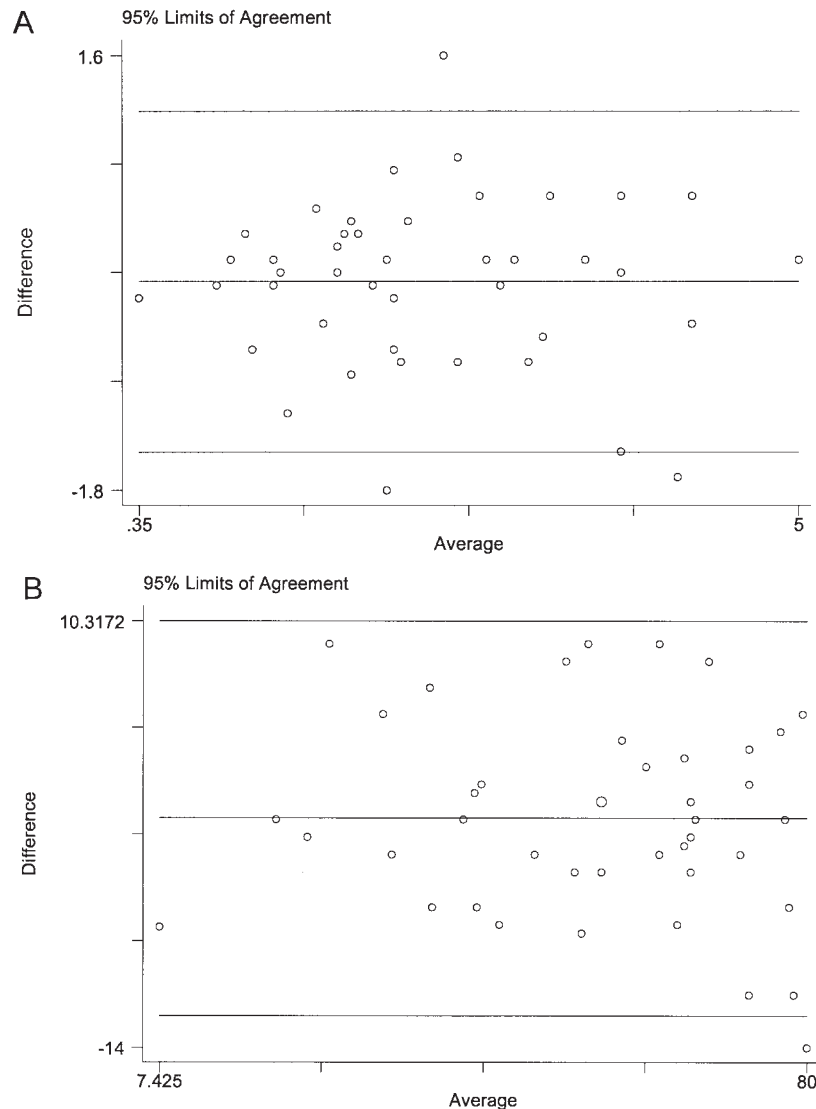


Figure 4. Bland-Altman plots of mean scores (x-axis) versus differences in the scores between the 2 observers (y-axis) in the measurement of lateral cervical rotation using either (A) tape-based, or (B) goniometer-based methods.

Table 3. Construct validity of the tape-based method of recording cervical rotation. Values represent the Spearman rho correlation.

Parameter	Cervical Rotation	
	Tape-based (p)	Goniometer-based
Age	-0.18 (0.004)	-0.41 (< 0.001)
Disease duration	-0.28 (< 0.001)	-0.42 (< 0.001)
BASDAI	-0.04 NS	-0.27 (0.001)
cmSASSS*	-0.30 (0.02)	-0.63 (< 0.001)
mSASSS*	-0.34 (0.01)	-0.60 (< 0.001)
cBASFI**	-0.23 (0.008)	-0.67 (< 0.001)

* Based on 56 patients. ** Item 8 of the BASFI. NS: not significant. mSASSS: modified Stoke AS Spinal Score.

therapy even when a 0–10 scoring scheme for cervical rotation was used²⁴.

A potential limitation of our study was that assessments

were conducted sequentially. This could serve to either increase measurement error through the phenomenon of warming up²⁵ or, conversely, minimize the degree of intraobserver error. Two previous reports that used sequential methods of assessment with multiple observers showed, however, that the major portion of measurement error was due to observer variability^{3,17}.

In conclusion, measurement of the difference in the suprasternal notch-to-tragus distance at the extremes of lateral rotation using a tape measure provides a simple, feasible, and reliable index of cervical rotation comparable to the information obtained from the use of a goniometer. Evaluation of responsiveness will require further study, though use of the goniometer-based approach should include raw scores in the calculation of responsiveness rather than the grading scheme suggested in the BASMI. Either approach should also be eval-

Table 4. Responsiveness of the tape-based and goniometer-based methods for recording cervical rotation in 33 patients who received either open label infliximab (n = 4), infliximab:placebo (8:3) (n = 11), open label pamidronate (n = 7), or adalimumab:placebo (1:1) (n = 11) for 12 weeks.

Parameter	Timepoint	Mean (SD)	Median (IQ range)	Effect Size	Standardized Response Mean	p
Tape-based	Baseline	2.4 (1.7)	1.8 (1.0–3.6)	0.15	0.26	0.14
	24 weeks	2.6 (1.7)	2.5 (0.9–4.0)			
Cervical EDASMI 0–4 score	Baseline	2.4 (1.6)	3.0 (1.0–4.0)	0.19	0.31	0.09
	24 weeks	2.1 (1.6)	2.0 (1.0–4.0)			
Goniometer-based	Baseline	42.7 (19.4)	45.5 (27.0–60.0)	0.34	0.86	< 0.001
	24 weeks	49.2 (22.2)	54.0 (32.5–65.5)			
Cervical BASMI 0–2 score	Baseline	1.1 (0.4)	1.0 (1.0–1.0)	0.21	0.24	0.18
	24 weeks	1.0 (0.6)	1.0 (1.0–1.0)			

EDASMI: Edmonton AS Metrology Index.

uated in other disorders that affect cervical mobility, such as rheumatoid arthritis and osteoarthritis.

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